SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

BILL: CS/SB 1578

SPONSOR: Education Committee and Senator Dawson

SUBJECT: Schools/Students/Prescriptions

DATE: April 21, 2004 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	deMarsh-Mathues	O'Farrell	ED	Favorable/CS
2.			HC	
3.				
4.				
5.				
6.				

I. Summary:

The committee substitute sets forth requirements regarding the provision of medication to children taken into protective custody, in child care settings, and public schools. The bill prohibits a child from being taken into custody due to a parent's refusal to administer psychotropic medications unless the refusal caused the child's neglect or abuse. The bill establishes requirements for obtaining parental authorization to administer medications to children in child care programs and criminal penalties created for violations of these requirements.

The bill requires school districts to adopt rules to prohibit school personnel from recommending the use of psychotropic medications for students and provides an exception. The bill prohibits school districts from requiring that a student, as a prerequisite to attendance or the reception of any other school district services, obtain a prescription for a controlled substance listed in schedule II under the federal Controlled Substances Act (21 U.S.C. s. 812(c), as amended by Title 21 C.F.R. part 1308).

The bill requires the Department of Education to develop rules for policies and procedures to prohibit school personnel from requiring a student to obtain a prescription for a controlled substance in violation of the new provision in law.

This bill amends ss. 39.401 and 1006.062, F.S., and creates s. 402.3127, F.S.

The bill provides an effective date of July 1, 2004.

II. Present Situation:

Children's Mental Health[1]

Primary care physicians identify approximately 19 percent of the children they see as having behavioral and emotional problems.[2] A number of treatment options are available to address mental health problems in children including psychotropic medications. The National Institute of Mental Health reports that psychotropic medications, while generally not the first option, may be prescribed when the possible benefits of the medications outweigh the risk and, in particular, when psychosocial interventions are not effective by themselves and there are potentially serious negative consequences for the child.[3] There are several major categories of psychotropic medications: stimulants, antidepressants, anti-anxiety agents, anti-psychotics, and mood stabilizers. These medications may be used to treat a variety of symptoms, including as follows:

- Stimulant medications are frequently used for Attention Deficit Hyperactivity Disorder (ADHD), which is the most common behavioral disorder of childhood;
- Anti-depressants and anti-anxiety medications are frequently used for depression, anxiety, and obsessive compulsive disorders;
- Anti-psychotic medications are used to treat children with schizophrenia, bipolar disorders, autism, and severe conduct disorders; and
- Mood stabilizing medications are also used to treat bipolar disorders.[4]

A substantial number of children in the United States have diagnosed mental disorders. According to research, a review of Medicaid prescription records (from unidentified states) during 1995 indicated that 150,000 preschoolers under the age of six were prescribed psychotropic medications.[5] Additionally, the 1999 MECA Study (Methodology for Epidemiology of Mental Disorders in Children and Adolescents) estimated that almost 21 percent of the children in the United States between the ages of nine and 17 had a diagnosable mental or addictive disorder that caused impairment, and 11 percent of these children (approximately 4 million) had a significant impairment that limited their ability to function.

Psychotropic medication is one of many treatment interventions that may be used to address mental health problems. Medication may be recommended and prescribed for children with mental, behavioral, or emotional symptoms when the potential benefits of treatment outweigh the risks. There has been growing public concern, however, over reports that very young children are being prescribed psychotropic medications with potentially adverse side effects.

The use of psychotropic medication by children has been a source of recent public controversy with many concerned that prescription psychotropic medications are overused and misapplied to children with mental health problems. Little information exists to help clarify the debate concerning national patterns of psychotropic medication use by children and adolescents. In a study examining two nationally representative data sets to track changes in the use of prescription

[1] Committee Staff Analysis for CS/SB 1140 and CS/CS for SB 2262.
[2] *President's New Freedom Commission on Mental Health: Report to the President*, May 2003.
[3] *Treatment of Children with Mental Disorders*, National Institute of Mental Health, updated June 18, 2001.
[4] *Ibid*.
[5] *Trends in the Prescribing of Psychotropic Medications to Preschoolers,* Zito, J.A., Safer, D.J., dosReis, S., Gardner, J.F., Boles, M., and Lynch, F., The Journal of the American Medical Association, Vol. 283, No.8, February 2000.

psychotropic medication by children and adolescents over a span of 10 years (1987 to 1996), researchers found that the overall rate of any psychotropic medication use increased from 1.4 to 3.9 per 100 children and adolescents, with increases evident across all geographic regions and all age, race/ethnicity, sex, and insurance groups examined After controlling for these demographic characteristics, the researchers found that the likelihood of using a psychotropic medication was nearly three times higher in 1996 than in 1987.[6]

Some of the concern regarding the use of psychotropic medications with children stems from the limited information that is available regarding the efficacy and the potential side effects of these drugs with children. Most clinical trials for these drugs were conducted on an adult population. The same results are not always obtained when these drugs are used with children, and the side effects for children are frequently different from those experienced by adults. The Food and Drug Administration (FDA) has publicly expressed concerns regarding the use of antidepressants in children and recently established an advisory committee to further study and evaluate the use of psychotropic medications with children.

Child Protection[1]

Chapter 39, F.S., provides the statutory framework for addressing child abuse, neglect, and abandonment. Child abuse under chapter 39, F.S., is defined as a willful or threatened act that results in physical, mental, or sexual injury to a child or results in harm that causes or is likely to cause the child's physical, mental, or emotional health to be significantly impaired [s. 39.01(2), F.S.]. Child neglect is the deprivation of basic necessities such as food, shelter, clothing, or medical treatment that can cause, or places, the child in danger of significant impairment to his or her physical, mental, or emotional health [s. 39.01(45), F.S.]. Procedures for DCF which guide the identification of child abuse, neglect, and abandonment identify an allegation of deprivation of medical treatment as medical neglect (CF Operating Procedures No. 175-28). This type of allegation can include that the parent has not sought medical attention for an illness or injury or is not following through with the medical treatment prescribed for an illness or injury. Pursuant to statute and the operating procedures, the lack of provision of the medical treatment is not in and of itself medical neglect but instead the neglect occurs when not providing the medical treatment results, or could result, in serious or long-term harm to the child.

Section 39.401, F.S., stipulates those conditions under which a child may be removed from the home and taken into the custody of DCF. Specifically, the child may be taken into the custody of DCF only under the following conditions:

- The child has been abused, neglected, or abandoned;
- The child is experiencing an illness or injury, or is in imminent danger of such illness or injury, that resulted from abuse, neglect, or abandonment;
- The parent or legal guardian has violated a court imposed condition of placement; or
- A parent, legal custodian, or responsible adult relative is not immediately known and available to care for the child.

Child Care[1]

The intent of child care regulation in most states is to protect the health, safety, and well-being of

[6] Olfson, M., Marcus, S. C., Weissman, M. M., & Jensen, P. S. 2002. "National trends in the use of psychotropic medications by children." *Journal of the American Academy of Child and Adolescent Psychiatry*. 41(5), 514-521.

the children. Basic health and safety regulations usually include the administration of medication. The National Health and Safety Performance Standards published by the American Public Health Association and the American Academy of Pediatrics include standards that recommend the limitation of administration of medications at child care facilities to prescription medications ordered by a health care provider for a specific child, with written permission of the parent or legal guardian, and to nonprescription medications recommended by a health care provider for a specific child or for a specific circumstance for any child in the facility, again with written permission of the parent or legal guardian. It is also recommended that facilities have standards for labeling and storing medications, training caregivers to administer medication, and maintaining written records on the administration of medications.

In Florida, licensing requirements for child care facilities, family day care homes, large family child care homes, and specialized child care facilities for the care of mildly ill children include standards for dispensing, storing, and maintaining records relative to medications (Chapters 65C-20, 65C-22, and 65C-25, F.A.C.). Basically, the standards require the prescription and nonprescription medications provided by the parents be in the original containers. Written authorization is required to dispense any non-prescription medication. Prescription medication is to be dispensed according to the label directions.

Public school and nonpublic school child care programs that are deemed to be child care pursuant to s. 402.3025, F.S., must comply with these child care licensing standards. These deemed public school and nonpublic school child care programs include those not operated or staffed directly by the public schools, those serving children under 3 years of age who are not eligible for the special education programs (P.L. No 94-142 or P.L. No. 99-457), and programs in private schools serving children between the ages of 3 and 5 years when a majority of children in the school are under 5 years of age. The administration of medication in child care programs operated and staffed by the school system is governed by s. 1006.062, F.S., and local school board policy. Section 1006.062, F.S., requires written authorization from the parents for the dispensing of prescription medications. Each school board is required to adopt policies and procedures for the administration of prescription medications and to provide training to school personnel in the administration of prescription medication.

Attention Deficit Hyperactivity Disorder and School Policy[1]

It is estimated that 1.46 to 2.46 million children, or 3 to 5 percent of the student population, have ADHD.[7] The diagnostic methods, treatment options, and medications have become a very controversial subject, particularly in education.[8] One of the concerns raised has been that school officials are reported to be offering their diagnosis of ADHD and urging parents to obtain drug treatment for the child.[9] These concerns have resulted in the consideration of federal legislation to require states to develop and implement policies and procedures prohibiting school personnel from requiring that a child obtain a prescription for a controlled substance in order to attend school.[10]

[7] *Identifying and Treating Attention Deficit Hyperactivity Disorder: A Resource for School and Home*, U.S. Department of Education, 2003, p.2.
[8] *Identifying and Treating Attention Deficit Hyperactivity Disorder,* Supra, p. 1.
[9] Child Medication Safety Act of 2003, 108th Congress, House of Representatives Report, May 21, 2003, p. 5
[10] Child Medication Safety Act of 2003, Supra, p. 3.

The National Conference of State Legislatures reports that a number of states are currently considering legislation related to psychotropic medications and psychiatric treatment.[11] States that passed laws particular to this issue prior to 2003 included Connecticut that prohibited school personnel from recommending the use of psychotropic drugs for any child, but did not prohibit recommending a child be evaluated by a medical practitioner or school personnel from consulting one. Similarly, Virginia directed the Board of Education to develop and implement policies prohibiting school personnel from recommending the use of psychotropic medications for any students.

Concerns raised as the federal legislation has been debated have been that the legislation may deter educators from talking to parents about concerns with a student's emotional well-being and mental health. Educators were identified as a critical source of information about a child's behavior but they may potentially refrain from identifying mental health problems in a child due to fear of violating the law.[12] Students with ADHD may need the services provided under the federal Individuals with Disabilities Education Act (IDEA) and Section 504 of the Rehabilitation Act of 1973 to assist them with their education needs. Schools are required by IDEA and Section 504 to provide special education or make modifications or adaptations for students whose ADHD adversely affects their educational performance. Adaptations available to assist ADHD students include "curriculum adjustments, alternative classroom organization and management, specialized teaching techniques and study skills, use of behavior management, and increased parent/teacher collaboration."[13] The position identified by the U.S. Department of Education relative to the role of the educators as it pertains to prescribing medications is that it is the responsibility of the medical professionals, not the educational professionals, to prescribe any medication.[14] However, it was recognized that the input the educators can provide about the student's behavior can often aid in a diagnosis.

Statutory Sanctions for Misuse of Medications with Children[1]

Sanctions are available through Florida law to respond to the harm that can be caused by misuse of medications including licensing sanctions, the child protection laws, and criminal penalties. Section 402.310, F.S., provides for sanctions for violating child care licensing standards, specifically imposing administrative fines and denial, suspension, or revocation of the license. Given the current statutory construction of these provisions, administrative fines are the primary sanction applied for violation of the requirements for administering medications. These child care licensing standards and, in turn, the sanctions, currently do not apply to family day care homes that are not required or choose not to be licensed, to certain programs in public and nonpublic schools deemed not to be child care pursuant to s. 402.3025, F.S., to religious exempt child care programs pursuant to s. 402.316, F.S., and to summer camps and child care services in transient establishments pursuant to s. 402.302(2), F.S.

Inappropriate administration of medication could be considered child abuse if harm is caused by the misuse of the medications. All child care programs with the exception of those programs in the public schools and nonpublic schools deemed not to be child care pursuant to s. 402.3025,

[11] *Psychotropic Medications in Schools*. National Conference of State Legislatures, April 1, 2004.
[12] Swindell, Bill, *House Votes to Bar School from Requiring Medication*, Congressional Quarterly, and Swindell, Bill, *Bill Would Prevent Schools from Requiring Drug Usage*, Congressional Quarterly.
[13] *Identifying and Treating Attention Deficit Hyperactivity Disorder,* Supra, p. 6.
[14] Letter from Richard Riley of the U.S. Department of Education to Congressman Peter Hoekstra, November 21, 2000.

F.S., would fall under the jurisdiction of Florida's child abuse laws in chapter 39, F.S. The state attorney, law enforcement agency, and licensing agency are to be automatically notified of all reports of child abuse in a child care program (s. 39.302, F.S.).

Section 827.03(1), F.S., establishes the crime of child abuse, which is the intentional infliction of, or intentional act that could result in, mental or physical injury to a child. Committing the crime of child abuse is a third degree felony if there is no great bodily harm, permanent disability, or permanent disfigurement to the child. If the abuse results in great bodily harm, permanent disability, or permanent disfigurement to the child, the crime becomes aggravated child abuse and is felony of the first degree (s. 827.03(2), F.S.). Third degree felonies are punishable by a term of imprisonment not to exceed 5 years, a $5,000 fine, or, in the case of a violent career criminal, a longer term of imprisonment (ss. 775.082, 775.083, and 775.084, F.S.). A first degree felony is punishable by a term of imprisonment not to exceed 30 years or, under certain circumstances, life, a fine of $10,000, or a longer term of imprisonment for the violent career criminal (ss. 775.082, 775.083, and 775.084. F.S.).

Controlled Substances

Federal law provides that Schedule II drugs or other substances:

- have a high potential for abuse.
- have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
- may lead, if abused, to severe psychological or physical dependence.[15]

Examples of schedule II drugs include opium and opiates. Federal rules governing Schedule II drugs are contained in 21 C.F.R. §1308. The Schedule II medications most commonly used in the management of ADHD include methylphenidate (e.g., Ritalin, Concerta) and amphetamine (e.g., Dexadrine, AdderallXR).[16]

Chapter 893, F.S., the Florida Comprehensive Drug Abuse and Prevention Act, contains standards and schedules, including Schedule II. Florida law (s. 893.04(1)(f), F.S., relating to pharmacists and practitioners) provides for dispensing schedule II drugs by pharmacists. A prescription for a controlled substance listed in Schedule II may be dispensed only upon a written prescription of a practitioner, except that in an emergency situation, as defined by regulation of the Department of Health, such controlled substance may be dispensed upon oral prescription.

Florida administrative rule (Rule 64F-13.001, F.A.C.) defines an emergency situation, for purposes of authorizing an oral prescription of a controlled substance listed in Schedule II of the Federal Controlled Substance Act. The term "emergency situation" means those situations in which the prescribing practitioner determines:

- That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and

[15] 21 U.S.C. § 812.

[16] See *Helping Parents Make Sense of ADHD Diagnosis and Treatment: Medications Frequently Used in the Management of ADHD and Its Co-morbidities,* Journal of Pediatric Health Care, 17(3): 149-153, 2003. See http://www.medscape.com/viewarticle/453700_9

- That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II of the Act; and
- That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

Chapter 465, F.S., provides for the regulation of pharmacists. Section 465.0276, F.S., governs dispensing practitioners, and provides for the revocation or suspension of a practitioner's registration if his or her respective board finds that he or she has dispensed medicinal drugs in violation of chapter 465, F.S.[17]

III. Effect of Proposed Changes:

Section 1. The bill amends s. 39.401, F.S., relating to taking a child alleged to be dependent into custody, to provide that the refusal of a parent, legal guardian, or other person responsible for a child's welfare to administer or consent to the administration of psychotropic medications to the child is not grounds to take the child into custody. The bill prohibits the court from entering an order for the department to take the child into custody based solely on this condition. The bill provides that the child may be taken into custody by the department or by order of the court if the refusal to administer the psychotropic medication or refusal to consent to such administration is found to cause the neglect or abuse of the child.

This provision does not alter the definition of abuse and neglect as it relates to the administration of psychotropic medication, only the conditions under which the child may be taken into custody.

Section 2. The bill creates s. 402.3127, F.S., to prohibit any employee, owner, household member,
volunteer, or operator of a child care facility, family day care home, or large family child care home, which is required to be licensed or registered, from administering any medication to a child attending the facility without the written authorization of the child's parent or legal guardian. This prohibition also applies to a child care program operated by a public or nonpublic school that is deemed to be child care pursuant to s. 402.3025, F.S. The written authorization from the parent is required to include certain information, such as the name of the child, dates for which the authorization is applicable, dosage instruction, and signature of the parent or legal guardian.

The bill allows for the identified individuals in the child care facility, family day care home, or large family child care home to administer medication without written permission if an emergency medical condition exists, the parents are not available, and the medication is administered pursuant to the instructions of a prescribing health care practitioner. An "emergency medical condition" is also defined by the bill as those "circumstances when a prudent layperson acting reasonably would believe that an emergency medical condition exists."

[17] Medicinal drugs are defined in s. 465.003(8), F.S., as those substances or preparations commonly known as "prescription" or "legend" drugs which are required by federal or state law to be dispensed only on a prescription, but must not include patents or proprietary preparations.

The parents or legal guardians of the child must be immediately notified by the child care facility, family day care home, or large family child care home of the emergency medical condition and the corrective measures taken. The child care facility, family day care home, or large family child care home is required to immediately notify the child's medical care provider if the parents or legal guardians cannot be located and the emergency medical condition persists.

The bill provides for criminal penalties for failure to comply with the requirements of s. 402.3127, F.S., that is, administering medication to a child attending a child care facility, family day care home, or large family child care home, without written authorization unless the stipulated emergency circumstances are met. It is a third degree felony if the requirements of this section are violated and the violation results in serious injury to the child. If the violation of these requirements does not result in serious injury to the child, it is a misdemeanor of the first degree.

Section 3. The bill amends s. 1006.062, F.S., to direct each school board to adopt rules to prohibit all school board employees from recommending the use of psychotropic medications for any student. All district school board personnel are specifically not prohibited from recommending that a student be evaluated by a medical practitioner. The bill also specifically provides that school board personnel are not prohibited from consulting with a medical practitioner with the consent of the student's parent.

The bill prohibits a school district from requiring that a student, as a prerequisite to attendance or the reception of any other school district services, obtain a prescription for a controlled substance listed in schedule II under s. 202(c) of the federal Controlled Substances Act, 21 U.S.C. s. 812(c), as amended by Title 21 C.F.R. part 1308.

The Department of Education must develop rules containing policies and procedures that prohibit school personnel from requiring a student to obtain a prescription for a controlled substance in violation of the new provision in law.

Section 4. The bill provides an effective date of July 1, 2004.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

There may be some minor costs associated with rulemaking.

VI. Technical Deficiencies:

During the 2002 School Code revision, rulemaking authority was vested with the State Board of Education. Accordingly, the bill should be amended to conform to this change.

VII. Related Issues:

Chapter 458, F.S., governs the regulation of the practice of medicine by the Board of Medicine. Section 458.305, F.S., defines the "practice of medicine" to mean the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition. The Board of Medicine within the Department of Health (DOH) regulates the practice of medical physicians. Chapter 459, F.S., the osteopathic medical practice act, similarly provides for the regulation of osteopathic physicians by the Board of Osteopathic Medicine in DOH. Section 459.003, F.S., defines the "practice of osteopathic medicine" to mean the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition, which practice is based in part upon educational standards and requirements which emphasize the importance of the musculoskeletal structure and manipulative therapy in the maintenance and restoration of health.

Section 456.065(2), F.S., specifies penalties for the unlicensed practice of a health care profession. Section 465.065(2)(a-c), F.S., provides administrative and civil penalties for unlicensed activity. Section 465.065(2)(d), F.S., provides criminal penalties in addition to the criminal violations and penalties listed in the individual health care practice acts.

There does not appear to be an exemption from these practice acts for school district personnel to require students to obtain a prescription to treat a medical condition to attend school. Consequently, school district personnel who attempt to implement this policy may be subject to criminal penalties prohibiting the unlicensed practice of medicine under the provisions of chapter 458, F.S., or chapter 459, F.S.

The requirements for administering medication in child care facilities allows for "medication" to be administered without written authorization of the parent in an emergency and in accordance with the instructions of a medical care provider. The bill does not stipulate whether this applies to prescription or nonprescription medications which could allow for a medication prescribed for

another child that is not authorized by a parent to be administered to a child.

VIII. Amendments:

None.