12/12/17The 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 Appropriations

BILL: CS/SB 434

INTRODUCER: Appropriations Committee (Recommended by Appropriations Subcommittee on Health and Human Services); Senator Passidomo and others

SUBJECT: Neonatal Abstinence Syndrome Pilot Project

DATE: February 2, 2018 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Favorable**
2.	Kidd	Williams	AHS	**Recommend: Fav/CS**
3.	Kidd	Hansen	AP	**Fav/CS**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 434 establishes a pilot project to approve facilities licensed to provide Prescribed Pediatric Extended Care (PPEC) services to treat neonatal abstinence syndrome (NAS) that will begin on January 1, 2019 and expire on June 30, 2021. The bill requires the Agency for Health Care Administration (AHCA), in consultation with the Department of Children and Families (DCF), to establish a program to approve licensed PPEC providers to offer a community-based inpatient care option to treat infants with NAS after they have been stabilized in a hospital. The bill also establishes minimum standards that a PPEC center must meet in order to be approved. The bill 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 appropriates $200,000 in FY 2018-2019 to AHCA for implementation of the pilot program. The bill appropriates $140,000 in FY 2018-2019 and $70,000 in FY 2019-2020 to DOH for the pilot project study.

The bill takes effect upon becoming a 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.[1] When a pregnant mother uses opiate drugs the fetus can become addicted to the drug in-utero. Since the baby is no longer receiving the opiate drug from its mother when born, the baby may go into opiate withdrawal. The baby may exhibit symptoms including blotchy skin coloring (mottling), diarrhea, excessive crying or high-pitched 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.[2] Most symptoms begin within 72 hours of birth, but some may appear immediately after birth or up to several weeks after birth. Symptoms can last between one week and 6 months.[3] Additional complications from NAS may include low birthweight, jaundice, the need for treatment in a neonatal intensive care unit (NICU), and the need for treatment with medicine.[4]

In correlation with the general increase in the rate of opioid addiction, the rate of NAS in 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).[5]

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 an infant 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.[6]

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, offers parental education, and

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

[2] Supra n. 2

[3] 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).

[4] Id.

[5] Department of Health, *Senate Bill 434 Analysis* (on file with the Senate Committee on Health Policy).

[6] 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).

makes referrals to addiction-recovery programs for caregivers when appropriate. The 7,500 square foot facility was donated and renovated by community volunteers and grant-funded staff to serve as an outpatient neonatal abstinence center.[7]

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 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.[8]

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.[9]

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 Department of Children and Families (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[10] 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.[11]

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,

[7] 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).
[8] Supra note 8
[9] Id.
[10] s. 39.01(2), F.S.0
[11] s. 39.01(30)(g), F.S.

an authorized agent of the DCF may take a child into custody 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.[12]

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 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 must immediately notify the DCF, whereupon the DCF must immediately begin a child protective investigation in accordance with the provisions of this chapter and must make every reasonable effort to notify immediately 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.

Prescribed Pediatric Extended Care Centers

PPEC centers are licensed by the AHCA under Part VI of ch. 400, F.S. PPEC centers provide continual medical care in a non-residential setting to Medicaid eligible children from birth through age 20 with medically-complex conditions. When approved, children can attend a PPEC up to a maximum of 12 hours per day while receiving nursing services, personal care, developmental therapies, and caregiver training.[13] Part VI of ch. 400, F.S., and ch. 59A-13, F.A.C., establish licensure standards for PPEC centers including, but not limited to, the requirement for child care standards,[14] the requirement that a PPEC center have a board licensed pediatrician as a medical director,[15] and requirements for nurse training and staffing ratios.[16] PPEC center staff are required to be background screened[17] and PPEC centers fall under the regulatory authority of part II of ch. 408, F.S.[18]

Section 409.968, F.S., addresses multiple topics relating to payments to and by Medicaid managed care plans under statewide Medicaid managed care. Subsection (3) of this section specifies that reimbursement for prescribed pediatric extended care services provided to children enrolled in a Medicaid managed care plan shall be paid to the prescribed pediatric extended care services provider by the agency on a fee-for-service basis.

[12] s. 39.401, F.S.
[13] Prescribed Pediatric Extended Care (PPEC), AHCA webpage, available at http://ahca.myflorida.com/Medicaid/childhealthservices/ppec/index.shtml. (Last visited on Feb. 1, 2018).
[14] Rule 59A-13.008, F.A.C.
[15] Rule 59A-13.009, F.A.C.
[16] Rule 59A-13.010, F.A.C.
[17] Section 400.9065, F.S.
[18] Section 400.907, F.S.

III. Effect of Proposed Changes:

This bill amends ss. 400.902 and 400.914, F.S., related to the licensure of PPEC centers, to conform those sections to the changes made in the bill allowing PPEC centers to provide inpatient, 24-hour a day treatment to infants with NAS.

The bill creates s. 400.917, F.S., to establish a pilot project to approve licensed PPEC centers to allow them to provide inpatient treatment to infants with NAS, beginning on January 1, 2019, and expiring on June 30, 2021.

The bill defines the terms:
- Eligible" to mean an infant who:
  - Has a gestational age or a corrected age (gestational age plus chronological age) of 37 weeks or greater;
  - Is being treated for neonatal abstinence syndrome as the primary active diagnosis;
  - If he or she requires pharmacologic therapy, has been treated through the initial escalation phase of treatment for signs of neonatal abstinence syndrome, and is in the weaning phase of management; and
  - Is not taking medications for treatment of any medical condition other than:
    - Neonatal abstinence syndrome;
    - Any side effects caused by neonatal abstinence syndrome or its treatment; or
    - Vitamin or mineral deficiencies that are common in infants.
- "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 withdrawal symptoms experienced by an infant who is exposed to opioids in utero or in neonatal hospitalization; to agents used to treat maternal opioid addiction; or to one or more other drugs including, but not limited to, barbiturates, selective serotonin re-uptake inhibitors, and benzodiazepines.
- "Pharmacologic therapy" to mean the use of prescribed medications recognized by the American Academy of Pediatrics to relieve moderate to severe signs and symptoms of neonatal abstinence syndrome and to prevent complications common to neonatal abstinence syndrome.
- "Stabilized" to mean within reasonable medical probability, no material deterioration of the infant's condition is likely to result from, or occur during, the transfer of the infant from the hospital to a facility licensed under this section.

The bill requires the AHCA, in consultation with the DCF, to establish a pilot project to approve one or more licensed PPEC centers 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 requires the AHCA, in consultation with the DCF, to adopt rules for minimum standards for approval including:
- Any additional requirements (in addition to requirements for licensure as a PPEC center) for physical plant and maintenance of facilities; compliance with local building and fire codes,

and sanitation as needed to ensure the safety and wellbeing of infants being treated at the facility, facility staff, and visitors to the facility;
- 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;
- Requirements for programs, 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.

A PPEC center is not required to obtain a certificate of need to be approved to provide NAS services.

The bill also establishes minimum requirements that, in order to be approved to provide NAS services and participate in the pilot project, each facility must:
- Be a private, not-for-profit Florida corporation;
- Have an on-call medical director;
- Adhere to all applicable standards for a PPEC center and all standards established by rule for the provision of NAS services;
- Provide to the AHCA a plan to:
  - Provide 24-hour nursing and nurturing care to infants with neonatal abstinence syndrome;
  - Provide for the medical needs of an infant being treated within the facility, including, but not limited to, pharmacologic therapy and nutrition management;
  - Maintain a transfer agreement with a nearby hospital that is not more than a 30-minute drive from the licensed facility;
  - 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. 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; and

- Identify, and refer parents to, social service providers, such as Healthy Start,[19] , or the MomCare network[20], Health Families[21], Early Steps,[22] and Head Start[23] programs, prior to discharge, if appropriate; and
- Become a Medicaid provider if the PPEC center is not already a Medicaid provider.

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

The bill also provides that the facility may require the mother or visitors to vacate the facility under any of the specified conditions:

- The mother refuses to allow her breast milk to be tested upon request of the facility or the breast milk tests positive for one or more nonprescription medications;
- The mother refuses to consent to a drug test at the request of the facility or the mother tests positive for one more nonprescription medications;
- The facility determines the mother poses a risk to the infant; or
- The facility determines the mother or a visitor is threatening, intimidating, or posing a risk to the infant, any other mother in the facility, or facility staff.

The bill provides that under circumstances where the mother is asked to leave, facility staff may refuse to allow the mother, parent, caregiver or legal custodian to remove the infant from the facility and may detain the infant if the provisions of s. 39.395, F.S., are met.

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 approved under the pilot project. The DOH must

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[19] 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.

[20] MomCare is an Administrative Services Organization representing all Healthy Start Coalitions providing risk appropriate care coordination and other services in accordance with s. 409.906.

[21] Healthy Families is established in s. 409.153, and is an evidenced based, voluntary home visiting program to prevent child abuse and neglect.

[22] 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).

[23] 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.

report the study results and recommendations for the continuation or expansion of the pilot project to the Legislature by June 30, 2020. 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 therapy of NAS. Facilities approved 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 requires that upon becoming law, the Agency for Health Care Administration shall begin the process of adopting rules. The agency is directed to begin the process of applying for any Medicaid Waivers or other permissions that may be required by the federal government to ensure PPEC centers approved to provide NAS services are able to have such services reimbursed by the Medicaid program.
The bill provides an appropriation of $200,000 from the Health Care Trust Fund to the Agency for Health Care Administration for purposes of implementing the bill.

The bill also provides a nonrecurring appropriation of $140,000 from the Maternal and Child Health Block Grant Trust Fund to the Department of Health, in Fiscal Year 2018-2019 to contract for the required study. The bill also provides a Fiscal Year 2019-2020 nonrecurring appropriation of $70,000 from the Maternal and Child Health Block Grant Trust Fund to the Department of Health to complete the required study.

The bill takes effect upon becoming a 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:

Families with infants with NAS who are able to use a facility approved under the bill's provisions and their health insurers may enjoy cost savings to the extent a stay at such a facility is less costly than an extended stay in a NICU.

The bill will have an indeterminate fiscal impact on PPEC centers that are allowed to provide the services established by the bill.

C. Government Sector Impact:

The AHCA has indicated a fiscal impact of $200,000 to implement the new licensure type for the pilot project facilities. Funds are appropriated from the Health Care Trust Fund.

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 $140,000 during the first year and $70,000 during the second year of the pilot project. Funds are appropriated from the Maternal and Child Health Block Grant Trust Fund.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

The bill amends the following sections of the Florida Statutes: 400.902 and 400.914.
The bill creates section 400.917 of the Florida Statutes and four new unnumbered sections of Florida law.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

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

CS by Appropriations on January 31, 2018:
The committee substitute:

- Eliminates all references to licensure for NAS facilities and, instead, creates a pilot project to allow licensed PPEC centers to be approved to provide the NAS services established in the bill. The CS amends two existing law sections to conform with the additional services
- Amends the definition of "neonatal abstinence syndrome" and adds definitions for "stabilized" and "pharmacologic therapy";
- Revises rule requirements for NAS services to not duplicate requirements already established for PPEC centers.

- Allows a facility to require a mother to vacate the facility if she, or her breast milk, tests positive for nonprescription medications.
- Removes the Medicaid Region 8 language allowing for the pilot project to be statewide;
- Changes the dates for the pilot project and directs the Agency for Health Care Administration to obtain any necessary approvals from the federal government;
- Provides for a facility to detain an infant in cases where the provisions of s. 39.395 are met; and
- Provides appropriations to the Agency for Health Care Administration and the Department of Health to implement the bill.

B. Amendments:

None.

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