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 Children, Families, and Elder Affairs Committee

BILL:	CS/SB 2718
INTRODUCER:	Children, Families, and Elder Affairs and Senator Storms
SUBJECT:	Psychotropic Medication
DATE:	March 19, 2010 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Preston	Walsh	CF	**Fav/CS**
2.			JU	
3.			HA	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

The committee substitute makes a number of changes to current law relating to psychotropic medication and children in out of home placements including:

- Providing that every child placed in out-of-home care be provided a comprehensive behavioral health assessment;
- Providing for legislative findings and intent;
- Providing definitions for terms used in a newly created section;
- Providing for the appointment of a Guardian ad Litem (GAL) for every child who is being prescribed a psychotropic medication and providing duties and responsibilities;
- Prescribing procedures for seeking to obtain and obtaining express and informed consent and assent;
- Requiring the development of a mental health treatment plan for children in out-of-home care who need mental health services;
- Providing procedures to be followed for the administration of psychotropic medication to a child in out-of-home care when parental consent has not been obtained and for the administration of psychotropic medication to a child in out-of-home care before court authorization has been obtained;

- Raising the age for obtaining pre-consent for prescribing and administering psychotropic medication; and
- Prohibiting a child in the custody of the Department of Children and Family Services (DCF or department) from participating in clinical trials involving psychotropic medication.

This bill creates s. 39.4071, and amends ss. 39.407 and 743.0645 of the Florida Statutes.

II. Present Situation:

Background

Many children in the United States receive psychotropic medications, and this number has increased over time. The use of multiple psychotropic medications has also been reported to have increased among children. The efficacy and short- and long-term safety knowledge base for pediatric psychopharmacology has increased in recent years but remains limited.[1]

An issue that has received increasing national attention over the past decade has been the concern for the overuse of psychotropic medications among our nation's youth in general, with a potentially disproportionate increase among children in foster care.[2] Among community-based populations, children in foster care tend to receive psychotropic medication as much as or more than disabled youth and 3-4 times the rate among children with Medicaid coverage based on family income.[3] Children in foster care and disabled youth have the greatest likelihood of receiving complex, poorly evidenced, high cost medication regimens.[4]

The few research studies available show rates of psychotropic medication use ranging from 13-50% among children in foster care, compared with approximately 4% in youth in the general population. [5] A 2006 report prepared by the Government Accountability Office found that 15 states identified the overuse of psychotropic medications as one of the leading issues facing their child welfare systems in the next few years.[6] In her testimony to Congress, Laurel Leslie stated:

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[1] Breland-Noble, A.M., Elbogen, E.B., Farmer, E.M.Z., et al. *Use of Psychotropic Medications by Youths in Therapeutic Foster Care and Group Homes.* Psychiatric Services. Vol. 55, No. 6. June 2004, pp. 706-708. Available at: http://ps.psychiatryonline.org. (Last visited March 13, 2010).

[2] Leslie, L.K. Testimony on behalf of the American Academy of Pediatrics before the U.S. House of Representatives, Committee on Ways and Means, Subcommittee on Income Security and Family Support, *Hearing on the Utilization of Psychotropic Medication for Children in Foster Care*. May 8, 200. Available at: http://www.aap.org/advocacy/washing/Testimonies-Statements-Petitions/05-08-08-Leslie-Psychotropics-Meds-Testimony.pdf. (Last visited February 16, 2010.)

[3] Zito, J.M. Testimony before the U.S. House of Representatives, Committee on Ways and Means, Subcommittee on Human Resources, *Prescription Psychotropic Drug Use Among Children in Foster Care*. Washington, D.C. May 8, 2008. Available at: www.hunter.cuny.edu/socwork/.../2.../Zito%20Medication%20handout.doc. (Last visited February 16, 2010).

[4] *Id.*

[5] Leslie, L.K. Testimony on behalf of the American Academy of Pediatrics before the U.S. House of Representatives, Committee on Ways and Means, Subcommittee on Income Security and Family Support, *Hearing on the Utilization of Psychotropic Medication for Children in Foster Care*. May 8, 2008. Available at: http://www.aap.org/advocacy/washing/Testimonies-Statements-Petitions/05-08-08-Leslie-Psychotropics-Meds-Testimony.pdf. (Last visited February 16, 2010.)

[6] US Government Accountability Office. *Child Welfare: Improving Social Service Program, Training, and*

> It is difficult to know from these preliminary analyses or the multitude of reports that are emerging in the media whether the use of these medications by children in foster care is appropriate, although at the very least the use of combinations of three or more medications remains controversial. Clearly, medication can be helpful to some children, but with the increasing use of these medications among children in general, there comes the added responsibility to ensure that children have access to an array of treatment strategies, from medication to community-based services that may augment or replace the need for medications in many circumstances. Furthermore, the failure to coordinate and provide continuity in services and the absence of clear guidelines and accountability to ensure that treatment decisions are in the child's best interest, create a greater risk that medications will be prescribed to control children's behaviors in the absence of individualized service plans that might offer the best chance for success.[7]

In Florida, prescribing psychotropic medications for children in out-of-home placements has been an issue for at least a decade. Reports of widespread use occurring in children in foster care under the supervision of DCF in south Florida was brought to the attention of the Statewide Advocacy Council (SAC) in 2001.

When an internal investigation by the department was conducted, it concluded that the use of psychotropic drugs in children in their care was not a problem. However, information received from the Agency for Health Care Administration (AHCA) revealed that more than 9,500 children in Florida on Medicaid had been treated with psychotropic drugs in the year 2000.

In 2004, the department studied the use of psychotropic medications with children in its custody over a specified period of time. The department determined that 13 percent of all children in state custody were receiving at least one psychotropic medication. Of this group, 8 percent were being treated with three or more medications concurrently. Findings also indicated that 3.5 percent of the children in state custody age five and under received at least one psychotropic medication. An additional finding was that 25 percent of the children living in a foster care setting were being treated with psychotropic medications, a rate five times higher than the general population of Medicaid eligible children. Despite initiatives by the department to identify children in its care who were on psychotropic medications and to determine the appropriateness of this treatment, limited information existed.[8]

In 2005, the Florida Legislature enacted CS/CS/SB 1090, which provided a comprehensive statutory framework relating to the use of psychotropic medications with children who are in out-of-home placements.

Technical Assistance Information Would Help Address Long-standing Service-Level and Workforce Challenges. Washington, DC: US GAO; 2006. Available at: http://www.gao.gov/new.items/d0775.pdf. (Last visited February 16, 2010).

[7] Leslie, L.K. Testimony on behalf of the American Academy of Pediatrics before the U.S. House of Representatives, Committee on Ways and Means, Subcommittee on Income Security and Family Support, *Hearing on the Utilization of Psychotropic Medication for Children in Foster Care*. May 8, 2008

[8] *See* Senate Staff Analysis and Economic Impact Statement, CS/CS/SB 1090, April 14, 2005.

Gabriel Myers

Seven-year old Gabriel Myers was adjudicated dependent on September 2, 2008, following the arrest of his mother and the filing of the abuse report that brought him into the care of the department on June 29, 2008. During the following ten months, Gabriel was initially sheltered in a licensed foster home until being placed with relatives. When the relative placement failed, he was returned to the licensed home where he was initially placed. When that placement also failed to work, he was sent to the licensed home in which he resided when he died. This particular home had previously served as a respite for Gabriel, and he was familiar with the surroundings.[9]

In February and March 2009, Gabriel experienced a number of significant life events, including changes in foster homes, therapists, and after-school programs. He lost privileges at home and visitation time with his mother, all of which more than likely contributed to his mental status at the time of his death.[10]

While in care, he received numerous mental health and behavioral assessments and underwent regular treatment from a psychiatrist and two therapists, one of whom documented that "it is clear that this child is overwhelmed with change and possibly re-experiencing trauma." Gabriel demonstrated a number of incidents of destructive behavior and conduct problems and was treated with counseling and several psychotropic medications. On April 16, 2009, 7-year-old Gabriel Myers hanged himself in the residence of his foster parents.[11]

A review of Gabriel's medical records by the Broward County Medical Examiner's office[12] indicates that Gabriel was prescribed Vyvanse and Symbax by Dr. Sohail Punjwani, M.D.[13,14]

The QA report issued by DCF on April 20, 2009,[15] stated that the Child Resource Record (CRR) for Gabriel containing medical information, including medications, was secured by law enforcement. Based on the information obtained from the documentation available for review, a timeline of prescribed medications is provided below.

- June 29, 2008, Adderall
- July 31, 2008, Adderall discontinued

[9] Department of Children and Family Services, Final Report of the Gabriel Myers Work Group, November 19. 2009.
[10] *Id.*
[11] *Id.*
[12] Broward County Medical Examiner, Classification of Pending Case, Gabriel Myers, September 3, 2009.
[13] Dr. Punjwani was the psychiatrist treating Gabriel at the time of his death. A warning letter dated February 4, 2010, from the U.S. Food and Drug Administration (FDA), stated that Dr. Punjwani overmedicated children who were enrolled in clinical trials for undisclosed drugs and that her "failure to conduct the requisite safety measures contributed to the unnecessary exposure of pediatric subjects to significant overdoses, which jeopardized the subjects' right, safety, and welfare".
[14] Department of Children & Families Secretary George Sheldon, who appointed a task force last year to study Gabriel's death, said Monday he is asking the FDA to compare a list of Florida foster children with lists of children enrolled in Punjwani's clinical trials. Sheldon said he was acting on concerns that children in state care may have been involved in clinical trials, which is against state law. Miami Herald, FDA warns psychiatrist who treated dead foster child, March 16, 2010. Available at: www.miamiherald.com/2010/03/16/1531156/psychiatrist-gets-warning-from.html. (Last visited March 16, 2010).
[15] Department of Children and Family Services, Issue Summary Update, Gabriel Myers, April 20, 2009.

- August 21, 2008, Dr. Punjwani noted medication was not indicated at that time
- December 09, 2008, Vyvanse[16] for ADHD prescribed
- February 03, 2009, Vyvanse continued and Lexapro prescribed
- March 18, 2009, Vyvanse continued, Lexapro discontinued, Symbyax[17] prescribed

Gabriel Myers Work Group

The Gabriel Myers Work Group was appointed in April 2009 to analyze and make recommendations relating to Gabriel Myers and the use of psychotropic medication for children in out-of-home care. The work group identified 147 findings in ten areas, resulting in 90 recommendations for action.[18]

The work group determined that a detailed framework of safeguards for Florida's foster children exists and is articulated in statute, administrative rule, and operating procedures. The **core failures** in the system, however, **stem from lack of compliance with this framework and with failures in communication, advocacy, supervision, monitoring, and oversight.**[19]

Of the 90 recommendations contained in the final report (with the exception of five that are related to funding requests), there were 10 recommendations directed at the legislature:

- The Legislature should amend the requirement for a pre-consent consultation for all children in out-of-home care under age six. Instead, the consultation should be expanded to include all children age eleven and under who are prescribed two or more psychotropic medications.
- The Legislature should review current statutes to ensure that procedural safeguards employed for the use of psychotropic medications are applied to all medications that alter brain function, regardless of the purpose of the prescription, to ensure they are adequate.
- The Legislature should amend Section 39.407, F.S., to change the term "medical report" to "medical treatment plan" so that interventions focus on treatment and the holistic needs of the child.
- The Legislature should authorize DCF to develop a single medical treatment plan form with standardized information that can be utilized in all judicial circuits across the state.
- The Legislature should ensure that statutes and department policies, procedures, and practices recognize that children should be fully involved and allowed to participate in

[16] Vyvanse is lisdexamfetamine, an amphetamine used for treating attention deficit hyperactivity disorder (ADHD) in certain patients. It is used as a part of a total treatment program that may include psychological, educational, and social therapy. Information available at: http://www.drugs.com/cdi/lisdexamfetamine.html. (Last visited March 16, 2010).
[17] Symbyax contains a combination of fluoxetine and olanzapine. Fluoxetine is an antidepressant in a group of drugs called selective serotonin reuptake inhibitors (SSRIs). Olanzapine is an antipsychotic medication. Symbyax is used to treat depression caused by bipolar disorder (manic depression). Symbyax is also used to treat depression after at least 2 other medications have been tried without successful treatment of symptoms. It is not known if Symbyax is safe and works in children under 18 years of age. Available at: http://www.drugs.com/symbyax.html. (Last visited on March 16, 2010).
[18] In August 2009, a Miami Herald article reporting on the Gabriel Myers Work Group stated that "the state has failed to implement recommendations from prior task forces that studied the deaths of foster children or the use of psychotropic drugs. Indeed, DCF has failed to even assign 'responsibility' or 'accountability' for implementing such reports."Miller, C.M. Miami Herald, *Child-welfare panel: Drugs misused on foster kids*, August 13, 2009.
[19] Department of Children and Family Services, Final Report of the Gabriel Myers Work Group, November 19. 2009.

court hearings and treatment decisions. As part of this, prescribers should be required to confer with and seek assent from each child and to document the child's position. DCF should be required to inform the Court of the child's position.

- The Legislature should review Florida statutes to ensure requirements are practical and clearly defined for:
  - Prescribing psychotropic medications;
  - Obtaining informed consent;
  - Obtaining the child's assent;
  - Requiring a parent, case worker, or other adult responsible for the child's care to attend each medical appointment with the child;
  - Administering and monitoring psychotropic medications;
  - Discontinuing, when appropriate, psychotropic medications. To include a formal plan for discontinuation;
  - Notifying involved parties; and
  - Reporting adverse incidents.
- The Legislature should require all prescribing physicians to report adverse consequences of psychotropic medications; all adverse effects should become a record in the medical file of a child in the care of the state.
- The Legislature should allow Advanced Registered Nurse Practitioners and Physician Assistants to provide information to parents and legal guardians in order to obtain express and informed consent for treatment.
- The Legislature should preclude any participation by children in state care in clinical trials relating to the development of new psychotropic medications.
- In any legislation arising from this report, the Legislature should utilize these guiding principles articulated by the work group as the statement of legislative intent and expected standards of care for children in the care of the state.

CS/SB 2718 addresses many of these recommendations as well as additional issues raised by other stakeholders.

III. Effect of Proposed Changes:

The CS makes a number of changes related to the provision of psychotropic medication to children who are in an out-of-home placement, including:

- **Comprehensive behavioral health assessment (CBHA)** – The bill requires that every child placed in out-of-home care receive a CBHA, specifies who is eligible for the assessment, and requires that the assessment must be provided to the physician involved in developing the mental health treatment plan for any child in need of mental health services.
- **Legislative findings and intent –** The bill provides legislative findings and intent that, due to multiple risk factors, children in out-of-home care are more likely to have behavioral and emotional disorders, receive mental health services, and be provided psychotropic medications at higher rates than other children. The bill states that it is the intent of the legislature that children in out-of-home care who need psychotropic medications receive them as part of a comprehensive treatment plan monitored by a court-appointed Guardian Ad Litem (GAL).

- **Definitions –** Definitions are created for the term "assent", "comprehensive behavioral assessment", "express and informed consent", "mental health treatment plan", and "psychotropic medication".
- **Appointment of a Guardian ad Litem** – The bill provides for the appointment of a GAL at the earliest possible time to represent the best interest of a child in DCF custody that is prescribed a psychotropic medication; provides duties and responsibilities of the guardian ad litem; and requires the department and its community-based care (CBC) lead agencies to notify the GAL within 24 hours after any change in the status of the child.
- **Express and informed consent and assent –** The bill provides responsibilities of the physician in obtaining express and informed consent of the parent or guardian and the assent of the child.
- **Administration of psychotropic medication to a child in care when parental consent has not been obtained –** The bill provides procedures to be followed by the department and the court in cases where a child is in an out-of-home placement and may need a psychotropic medication, but parental consent has not been obtained.
- **Administration of psychotropic medication to a child in out-of-home care before court authorization has been obtained –** The bill outlines procedures to be followed to administer psychotropic medication before a court order has been obtained, including cases when a child receives a one-time dose of medication.
- **Discontinuation, alteration, or destruction of medication** – The bill provides procedures for discontinuing or altering the provision of psychotropic medication to a child and requires the department to ensure destruction of unused medication that is no longer being taken by a child.
- **Development of Mental Health Treatment Plan –** The bill requires that any child who needs mental health services must have a mental health treatment plan. This provision establishes a new requirement that places specific time and role responsibilities on the child protective investigator or case manager to initiate a referral for a behavioral assessment and specifies what information is to be included in the treatment plan.
- **Pre-consent review** - The bill provides that no child under 11 years of age may be prescribed psychotropic medication absent a finding of compelling governmental interest. The current age requirement for pre-consent review is any child under 6 years of age.
- **Clinical trials –** The bill prohibits a child in the custody of the department from participating in clinical trials relating to the development of new psychotropic medications.
- **Judicial review** – The bill provides for additional information relating to psychotropic medication to be added to judicial review hearings.
- **Rulemaking –** The bill provides rulemaking authority for the department.

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:

None.

C. Government Sector Impact:

An analysis from the Department of Children and Family Services stated that the fiscal impact of the bill on the DCF is anticipated to be covered within existing resources. The fiscal impact will be a result of the increase in the number of pre-consent authorizations. This cost is based on $160 per authorization, at an average of 3 pre-consent reviews (as medications change) per child for 917 children aged 10 and under and who are on psychotropic medication: $480 X 917 = $440,160. An additional $4,000 to establish an online submission capacity for pre-consent reviews is added into this recommendation for a total of $444,160.

The Guardian Ad Litem Program has not submitted a separate fiscal analysis, but estimates the fiscal impact to the program to be minimal.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Children, Families, and Elder Affairs on March 18, 2010:
The committee substitute amends the bill as filed and:

- Requires that every child placed in out-of-home care receive a CBHA, specifies who is eligible for the assessment, and requires that the assessment must be provided to the physician involved in developing the mental health treatment plan for any child in need of mental health services.
- Provides a process for discontinuing or altering the provision of psychotropic medication to a child and requires the department to ensure destruction of unused medication that is no longer being taken by a child.
- Requires that any child who needs mental health services must have a mental health treatment plan (The bill provided a plan for every child). This provision establishes a new requirement that places specific time and role responsibilities on the child protective investigator or case manager to initiate a referral for a behavioral assessment and specifies what information is to be included in the treatment plan.
- Provides for additional information relating to psychotropic medication to be added to judicial review hearings.
- Provides rulemaking authority for the department.

B. Amendments:

None.

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