

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 227 Prescription Drug Abuse
SPONSOR(S): Health & Human Services Quality Subcommittee; Stargel
TIED BILLS: **IDEN./SIM. BILLS:** SB 402

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Quality Subcommittee	11 Y, 0 N, As CS	Poche	Calamas
2) Justice Appropriations Subcommittee	12 Y, 0 N, As CS	McAuliffe	Jones Darity
3) Health & Human Services Committee			

SUMMARY ANALYSIS

House Bill 227 establishes the Statewide Task Force on Prescription Drug Abuse and Newborns to study the breadth and depth of Neonatal Withdrawal Syndrome in the state. Neonatal Withdrawal Syndrome is the complex group of physiological and behavioral symptoms and problems suffered by newborn children as a result of withdrawal from exposure to narcotics in the womb. Due to the prescription drug abuse problem in Florida, health care providers and facilities are experiencing a sharp increase in the number of babies born with Neonatal Withdrawal Syndrome.

The bill requires the Task Force to collect and analyze data, examine ways to increase public awareness, and explore possible solutions to the problem. The bill also specifies membership and other duties of the Task Force. The Task Force is required to submit an interim report and a final report to the Speaker of the House of Representatives and the President of the Senate containing policy recommendations to address the problem.

The bill has an insignificant fiscal impact on the Department of Legal Affairs which can be absorbed with existing resources.

The bill provides an effective date of immediately upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Prescription Drug Abuse

Prescription drug abuse is the fastest growing drug problem in the United States, constituting an epidemic, according to the Centers for Disease Control and Prevention.¹ Certain prescription drugs – opioid substances, central nervous system depressants, and stimulants – when abused can alter the brain's activity and lead to dependence and possible addiction. According to research by the National Institute on Drug Abuse, the three most abused classes of prescription drugs are:

- Opioids, used to treat pain. Examples include codeine (Schedules II, III, V), oxycodone (OxyContin, Percocet – Schedule II), and morphine (Kadian, Avinza -Schedule II);
- Central nervous system depressants, used to treat anxiety and sleep disorders. Examples include barbiturates (Mebaral, Nembutal) and benzodiazepines (Valium, Xanax) (all in Schedule IV); and
- Stimulants, used to treat ADHD, narcolepsy, and obesity. Examples include dextroamphetamine (Dexedrine, Adderall) and methylphenidate (Ritalin, Concerta) (all in Schedule II).²

The Substance Abuse and Mental Health Services Administration (SAMHSA) sponsors an annual national survey on drug use and health. The most recent survey indicates there are seven million persons aged 12 or older who used prescription-type psychotherapeutic drugs non-medically within the past month in 2010.³ Of those seven million persons, 5.1 million used pain relievers non-medically within the past month in 2010.⁴ It is estimated that 1.9 million people in the United States meet abuse or dependence criteria for prescription opioids.⁵ Deaths from prescription painkiller overdoses have more than tripled in the past decade.⁶

The prescription drug abuse problem in Florida is particularly acute. The abuse of prescription drugs is becoming more prevalent and more deadly than the abuse of illicit drugs, such as heroin, cocaine, and methamphetamine.⁷ The Florida Medical Examiners Commission reports on drug-related deaths in Florida, and specifically tracks deaths caused by the abuse of prescription drugs. According to the Commission, prescription drugs are found in deceased persons in lethal amounts more often than illicit drugs.⁸ The most recent report found 5,647 deaths caused by one or more prescription drugs.⁹ The rate of deaths caused by prescription drugs during 2010 averaged more than 15 fatalities per day.¹⁰

Florida may experience a downturn in prescription drug abuse due to reduced supply. Data from the Department of Health on controlled substance purchases by Florida physicians and pharmacies

¹ Centers for Disease Control and Prevention, Vital Signs, *Prescription Painkiller Overdoses in the U.S.*, November 1, 2011, available at www.cdc.gov/vitalsigns/PainkillerOverdoses/ (last viewed on January 11, 2012).

² National Institutes of Health, National Institute on Drug Abuse, *Prescription Medications*, available at www.drugabuse.gov/drugs-abuse/prescription-medications (last viewed January 12, 2012).

³ U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, *2010 National Survey on Drug Use and Health: Summary of National Findings*, www.samhsa.gov/data/NSDUH/2k10NSDUH/2k10Results.htm (last viewed on January 10, 2012).

⁴ *Id.*

⁵ National Institutes of Health, National Institute on Drug Abuse, *Topics in Brief: Prescription Drug Abuse*, available at www.drugabuse.gov/publications/topics-in-brief/prescription-drug-abuse (last viewed on January 12, 2012).

⁶ *See supra* at FN 1.

⁷ Florida Department of Law Enforcement, Medical Examiners Commission, *Drugs Identified in Deceased Persons by Florida Medical Examiners 2010 Report*, August 2011, page ii.

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

indicate a sharp decline in oxycodone purchases.¹¹ In the first five months of 2010, physicians purchased over 35 million dosage units of oxycodone; in the first five months of 2011, physicians purchased only about 925,000 dosage units of oxycodone.¹² Similarly, in the first five months of 2010, pharmacies purchased over 236 million dosage units of oxycodone; in the first five months of 2011, pharmacies purchased only about 225 million dosage units of oxycodone.¹³ These changes may be a result of, or market anticipation of, legislative changes in 2009 and 2011 to address the problem of prescription drug abuse in Florida.¹⁴

Neonatal Withdrawal Syndrome

Neonatal Withdrawal Syndrome (NWS), also known to as Neonatal Abstinence Syndrome, is defined as a complex group of physiological and behavioral signs and symptoms that a newborn exhibits and experiences when withdrawing from exposure to narcotics, including prescription medication, in the womb.¹⁵ It is a multisystem disorder that involves the central nervous system, the gastrointestinal system, and the respiratory system.¹⁶ Most drugs used by the mother are transferred to the fetus by the placenta. The amount and rate of drug transferred depend on the properties of the drug, including its half-life, or rate at which the drug is processed by the body.

Opiates produce the most dramatic effects on both the mother and the fetus. Because of its short half-life, withdrawal from opiates may start as early as 24 hours after birth in 50 percent to 80 percent of infants born to mothers addicted to opiates.¹⁷ Narcotics are the most frequent cause of NWS, including methadone, morphine, oxycodone, codeine, and buprenorphine.¹⁸ NWS symptoms usually peak at three to four days following birth, but may not appear for ten to fourteen days following birth.¹⁹ Complete withdrawal from opiate addiction in infants may last for four to six months.²⁰

NWS presents as neurologic symptoms, dysfunction of the gastrointestinal system, and other conditions. The kind and severity of symptoms depend on the type of drug used by the mother, how much of the drug was taken and for how long during the pregnancy, and whether the baby was born full-term or premature.²¹ Neurologic symptoms include:

- Tremors
- Irritability
- Increased wakefulness
- High-pitched crying
- Increased muscle tone
- Seizures
- Increased sweating
- Frequent yawning and sneezing

Dysfunction of the gastrointestinal system includes:

¹¹ Florida Department of Health, Division of Medical Quality Assurance, *Implementation of House Bill 7095 Relating to Prescription Drugs*, PowerPoint presentation to Health and Human Services Committee on September 21, 2011 (on file with committee staff).

¹² *Id.* at slide 11.

¹³ *Id.* at slide 12.

¹⁴ Ch. 2009-197, Ch. 2009-198, and Ch. 2011-141, Laws of Fla.

¹⁵ Hamdan, M.D., A., Rosenkrantz, M.D., T., et. al, *Neonatal Abstinence Syndrome*, Medscape Reference, Drugs, Diseases, & Procedures, March 3, 2010, available at <http://emedicine.medscape.com/article/978763-overview> (last viewed on January 10, 2012).

¹⁶ *Id.*

¹⁷ *Id.*; see also Lucile Packard Children's Hospital at Stanford University Health Library, *Neonatal Abstinence Syndrome*, available at www.lpch.org/DiseaseHealthInfo/HealthLibrary/hrnewborn/nas.html (last viewed January 11, 2012).

¹⁸ Naga, M.D., Osama, *Neonatal Abstinence Syndrome*, PowerPoint presentation, Texas Tech University Health Sciences Center, slide 3, available at www.ttuhschool.edu/fostersom/pediatrics/neonatology/documents/NAGA-Neonatal_Abstinence_Syndrome.pdf (last viewed on January 10, 2012).

¹⁹ *Id.* at slide 4.

²⁰ *Id.*

²¹ National Institutes of Health, National Library of Medicine, Medline Plus Medical Encyclopedia, *Neonatal abstinence syndrome*, available at www.nlm.nih.gov/medlineplus/ency/article/007313.htm (last viewed on January 10, 2012).

- Poor feeding
- Uncoordinated and constant sucking
- Vomiting
- Diarrhea
- Dehydration
- Poor weight gain

Other conditions indicative of NWS include:

- Increased sweating
- Nasal stuffiness
- Fever
- Mottling (discolored patches on the skin)
- Temperature instability²²

Treatment of infants with NWS includes gentle handling, reduction of noise and light stimuli, swaddling, and demand feeding.²³ Many infants must be “readdicted” to the opiate to which they were exposed in utero, usually morphine sulfate administered orally or buprenorphine, to ease the symptoms of withdrawal, then slowly weaned off of the medication.²⁴

Task Forces in Florida

A task force is defined in Florida statute as, in part, an advisory body created by specific statutory enactment for a time not to exceed 3 years and appointed to study a specific problem and recommend a solution or policy alternative with respect to the problem.²⁵ The existence of the task force ends once it completes its appointed task or duty.²⁶

Effect of Proposed Changes

House Bill 227 creates the Statewide Task Force on Prescription Drug Abuse and Newborns (Task Force) within the Department of Legal Affairs in the Office of the Attorney General to study NWS as a result of maternal prescription drug abuse during pregnancy. The Task Force is charged with researching the impact of prescription drug use and NWS in the state and evaluating effective strategies for treatment and prevention of NWS. In order to complete these tasks, the bill requires the Task Force to collect and organize data relating to the nature and scope of NWS as a result of prescription drug abuse. Also, the Task Force is to collect information that reflects the costs associated with treating pregnant women and newborns suffering from NWS. The Task Force must identify federal, state, and local programs that provide services to pregnant women addicted to prescription drugs and newborns suffering from NWS. Lastly, the Task Force must evaluate methods to increase public awareness of the dangers associated with prescription drug abuse by pregnant women and the dangers posed to newborns as a result of maternal prescription drug abuse during pregnancy.

The bill specifies 14 members of the Task Force:

- The Attorney General, who will serve as chairperson;
- The State Surgeon General, who will serve as vice chairperson;
- The Secretary of the Department of Children and Family Services;
- The Secretary of the Agency for Health Care Administration;
- The Executive Director of the Department of Law Enforcement;
- One Legislator, appointed by the President of the Senate;
- One Legislator, appointed by the Speaker of the House of Representatives;
- A representative from the Florida Medical Association;

²² American Academy of Pediatrics, Committee on Drugs, *Neonatal Drug Withdrawal*, Pediatrics, vol. 101, page 1079 (1998).

²³ See *supra* at FN 13, slide 14.

²⁴ See *supra* at FN 13, slides 16 through 18.

²⁵ S. 20.03(8), F.S.

²⁶ *Id.*

- A representative from the Florida Hospital Association;
- A representative from an addiction and recovery association, appointed by the Attorney General;
- A representative from the Florida Osteopathic Medical Association;
- A representative from the March of Dimes;
- A representative from Healthy Start; and
- A resident of the state, appointed by the Attorney General.
- A representative of the Florida Nurses Association.

The Task Force is directed to submit an interim report to the Speaker of the House of Representatives and the President of the Senate with its initial policy recommendations on or before January 15, 2013. The Task Force is directed to submit a final report including policy recommendations by January 15, 2015.

The bill is effective upon becoming a law.

B. SECTION DIRECTORY:

Section 1: Creates an unnumbered section of law, establishing the Statewide Task Force on Prescription Drug Abuse and Newborns.

Section 2: Provides an effective date of immediately upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The Department of Legal Affairs will provide staff to assist the task force in completing its duties. Further, members of the task force will be entitled to per diem payments and travel reimbursement under current law.²⁷ The Office of the Attorney General estimates a fiscal impact of approximately \$14,500, which includes per diem payments, travel reimbursement, and staff costs.²⁸ The Department of Legal Affairs has identified settlement funds to offset any task force costs (see FISCAL COMMENTS).

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

²⁷ S. 112.061, F.S. (per diem and travel expenses); Rule 69I-42.006, F.A.C. (per diem and subsistence allowance); Rule 69I-42.007, F.A.C. (transportation by common carrier); Rule 69I-42.008, F.A.C. (transportation by private vehicle); Rule 69I-42.010, F.A.C. (other incidental traveling expenses)

²⁸ Department of Legal Affairs, *HB 227 Bill Analysis*, page 2 (January 13, 2012).

None.

D. FISCAL COMMENTS:

In 2008, the Attorney General, along with the Attorneys General from 27 other states and the District of Columbia, entered into an Assurance of Voluntary Compliance and Discontinuance agreement with Express Scripts, Inc. (ESI), a pharmacy benefits management corporation.²⁹ The agreement resolved allegations of violations of the states' consumer protection statutes by ESI as a result of the company's advertising, marketing and other business practices.³⁰ As part of the settlement, ESI paid \$7 million, to be apportioned among the states involved in the matter.³¹ Provisions of the agreement grant the Attorney General wide discretion in how the settlement funds are to be used by the state.³² The Attorney General proposes to use the funds from Florida's portion of the settlement to cover the estimated \$14,500 in costs associated with the operation of the Task Force.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 17, 2012, the Health and Human Services Quality Subcommittee adopted a strike-all amendment for House Bill 227. The strike-all amendment made the following changes to the bill:

- Added four members to the Task Force: a representative of the Florida Osteopathic Medical Association, a representative from the March of Dimes, a representative from Healthy Start, and a resident of the state to be appointed by the Attorney General; and
- Required an interim report containing recommendations to be submitted to the Speaker of the House of Representatives and the President of the Senate by January 15, 2013 and a final report containing policy recommendations to be submitted by January 15, 2015.

²⁹ *In the Matter of: Express Scripts, Inc., Assurance of Voluntary Compliance and Discontinuance*, May 23, 2008 (on file with Health and Human Services Quality Subcommittee staff).

³⁰ *See id.* at pages 2-3.

³¹ *See id.* at page 33.

³² *See id.* at page 34.

The bill was reported favorably as a committee substitute. The analysis reflects the committee substitute.

On January 30, 2012, the Justice Appropriations Subcommittee adopted one amendment to the bill which added a representative of the Florida Nurses Association to the Statewide Task Force on Prescription Drug Abuse and Newborns.

The bill was reported favorably as a committee substitute. The analysis reflects the committee substitute.