

STORAGE NAME: h1985z.hcs

DATE: June 3, 1999

****FINAL ACTION****

****SEE FINAL ACTION STATUS SECTION****

**HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH CARE SERVICES
FINAL ANALYSIS**

BILL #: HB 1985 (passed as part of HB 1885)

RELATING TO: Biomedical Research

SPONSOR(S): Reps. Fasano & Littlefield

COMPANION BILL(S): SB 2558 (i)

ORIGINATING COMMITTEE(S)/COMMITTEE(S) OF REFERENCE:

- (1) HEALTH CARE SERVICES YEAS 12 NAYS 0
- (2) GOVERNMENTAL OPERATIONS (W/D)
- (3) GOVERNMENTAL RULES AND REGULATIONS (W/D)
- (4) GENERAL APPROPRIATIONS
- (5)

I. FINAL ACTION STATUS:

Approved by Governor 5/13/99; Chapter No. 99-167

II. SUMMARY:

HB 1985, as amended by the Health Care Services Committee, and as adopted as section 2 of HB 1885, provides for the creation of a biomedical research program to support research initiatives that address the health care problems of Floridians in the areas of cancer, cardiovascular disease, stroke, and pulmonary disease, to be established within the Department of Health.

The bill provides for funds to be appropriated from the Lawton Chiles Endowment Fund to the Department of Health for the exclusive purpose of awarding grants and fellowships under the biomedical research program and for administrative expenses. Such research must relate to the diagnosis and treatment of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease.

In addition, the bill:

- provides for a 9-member Biomedical Research Advisory Council to be created within the Department of Health to advise the Secretary of Health as to the direction and scope of the biomedical research program;
- provides that any university or established research institute in the state may submit applications for biomedical research funding under the program, and grants and fellowships will be awarded by the Secretary of Health, after consultation with the council, on the basis of scientific merit;
- requires the Secretary of Health to appoint a peer review panel to review scientific content of each proposal and establish its scientific priority score;
- requires the council and peer review panel to establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflict of interest;
- allows the Department of Health to contract on a competitive-bid basis with an appropriate entity to administer the program;
- authorizes the Department of Health to adopt rules as necessary to implement the program, after consultation with the council; and
- requires an annual progress report on the state of biomedical research in Florida, to be submitted by the council to the Governor, the Secretary of Health, the President of the Senate, and the Speaker of the House of Representatives.

The effective date of this bill is July 1, 1999.

III. SUBSTANTIVE ANALYSIS:

A. PRESENT SITUATION:

Chapter 385, F.S., is the Chronic Disease Act and states that the Legislature finds that "chronic diseases exist in high proportions among the people of this state. These chronic diseases include, but are not limited to, heart disease, hypertension, diabetes, renal disease, cancer, and chronic obstructive lung disease. These diseases are often interrelated, and they directly and indirectly account for a high rate of death and illness." The Department of Health Chronic Disease Control Program established under s. 385.103, F.S., is responsible for mobilization of scientific, medical, and educational resources under one comprehensive chronic disease program. The primary goals of the program are to reduce the incidence of disease, delay the onset of disability, alleviate the severity of disease, and prolong life by identifying and addressing factors affecting chronic disease.

Section 381.85, F.S., is the Biomedical and Social Research Act, and "the purpose of this section is to provide a procedure by which proposed research on children or adults will be supported with funds appropriated to the department, and can be efficiently and expeditiously assessed for compliance with the substantive and procedural requirements established by the Review Council for Biomedical and Social Research in rules adopted by the department." The review council was never funded and rules have never been developed.

According to the Department of Health Florida Vital Statistics Annual Report, in 1997 heart disease was the leading cause of death -- almost one of every three deaths. Of the 153,830 deaths in Florida in 1997, 63,536 were related to cardiovascular disease, 37,813 were related to cancer, 9,986 were caused by stroke, and 8,067 were related to pulmonary disease.

Tobacco use is often to blame as the cause of a variety of diseases including cancer, cardiovascular disease, stroke, and pulmonary disease. According to the Florida Coalition on Smoking OR Health, which is a tri-agency made up of the American Cancer Society, the American Heart Association, and the American Lung Association, it is estimated that tobacco use causes up to 37 percent of all cancer deaths, 28 percent of all cardiovascular mortality, and 80 percent of all chronic obstructive pulmonary disease. According to the coalition, collectively, tobacco is estimated to cause one in five deaths in the United States.

Recently the Florida Coalition on Smoking OR Health developed a proposal for a biomedical research endowment. The coalition's proposal suggests that 15 percent of the Tobacco Settlement funds be put into the endowment to support research initiatives that address the health care problems of Floridians in the areas of cancer, cardiovascular diseases, stroke, and pulmonary disease. The long-term goals of the endowment would be to: (1) improve the health of Florida's citizens; (2) expand the foundation of biomedical knowledge related to the diagnosis and treatment of tobacco-related diseases; (3) improve the quality of Florida's academic health centers; (4) increase the amount of federal research dollars that flow into Florida; and (5) stimulate economic activity in the pharmaceutical and biotechnology areas. The coalition believes that because it is estimated that one in five deaths are caused by tobacco use, it is appropriate that some of the money derived from the tobacco settlement be devoted to research to develop better treatments of diseases caused by tobacco use, which include cancer, cardiovascular diseases, stroke, and pulmonary disease.

Chapter 240, F.S., relates to post-secondary education, and it states in s. 240.105, F.S. that the Legislature finds it is in the public interest to provide a system of higher education "which offers selected professional, graduate, and research programs with emphasis on state and national needs." Within ch. 240, F.S., the Cancer Control and Research Act is created under s. 240.5121, F.S. This act creates the Florida Cancer Control and Research Fund to provide grants and contracts to qualified nonprofit associations and governmental agencies for cancer control, prevention, education, training, and research. The act provides that the Board of Regents is responsible for awarding grants and contracts to qualified nonprofit associations and governmental agencies in order to plan, establish, or conduct programs in cancer control and prevention, cancer education and training, and cancer research.

B. EFFECT OF PROPOSED CHANGES:

A biomedical research program to support research initiatives that address the health care problems of Floridians in the areas of cancer, cardiovascular disease, stroke, and pulmonary disease will be established within the Department of Health.

Funds will be appropriated from the Lawton Chiles Endowment Fund to the Department of Health for the exclusive purpose of awarding grants and fellowships, under the biomedical research program, for research relating to the diagnosis and treatment of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease, and for administrative expenses of the program.

A Biomedical Research Advisory Council consisting of nine members will be created within the Department of Health. The council will advise the Secretary of Health as to the direction and scope of the biomedical research program.

Any university or established research institute in the state may submit applications for biomedical research funding under the program, and grants and fellowships will be awarded by the Secretary of Health, after consultation with the council, on the basis of scientific merit.

The Secretary of Health will be required to appoint a peer review panel to review scientific content of each proposal and establish its scientific priority score.

The council and peer review panel will be required to establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflict of interest.

The Department of Health may contract on a competitive-bid basis with an appropriate entity to administer the program and will have the authority to adopt rules as necessary to implement the program, after consultation with the council.

An annual progress report on the state of biomedical research in Florida will be submitted by the council to the Governor, the Secretary of Health, the President of the Senate, and the Speaker of the House of Representatives.

C. APPLICATION OF PRINCIPLES:

1. Less Government:

a. Does the bill create, increase or reduce, either directly or indirectly:

(1) any authority to make rules or adjudicate disputes?

Yes. The Department of Health is authorized to adopt rules, after consultation with the Biomedical Research Advisory Council, to implement the provisions of the section created in the bill.

(2) any new responsibilities, obligations or work for other governmental or private organizations or individuals?

Yes. A biomedical research program will be established within the Department of Health with a list of long-term goals to achieve.

(3) any entitlement to a government service or benefit?

No.

b. If an agency or program is eliminated or reduced:

- (1) what responsibilities, costs and powers are passed on to another program, agency, level of government, or private entity?

N/A

- (2) what is the cost of such responsibility at the new level/agency?

N/A

- (3) how is the new agency accountable to the people governed?

N/A

2. Lower Taxes:

- a. Does the bill increase anyone's taxes?

No.

- b. Does the bill require or authorize an increase in any fees?

No.

- c. Does the bill reduce total taxes, both rates and revenues?

No.

- d. Does the bill reduce total fees, both rates and revenues?

No.

- e. Does the bill authorize any fee or tax increase by any local government?

No.

3. Personal Responsibility:

- a. Does the bill reduce or eliminate an entitlement to government services or subsidy?

No.

- b. Do the beneficiaries of the legislation directly pay any portion of the cost of implementation and operation?

No.

4. Individual Freedom:

- a. Does the bill increase the allowable options of individuals or private organizations/associations to conduct their own affairs?

No.

- b. Does the bill prohibit, or create new government interference with, any presently lawful activity?

No.

5. Family Empowerment:

a. If the bill purports to provide services to families or children:

(1) Who evaluates the family's needs?

N/A

(2) Who makes the decisions?

N/A

(3) Are private alternatives permitted?

N/A

(4) Are families required to participate in a program?

N/A

(5) Are families penalized for not participating in a program?

N/A

b. Does the bill directly affect the legal rights and obligations between family members?

No.

c. If the bill creates or changes a program providing services to families or children, in which of the following does the bill vest control of the program, either through direct participation or appointment authority:

(1) parents and guardians?

N/A

(2) service providers?

N/A

(3) government employees/agencies?

N/A

D. STATUTE(S) AFFECTED:

Section 215.5602, F.S., is created. (HB 1885 also creates s. 215.5601, F.S.)

E. SECTION-BY-SECTION ANALYSIS:

See EFFECT OF PROPOSED CHANGES above.

IV. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE AGENCIES/STATE FUNDS:

1. Non-recurring Effects:

The bill provides for funds to be appropriated from the Lawton Chiles Endowment Fund to the Department of Health for the exclusive purpose of awarding grants and fellowships under the biomedical research program and for administrative expenses.

According to the Department of Health, necessary non-recurring funds for the administration of the program are set out below.

	<u>Year 1</u>	<u>Year 2</u>
First-Year Start-Up Effect:		
EXPENSE:		
Professional Package (furniture, software) 6@ \$2,855 & 1@ \$2,387	\$ 19,517	
OCO: 7@ \$4,177	\$ 29,239	
Total Non-Recurring Expenses	\$ 48,756	

2. Recurring Effects:

	<u>Year 1</u>	<u>Year 2</u>
SALARIES/BENEFITS:		
1 Senior Epidemiologist	\$ 42,763	\$ 58,728
1 Biological Scientist IV	\$ 30,670	\$ 42,120
1 Biological Scientist III	\$ 25,600	\$ 35,157
1 Operations & Management Consultant II	\$ 27,188	\$ 37,338
1 Accountant III	\$ 20,437	\$ 28,067
1 Senior Management Analyst I	\$ 25,600	\$ 35,157
1 Administrative Assistant I	\$ 17,636	\$ 24,220
EXPENSES:		
Professional Package Senior Epidemiologist (medium travel)	\$ 15,733	\$ 15,733
Biological Scientist IV (medium travel)	\$ 15,733	\$ 15,733
Biological Scientist III (medium travel)	\$ 15,733	\$ 15,733
Operations & Management Consultant II	\$ 9,019	\$ 9,019
Accountant III	\$ 9,019	\$ 9,019
Senior Management Analyst I	\$ 13,006	\$ 13,006
Administrative Assistant I	\$ 8,700	\$ 8,700
Travel to Council Meetings to Tallahassee	\$ 10,800	\$ 10,800
Travel to Peer Review Committee Members	\$ 24,000	\$ 24,000
Printing Report	\$ 5,000	\$ 5,000

Total Recurring Expenses	\$316,637	\$387,530
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3. Long Run Effects Other Than Normal Growth:

None.

4. Total Revenues and Expenditures:

According to the Department of Health, total expenditures for administration of the program would be \$365,393 for Year 1 and \$387,530 for Year 2. Although the bill does not specify the level of funding from the Lawton Chiles Endowment Fund to the Florida Biomedical Research Program, it does state that the administrative expenses may not exceed 15 percent of the total funds available to the program in any given year.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS AS A WHOLE:

1. Non-recurring Effects:

None.

2. Recurring Effects:

None.

3. Long Run Effects Other Than Normal Growth:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

1. Direct Private Sector Costs:

None.

2. Direct Private Sector Benefits:

None.

3. Effects on Competition, Private Enterprise and Employment Markets:

None.

D. FISCAL COMMENTS:

None.

V. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

This bill does not require counties or municipalities to expend funds nor does it require them to take an action requiring the expenditures of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This bill does not reduce the authority that municipalities or counties have to raise revenues in the aggregate.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of a state tax shared with counties or municipalities.

VI. COMMENTS:

None.

VII. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

On April 12, 1999, the Committee on Health Care Services passed a strike-everything amendment to HB 1985 sponsored by Representative Fasano. This amendment did the following:

- Named the biomedical research program the Connie Mack Biomedical Research Program and included the program within the Lawton Chiles Endowment Fund.
- Provided for specific appropriations from the Lawton Chiles Endowment Fund to be distributed on a competitive-project basis for biomedical research funding and to eight institutions. These eight institutions include:
 - University of Florida Cancer Center;
 - University of Miami Medical Center;
 - H. Lee Moffitt Cancer Center and Research Institute;
 - Florida State University, Biomedical Research;
 - Florida Agricultural and Mechanical University, Pharmacy Research;
 - Mayo Clinic;
 - University of South Florida, Biomedical Research; and
 - Walt Disney Memorial Cancer and Research Institute.
- Clarified that research funded by this bill should include the *prevention* of tobacco-related diseases as well as the *diagnosis and treatment* of such diseases.

HB 1985 died in the House Committee on General Appropriations, but similar language was adopted by the House and Senate in amendments to HB 1885 which created the Lawton Chiles Endowment Fund.

VIII. SIGNATURES:

COMMITTEE ON HEALTH CARE SERVICES:

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FINAL ANALYSIS PREPARED BY THE COMMITTEE ON HEALTH CARE SERVICES:

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