

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.)

Prepared By: Health and Human Services Appropriations Committee

BILL: CS/SB 1926

SPONSOR: Health Care Committee and Senator Margolis

SUBJECT: Inflammatory Bowel Disease

DATE: April 22, 2005

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Harkey</u>	<u>Wilson</u>	<u>HE</u>	<u>Fav/CS</u>
2.	<u>Fabricant</u>	<u>Peters</u>	<u>HA</u>	<u>Favorable</u>
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

This bill requires the Department of Health (DOH), in conjunction with the University of Florida College of Public Health and Health Professions, to conduct an epidemiological study of inflammatory bowel disease and to report its findings to the Governor and Legislature by February 1, 2006. The bill requires the Agency for Health Care Administration (AHCA) to conduct a chronic disease study on coverage standards provided by Medicaid for inflammatory bowel disease therapies and to report its findings to the Governor and Legislature by February 1, 2006.

This bill creates two unnumbered sections of law.

II. Present Situation:

According to the Mayo Clinic, it is estimated that more than 1 million Americans have ulcerative colitis or Crohn's disease, the two most common forms of inflammatory bowel disease. These conditions, which can be painful and debilitating, cause chronic inflammation of the digestive tract. According to DOH, while the cause of inflammatory bowel disease remains unknown, certain features of the disease suggest that familial or genetic, infectious, immunologic and psychological factors may be of importance. The disease has been reported in every decade of life, and peaks between the ages of 15 and 35. Although it is estimated that approximately one-third to one-half million persons in Florida are affected by inflammatory bowel disease, there has been no study on the disease in Florida. Currently, there is little data about what factors are associated with the disease, who is at risk, and how the medical and public health community should respond to prevent the disease and serve patients.

In November 2004, the United States Congress passed P.L. 108-427, the “Research Review Act of 2004,” which required the Secretary of Health and Human Services, acting through the director of the Centers for Disease Control and Prevention, to prepare a report outlining the epidemiological studies currently underway at the centers, including the inflammatory bowel disease epidemiological study. The report is due May 1, 2005. The law requires the U.S. Comptroller General to conduct a study of the coverage standards that apply under Medicare and Medicaid to patients with inflammatory bowel disease for the following therapies:

- Parenteral nutrition;
- Enteral nutrition formula;
- Medically necessary food products;
- Ostomy supplies; and
- Therapies approved by the Food and Drug Administration for Crohn’s disease and ulcerative colitis.

The study must take into account the appropriate home health care or outpatient delivery setting. The law also requires the Comptroller General to conduct a study of the problems patients encounter when applying for disability insurance benefits under Title II of the Social Security Act. Both reports required of the Comptroller General are due six months after the enactment of the law.

III. Effect of Proposed Changes:

The bill requires DOH, in conjunction with the University of Florida College of Public Health and Health Professions, to conduct an epidemiological study to measure the prevalence of inflammatory bowel disease and identify characteristics of the population affected by the disease in Florida. According to DOH, to conduct the study the department would:

- Search out literature and compile information on inflammatory bowel disease that is currently available.
- Establish an ad hoc advisory committee to provide guidance for the study.
- Identify existing sources of data that may be useful to the study.
- Design a plan for the study.
- Conduct the epidemiological study, collect, and analyze the data.
- Develop and disseminate a report based on the findings.

The bill authorizes DOH to convene a study group for the epidemiological study and specifies the membership of the study group, as follows:

- A representative of the Crohn's and Colitis Foundation of America;
- A representative from one or more of the major universities researching this disease;
- A representative from AHCA;
- A representative from DOH, including department epidemiologists;
- A representative from medical providers;
- One member of the House of Representatives;
- One member of the Senate; and

- Any other individual DOH considers appropriate to participate in the study group.

DOH must submit a report to the Governor, President of the Senate, and Speaker of the House of Representatives by February 1, 2006.

AHCA must conduct a chronic disease study on Medicaid coverage for therapies required by patients with inflammatory bowel disease, such as ostomy supplies, parenteral nutrition, enteral nutrition, medically necessary food products, and therapies approved by the Food and Drug Administration for Crohn's disease and ulcerative colitis. The study will take into consideration the appropriate outpatient or home health care settings, identify gaps in Medicaid coverage that impact the health and quality of life for inflammatory bowel disease patients, and empower the inflammatory bowel disease community to pursue appropriate changes in the Medicaid reimbursement policy. AHCA must submit a report of its findings to the Governor, the President of the Senate, and the Speaker of the House of Representatives by February 1, 2006.

The bill takes effect July 1, 2005.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

Currently, DOH does not have resources to carry out specific activities directed at inflammatory bowel disease, nor does the bill provide specific appropriations to fund the epidemiological study. According to DOH, the department would need additional staff

and an expense budget to carry out the activities outlined in this bill. The senior epidemiologists, statisticians and an administrative assistant of the Bureau of Epidemiology would provide technical support for this study. The ad hoc advisory committee composed of DOH epidemiologists, medical providers, and university staff, would provide guidance and oversight for the study. The implementation and completion of the study would require at least two in-person ad hoc advisory committee meetings and two telephone conferences. The following is a breakdown of the fiscal impact:

Contract Epidemiologist	\$53,760
Two Face-to-face Advisory Committee Meetings	\$ 6,000
Two Telephone Conferences (Conference Room space and conference call charges)	
Travel Expenses for committee members and Epidemiologist	\$ 4,000
Epidemiological study (Collection & Analysis, Report Development)	\$15,000
Total	<u>\$78,760</u>

AHCA did not provide a statement of cost for the study to be conducted by the agency.

The senate budget does not provide funds for what is required in this bill. The house budget includes \$75,000.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Summary of Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.
