



## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. HOUSE PRINCIPLES ANALYSIS:

**Provide Limited Government** – The CS creates Medicaid eligibility for a new group of individuals.

**Empower Families** – The CS increases dependence of families upon government support and assistance.

#### B. EFFECT OF PROPOSED CHANGES:

### BACKGROUND

#### Familial Dysautonomia Syndrome

Familial Dysautonomia (FD) --- or Riley-Day Syndrome --- is an example of a group of disorders known as “hereditary sensory and autonomic neuropathies” (HSAN) characterized by widespread sensory dysfunction resulting from incomplete development of sensory and autonomic neurons.<sup>1</sup> First identified in a report by Drs. Conrad Riley and Richard Day in 1949, FD is a debilitating disease that is present from birth, and results in lifelong progressive neuronal degeneration.<sup>2</sup>

Prior to 1960, approximately 50% of patients suffering from FD died before reaching the age of five.<sup>3</sup> However, recent advances in supportive treatment approaches have extended the life expectancy of individuals with FD, and the probability of reaching age 20 has now increased to 60%,<sup>4</sup> and roughly half of patients diagnosed with FD live to the age of 30.

#### Transmission

Unlike other HSAN, Familial Dysautonomia has been observed only in individuals of Eastern European Jewish Ancestry (Ashkenazi Jewish extraction), and it is estimated that one in 27 individuals of Eastern European Jewish origin are carriers of the FD gene.<sup>5</sup> The Dysautonomia Foundation, Inc. in New York reports that, based on information available from the FD world-wide registry, as of January 2004 there were over 340 people worldwide living with FD. One-third of these individuals live in the metropolitan New York City area, one-third reside in Israel, and the remaining third live elsewhere in the United States and worldwide.<sup>6</sup> It has been reported by the Agency for Health Care Administration (AHCA) that 18 persons with FD (**10 children and 8 adults**) are residents of Florida.

Familial Dysautonomia is an autosomal recessive disorder<sup>7</sup>, meaning that a child must inherit a copy of the FD gene from each of their birth parents. All parents of children with Familial Dysautonomia are

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<sup>1</sup> *More About FD*, 2005, the NYU School of Medicine Department of Pediatrics Dysautonomia Treatment & Evaluation Center, available at: <http://www.med.nyu.edu/fd/fdcenter.html>.

<sup>2</sup> *Familial Dysautonomia*, January 10, 2005, report by GeneTest (funded by the National Institutes of Health), available at: <http://www.genetests.org/profiles/fd>.

<sup>3</sup> *Familial Dysautonomia (FD)*, accessed March 9, 2006, Jewish Genetic Diseases: A Mazornet Guide, available at: [http://www.mazornet.com/genetics/familial\\_dysautonomia.asp](http://www.mazornet.com/genetics/familial_dysautonomia.asp).

<sup>4</sup> *Ibid.*

<sup>5</sup> *FD 101: What is FD?*, accessed March 6, 2006, Familial Dysautonomia Hope Foundation, available at: <http://www.fdhope.org/FamilialDysautonomia/AboutFD/FD101.htm>.

<sup>6</sup> *FD History and Statistics*, accessed March 6, 2006, the Dysautonomia Foundation, Inc., available at: <http://www.familialdysautonomia.org/history.htm>.

<sup>7</sup> *About Familial Dysautonomia: Genetics*, accessed March 6, 2006, Familial Dysautonomia Hope Foundation, available at: <http://www.fdhope.org/FamilialDysautonomia/AboutFD/genetics.htm>.

carriers of the recessive gene that transmits the disease, although a parent or carrier of the gene has no symptoms or warning signs of being a carrier until a child's birth.<sup>8</sup>

### Symptoms

Familial Dysautonomia primarily affects the body's autonomic nervous system (responsible for the subconscious regulation of bodily functions and the activities of specific organs) and its sensory nervous system (which controls the body's perceptions of hot/cold and taste, and regulates its protective reactions to pain and other external stimuli).<sup>9</sup>

Although symptoms vary with age, the hallmark clinical feature of Familial Dysautonomia is the absence of overflow tears typically associated with emotional crying.<sup>10</sup> Corneal sensitivity and various other severe eye problems occur frequently in FD patients as a result.

Feeding difficulty is observed in 60% of infants with FD in the neonatal period, and poor suck and misdirected swallows often persist and put the patient at risk for aspiration pneumonia (a major cause of lung infections). Other clinical manifestations of the disorder include: decreased responsiveness to pain and temperature, extreme fluctuations in blood pressure, red blotching of the skin, and increased sweating. Additionally, individuals suffering from Familial Dysautonomia often have delayed acquisition of speech and walking abilities, unsteady gait, breath-holding episodes and poor growth patterns. By age 13, 90% of FD patients experience some spinal curvature.<sup>11</sup>

Familial Dysautonomia patients can be expected to function independently if treatment is begun early and major disabilities are avoided. Affected individuals typically are of normal intelligence.

### Dysautonomia Crisis

Roughly 40% of individuals with FD will react to stressors or stress events (frequently caused by physical infection or emotional events) with what is termed a "dysautonomia crisis." In addition to vomiting, an individual having a dysautonomia crisis experiences elevated heart rate and blood pressure, irritability and insomnia, severe dysphagia and drooling, and excessive sweating and blotching of the face and trunk.<sup>12</sup>

### Treatment

As there is still no cure for Familial Dysautonomia, treatment approaches remain preventative, supportive, and largely symptomatic, and include:<sup>13</sup>

- artificial tears;
- special feeding techniques;
- special occupational, physical and speech therapies;
- special drug management of autonomic manifestations;
- respite care
- orthopedic treatment (for complications from tibial torsion and spinal curvature); and
- compensation for labile blood pressures.

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<sup>8</sup> *More About FD*, the NYU School of Medicine Department of Pediatrics Dysautonomia Treatment & Evaluation, *supra*.

<sup>9</sup> What is Familial Dysautonomia?, accessed March 6, 2006, the Dysautonomia Foundation, Inc., available at: <http://www.familialdysautonomia.org/whatisfd.htm>.

<sup>10</sup> *More About FD*, the NYU School of Medicine Department of Pediatrics Dysautonomia Treatment & Evaluation, *supra*, noting that, although the absence of overflow tears is the most distinctive feature of Familial Dysautonomia, it is typical for a child not to have tears until reaching 7 months of age.

<sup>11</sup> *Ibid.*

<sup>12</sup> *Ibid.*

<sup>13</sup> *Familial Dysautonomia (FD)*, Jewish Genetic Diseases: A Mazornet Guide, *supra*.

## Funding for Familial Dysautonomia Services

The Department of Health, Children's Medical Services (CMS), currently provides services to children diagnosed with FD whose families meet certain income limitations. Under certain federal requirements of the Omnibus Budget Reconciliation Act of 1989 (OBRA 89) specifying that Medicaid programs meet children's medical needs, CMS is able to provide care coordination for a range of needed services and therapies. However, CMS does not have funding to provide families of FD children with respite or behavioral services. Persons with FD are not served by the Agency for Persons with Disabilities (APD).<sup>14</sup>

## **Medicaid Home and Community-based Waivers**

In 1981, Congress authorized the waiver of certain federal requirements to enable a state to provide home and community-based services (other than room and board) to individuals who would otherwise require institutional care reimbursed by Medicaid. The waiver programs are called "1915(c) waivers." Under 1915(c) waiver authority, states can provide services not traditionally covered by the Medicaid program, as long as these services are integral to preventing an individual's institutionalization. A 1915(c) waiver may include a waiver of the requirements of the following sections of the Social Security Act:<sup>15</sup>

- 1902(a)(1), relating to statewideness. This allows states to target waivers to particular areas of the state where the need is greatest, or perhaps where certain types of providers are available;
- 1902(a)(10)(B), relating to comparability of services. This allows states to make waiver services available to the Medicaid population at large. States use this authority to target services to particular groups, such as elderly individuals, technology-dependent children, or persons with mental retardation or developmental disabilities; and
- 1902(a)(10)(c)(i)(III), relating to community income and resource rules for the medically needy. This allows states to provide Medicaid to individuals who would otherwise be eligible only in an institutional setting, often due to the income and resources of a spouse or parent. States may also use spousal impoverishment rules to determine financial eligibility or waiver services.

A 1915(c) waiver is initially authorized for three years, and renewals are required every five years thereafter. Within the parameters of broad federal guidelines, 1915(c) waiver authority provides states with flexibility in structuring home and community-based waiver programs designed to meet the specific needs of targeted populations. Federal requirements for states choosing to implement a home and community-based waiver program include:

- demonstrating that provision of waiver services to a target population is no more costly than the cost of services such individuals would receive in an institutional setting;
- ensuring that measures will be taken to protect the health and welfare of consumers;
- assuring financial accountability for funds expended under the waiver authority;
- providing adequate and reasonable provider standards intended to meet the needs of the target population; and
- ensuring that services are provided in accordance with a plan of care.

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<sup>14</sup> The Agency for Persons with Disabilities was formerly the Development Disabilities Program of the Department of Children and Families. Pursuant to s. 20.197(2), APD is charged with administering waivers established to provide services to persons with developmental disabilities. Familial Dysautonomia is not a "developmental disability" pursuant to s. 393.063(10), F.S."

<sup>15</sup> HCBS Waivers Section 1915(c), accessed March 29, 2006, U.S. Department of Health and Human Services Center for Medicare and Medicaid Services, available at: [http://www.cms.hhs.gov/MedicaidStWaivProgDemoPGI/05\\_HCBSWaivers-Section1915\(c\).asp#TopOfPage](http://www.cms.hhs.gov/MedicaidStWaivProgDemoPGI/05_HCBSWaivers-Section1915(c).asp#TopOfPage).

## Previous Legislation

Chapter 2005-115, L.O.F., enacting HB 17, directed the Agency for Health Care Administration (AHCA) to work with APD in developing a model home and community-based waiver to serve children diagnosed with FD. The legislation required AHCA to seek federal waiver approval and implement the approved waiver, subject to the availability of funds and any limitations provided in the General Appropriations Act. The act also appropriated \$171,840 from the General Revenue Fund and \$246,160 from the Medical Care Trust Fund for FY 2005-06.

On March 20, 2006, AHCA submitted an application for a section 1915(c) home and community-based waiver to authorize operation of a Familial Dysautonomia Model Home and Community-Based Services Waiver. By electing to structure the waiver as a “Model” waiver,<sup>16</sup> federal regulations require that no more than 200 individuals are to be served by the waiver at any one time.<sup>17</sup>

The Department of Children and Family Services (DCF) reports that, for purposes of establishing Medicaid eligibility under the waiver, children and single adults are considered a “family of one”, and only the income and assets of the child or single adult individually are considered by the department when assessing eligibility.

## PROPOSED CHANGES

The CS for HB 1247 amends s. 409.912(51), F.S., to add adults as participants in the Familial Dysautonomia home and community-based waiver, and to delete a provision specifying that implementation of the waiver is “subject to the availability of funds and any limitations provided in the General Appropriations Act.”

By deleting the reference to a “model” home and community-based waiver in s. 409.912(51), F.S., the CS requires that the waiver be structured as a regular home and community-based waiver pursuant to 42 C.F.R. s. 441.305(a). Therefore, the CS makes the 200-participant limited enrollment provision for “model” waivers<sup>18</sup> inapplicable.

The CS is effective upon becoming law.

### C. SECTION DIRECTORY:

**Section 1:** Amends s. 409.912, F. S., adding adults diagnosed with Familial Dysautonomia to the home and community-based waiver developed by AHCA and APD; deleting a provision indicating that implementation of the waiver is subject to the availability of funds and any other limitation provided in the General Appropriations Act.

**Section 2:** Provides that the CS is effective upon becoming a law.

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<sup>16</sup> The “Model” waiver submitted by AHCA is different from the model waiver authorized under section 134 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA 134), commonly referred to as the “Katie Beckett” waiver. A waiver under this provision in TEFRA allows a state to make the full array of Medicaid services available to a disabled child irrespective of the income and assets of the child’s parents. Such children are “deemed” eligible. A Katie Beckett waiver is not a means of providing Medicaid funds or services to adults.

<sup>17</sup> 42 C.F.R. s. 441.305(b).

<sup>18</sup> *Ibid.*

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

AHCA advises that no additional funding is necessary to administer this legislation.

### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

### C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

AHCA reports that the CS creates no direct economic impact on the private sector.

### D. FISCAL COMMENTS:

None.

## III. COMMENTS

### A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This CS does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This CS does not reduce the percentage of a state tax shared with counties or municipalities. This CS does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

### B. RULE-MAKING AUTHORITY:

None.

### C. DRAFTING ISSUES OR OTHER COMMENTS:

Should this legislation be enacted, it would require AHCA to amend its pending application to reflect "regular" waiver status, rather than "model."

## IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

At its April 4, 2006 meeting the Elder and Long-Term Care Committee adopted an amendment to HB 1247, removing the appropriations made to AHCA for the purpose of implementing this act during FY 2006-07. Appropriations staff reports that the funds appropriated from the General Revenue and Medical Care Trust

Funds for the purpose of implementing the 2005 legislation are recurring and, therefore, no additional appropriations are necessary.

The Committee favorably reported a Committee Substitute, and this analysis is drafted to the Committee Substitute.