

**HOUSE OF REPRESENTATIVES STAFF ANALYSIS**

**BILL #:** CS/HB 889 Biomedical and Social Research  
**SPONSOR(S):** Health & Family Services Policy Council; Adkins  
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 2100

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	<b>REFERENCE</b>	<b>ACTION</b>	<b>ANALYST</b>	<b>STAFF DIRECTOR</b>
1)	Health & Family Services Policy Council	14 Y, 0 N, As CS	Holt	Gormley
2)	_____	_____	_____	_____
3)	_____	_____	_____	_____
4)	_____	_____	_____	_____
5)	_____	_____	_____	_____

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**SUMMARY ANALYSIS**

This bill deletes outdated or obsolete language relating to the following biomedical research provisions:

- Center for Health Technologies;
- Florida Biomedical and Social Research Act;
- Cervical Cancer Elimination Task Force; and
- The Florida Cancer Council.

The Center for Health Technologies is currently inactive. The Florida Biomedical and Social Research Act became obsolete when section 381.86, F.S., the Institutional Review Board, was enacted by the Legislature in order to comply with federal law and achieved a similar purpose to that of the Biomedical and Social Research Act. The Cervical Cancer Elimination Task Force statutorily sunset on June 30, 2008. Finally, the Florida Cancer Council was never funded and is currently inactive.

Repealing these provisions will not affect the funding to any existing programs.

The bill appears to have no fiscal impact on state or local government.

The bill takes effect July 1, 2010.

## HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. EFFECT OF PROPOSED CHANGES:

The bill repeals the Center for Health Technologies, Florida Biomedical and Social Research Act, the Council Cervical Cancer Elimination Task Force, and Florida Cancer Council. Repealing these provisions will not affect the funding to any existing programs.

#### Current Situation

##### *Center for Health Technologies*

In 1989, section 381.0404, F.S., was enacted creating the Center for Health Technologies ("Center"). The Center is statutorily required to be located and administered by a statutory teaching hospital located in Miami-Dade County.<sup>1,2</sup> The purpose of the Center is to encourage the development and growth of the health sciences in the state, with emphasis on:<sup>3</sup>

- Technologies which help prevent illness and reduce health care costs;
- Coordination between educational institutions, health care providers, and persons engaged in research and development of health care products;
- Services to persons and incipient firms engaged in the incubation of health care products;
- Assisting in technology transfer;
- Establishing academic laboratories, libraries, and other resource facilities to be shared among the Center's constituents.

The Center is authorized to apply for and accept gifts, grants, and other contributions and establish a banking account.<sup>4</sup> Additionally, the Center is required to submit a report annually to the Governor and Legislature to provide an accounting of expenditures and status on research and development programs.<sup>5</sup> According to the Department of Financial Services, the Center is inactive and no historical

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<sup>1</sup> s. 381.0404(1)(a), F.S.

<sup>2</sup> There are two statutory teaching hospitals located in Miami-Dade County: Jacksonville Memorial and Mount Sinai Medical Center. The Center was located at the Mount Sinai Medical Center and was created sometime between 1989 and 1991, but is currently inactive.

<sup>3</sup> s. 381.0404(1)(b), F.S.

<sup>4</sup> s. 381.0404(3)(b), F.S.

<sup>5</sup> s. 381.0404(4), F.S.

funding source can be identified.<sup>6</sup> According to the Department of Health (“DOH”), this provision has no impact to DOH.<sup>7</sup>

The bill repeals section 381.0404, F.S., because the Center is inactive.

#### *Florida Biomedical and Social Research Act*

Section 381.85, F.S., creates the Florida Biomedical and Social Research Act (“act”). The purpose of the act was to provide a procedure which ensures that any proposed research that is funded by the DOH and conducted on humans is reviewed and approved. The act provides DOH rule making authority to adopt ethical standards, procedures and criteria of how to review, approve, and conduct research involving human beings. In addition, the provision creates a nine member Review Council for Biomedical and Social Research (“Review Council”) that must review and approve any research conducted on human beings under the purview of DOH.<sup>8</sup>

According to DOH, the Review Council no longer exists and section 381.85, F.S. should have been repealed in 2004 when section 381.86, F.S. was enacted<sup>9</sup> creating the Institutional Review Board (IRB).<sup>10</sup> The IRB was created to meet federal requirements<sup>11</sup> and is responsible for reviewing all biomedical and behavioral research on human subjects which are funded or supported by DOH.<sup>12</sup> According to DOH, the Biomedical and Social Research Act did not comply with these federal requirements.<sup>13</sup> Pursuant to federal law,<sup>14</sup> the State Surgeon General is responsible for determining and appointing membership to the IRB.<sup>15</sup>

The bill repeals section 381.85, F.S., because the purpose is being achieved under another statutory provision that complies with federal law.

#### *Cervical Cancer Elimination Task Force*

In 2004, section 381.912, F.S., was enacted, creating an eleven member Cervical Elimination Task Force (“Task Force”). The purpose of the Task Force is to recommend actions and strategies to reduce costs and burdens associated with cervical cancer in Florida.<sup>16</sup> The Task Force was required to present interim reports on January 1, 2006 and July 1, 2007 with the final report due on June 30, 2008. The reports were to be sent to the Speaker of the House, Senate President, Governor, the Florida Center for Universal Research to Eradicate Disease (FL CURED), the Florida Cancer Council, and the Florida Public Health Foundation, Inc.<sup>17</sup> The provision further stipulates that, after submitting its final report on or before June 30, 2008, the Task Force is dissolved.<sup>18</sup> According to DOH, the Task Force was never implemented because the funding line item was vetoed, and there was no authority to spend general revenue on staff support.<sup>19</sup>

The bill deletes section. 627.7065(5), F.S., because the statute sunset June 30, 2008.

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<sup>6</sup> Email correspondence with the Department of Financial Services on file with Health Care Regulation Policy Committee staff (September 18, 2007).

<sup>7</sup> Department of Health Bill Analysis, Economic Statement and Fiscal Note for House Bill 947 (February 16, 2010).

<sup>8</sup> s. 381.85(3)-(4), F.S.

<sup>9</sup> Chapter 2004-350, L.O.F.

<sup>10</sup> Department of Health Bill Analysis, Economic Statement and Fiscal Note on House Bill 889 (February 16, 2010).

<sup>11</sup> 45 C.F.R. part 46; 21 C.F.R. part 50; and 21 C.F.R. part 56 relating to the protection of human subjects.

<sup>12</sup> s. 381.86(1), F.S.

<sup>13</sup> *Id.*

<sup>14</sup> According to federal requirements an IRB must consist of at least five members that have varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.

<sup>15</sup> s. 381.86(2), F.S.

<sup>16</sup> s. 381.912(1), F.S.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> Department of Health Bill Analysis, Economic Statement and Fiscal Note on House Bill 889 (February 16, 2010).

Section 381.92, F.S., creates the Florida Cancer Council (“Council”) within DOH. The purpose of the Council is to make the state a center of excellence for cancer research.<sup>20</sup> The Council membership is required to consist of representatives from the state’s cancer centers, hospitals, and patient groups.<sup>21</sup>

Section 381.921, F.S., outlines the mission and duties of the Council. The Council is required to work with the FL CURED to identify, implement, and facilitate endeavors that:

- Encourage the expansion of cancer research capacity in the state;<sup>22</sup>
- Improve research and treatment by encouraging greater participation in clinical trials networks,<sup>23</sup> and
- Improve efforts to reduce the incidence of cancer among disparate groups.<sup>24</sup>

In addition, the Council is statutorily required to institute a peer-reviewed, competitive process to identify and fund the best proposals that demonstrate the greatest opportunity to attract federal research grants and private financial support.<sup>25</sup> By December 15 of each year the Council is required to submit an annual report to FLCURED, the Governor, and the Legislature which includes policy and funding recommendations regarding cancer research capacity and related issues.<sup>26</sup>

According to DOH, the Council is not active. The council was never funded, met only once, and produced only one annual report.<sup>27</sup>

In 2006, the William G. “Bill” Bankhead, Jr., and David Coley Cancer Research Program (“Program”), was created to provide grants for cancer research to further the search for cures for cancer.<sup>28</sup> Statutory authority for the Program cross references the goals identified in section 381.921, F.S., with regard to improving cancer research and treatment in the state. Consequently, repealing s. 381.921, F.S., deletes some of the goals of the Program that are provided by cross-reference. To ensure that the mission and goals of the program are not diminished, the bill reassigns the Council goals to the Program.

The bill repeals s. 381.921, F.S., because the Council is inactive and reassigns the mission and goals of the Council to the Bankhead-Coley Program.

### Effects of the Bill

This bill deletes outdated or obsolete language relating to four biomedical research provisions. The Center for Health Technologies is repealed because the Center is inactive. The Florida Biomedical Research Act is repealed, because the purpose of this provision is being achieved under another statutory provision (i.e., the Institutional Review Board). The Cervical Cancer Elimination Task Force is repealed because the statute sunset June 30, 2008. The Florida Cancer Council and its mission and duties are repealed because the Council is inactive. The bill reassigns the Florida Cancer Council mission and goals that are provided by cross reference to the Bankhead-Coley program. Restating these goals insures that the repeal of s. 381.921, F.S. has no substantive effect. Finally, the bill deletes cross-references.

Repealing these provisions will not affect the funding to any existing programs.

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<sup>20</sup> s. 381.92(1), F.S.

<sup>21</sup> s. 381.92(2), F.S.

<sup>22</sup> s. 381.921(1), F.S.

<sup>23</sup> s. 381.921(2), F.S.

<sup>24</sup> s. 381.912(3), F.S.

<sup>25</sup> s. 381.921(1)(b-c), F.S.

<sup>26</sup> s. 381.92(3), F.S.

<sup>27</sup> Department of Health Bill Analysis, Economic Statement and Fiscal Note on House Bill 889 (February 16, 2010).

<sup>28</sup> s. 381.922, F.S.

**B. SECTION DIRECTORY:**

- Section 1.** Repeals s. 381.0404, F.S., relating to the Center for Health Technologies.
- Section 2.** Repeals s. 381.85, F.S., relating to biomedical and social research.
- Section 3.** Amends s. 381.855, F.S., relating to the Florida Center for Universal Research to Eradicate Disease.
- Section 4.** Repeals s. 381.912, F.S., relating to the Cervical Elimination Task Force.
- Section 5.** Repeals s. 381.92, F.S., relating to the Florida Cancer Council.
- Section 6.** Amends s. 381.922, F.S., and transfers s.381.921, F.S., relating to the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program and the Florida Cancer Council mission and duties.
- Section 7.** Provides an effective date of July 1, 2010.

**II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT**

**A. FISCAL IMPACT ON STATE GOVERNMENT:**

- 1. Revenues:  
Not applicable.
- 2. Expenditures:  
Not applicable.

**B. FISCAL IMPACT ON LOCAL GOVERNMENTS:**

- 1. Revenues:  
Not applicable.
- 2. Expenditures:  
Not applicable.

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

None identified.

**D. FISCAL COMMENTS:**

None.

**III. COMMENTS**

**A. CONSTITUTIONAL ISSUES:**

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to: require counties or municipalities to spend funds or take an action requiring the expenditure of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of a state tax shared with counties or municipalities.

2. Other:

None.

**B. RULE-MAKING AUTHORITY:**

No rule-making authority is provided in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

**IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES**

On March 1, 2010, the Health & Family Services Policy Council adopted a strike-all amendment and reported the bill favorably as a council substitute. The strike-all:

- Repeals s. 381.0404, F.S., relating to the Center for Health Technologies because it's inactive; and
- Amends s. 381.922, F.S., restating the goals of the Bankhead-Coley Program that were provided by cross-reference to s. 381.921, F.S. Restating these goals ensures that the repeal of s. 381.921, F.S. has no substantive effect.

This analysis is drafted to the council substitute.