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 Health Regulation Committee

BILL:	PCB 7000
INTRODUCER:	For consideration by the Health Regulation Committee
SUBJECT:	OGSR - Donor Personal Identifying Information
DATE:	January 6, 2011 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	O'Callaghan	Stovall		**Pre-meeting**
2.				
3.				
4.				
5.				
6.				

I. Summary:

The proposed committee bill is the result of an Open Government Sunset Review of the public records exemptions for the Florida Center for Brain Tumor Research (FCBTR). The proposed committee bill saves from repeal and re-enacts the exemption related to information received from an individual from another state or nation or the Federal Government that is otherwise confidential or exempt pursuant to the laws of that jurisdiction. Instead of re-enacting the exemption for an individual's medical record, the proposed committee bill revises the law to exempt information which identifies a donor of specimens or information to the brain tumor registry and repository. In addition, the proposed committee bill authorizes disclosure of exempted information maintained by the FCBTR for bona fide research under specified conditions.

This bill substantially amends s. 381.8531, F.S.

II. Present Situation:

Florida's Public Records Laws

Florida has a long history of providing public access to the records of governmental and other public entities. The Legislature enacted its first law affording access to public records in 1892.[1] In 1992, Florida voters approved an amendment to the State Constitution which raised the statutory right of access to public records to a constitutional level.

[1] Section 1390, 1391 F.S. (Rev. 1892).

Section 24(a), Art. I, of the State Constitution, provides that:

> Every person has the right to inspect or copy any public record made or received in connection with the official business of any public body, officer, or employee of the state, or persons acting on their behalf, except with respect to records exempted pursuant to this section or specifically made confidential by this Constitution. This section specifically includes the legislative, executive, and judicial branches of government and each agency or department created thereunder; counties, municipalities, and districts; and each constitutional officer, board, and commission, or entity created pursuant to law or this Constitution.

The Public Records Act is contained in ch. 119, F.S., and specifies conditions under which the public must be given access to governmental records. Section 119.07(1)(a), F.S., provides that every person who has custody of a public record[2] must permit the record to be inspected and examined by any person, at any reasonable time, under reasonable conditions, and under supervision by the custodian of the public record. Unless specifically exempted, all agency[3] records are to be available for public inspection.

The Florida Supreme Court has interpreted the definition of "public record" to encompass all materials made or received by an agency in connection with official business which are "intended to perpetuate, communicate, or formalize knowledge."[4] All such materials, regardless of whether they are in final form, are open for public inspection unless made exempt.[5]

Only the Legislature is authorized to create exemptions from open government requirements.[6] Exemptions must be created by general law and such law must specifically state the public necessity justifying the exemption. Further, the exemption must be no broader than necessary to accomplish the stated purpose of the law.[7] A bill enacting an exemption may not contain other substantive provisions, although it may contain multiple exemptions relating to one subject.[8]

There is a difference between records that the Legislature exempts from public inspection and those that the Legislature makes confidential and exempt from public inspection. If a record is made confidential with no provision for its release so that its confidential status will be

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[2] Section 119.011(12), F.S., defines "public records" to include "all documents, papers, letters, maps, books, tapes, photographs, film, sound recordings, data processing software, or other material, regardless of the physical form, characteristics, or means of transmission, made or received pursuant to law or ordinance or in connection with the transaction of official business by any agency."

[3] Section 119.011(2), F.S., defines "agency" as "any state, county, district, authority, or municipal officer, department, division, board, bureau, commission, or other separate unit of government created or established by law including, for the purposes of this chapter, the Commission on Ethics, the Public Service Commission, and the Office of Public Counsel, and any other public or private agency, person, partnership, corporation, or business entity acting on behalf of any public agency."

[4] *Shevin v. Byron, Harless, Schaffer, Reid, and Assocs., Inc.,* 379 So. 2d 633, 640 (Fla. 1980).

[5] *Wait v. Florida Power & Light Co.,* 372 So. 2d 420 (Fla. 1979).

[6] FLA. CONST. art. I, s. 24(c) (1992).

[7] *Memorial Hospital-West Volusia, Inc. v. News-Journal Corporation,* 729 So. 2d 373, 380 (Fla. 1999); *Halifax Hospital Medical Center v. News-Journal Corporation,* 724 So. 2d 567 (Fla. 1999).

[8] *Supra* fn. 6.

maintained, such record may not be released by an agency to anyone other than the person or entities designated in the statute.[9] If a record is simply exempt from mandatory disclosure requirements, an agency is not prohibited from disclosing the record in all circumstances.[10]

Access to public records is a substantive right and therefore, a statute affecting that right is presumptively prospective in its application.[11] There must be a clear legislative intent for a statute affecting substantive rights to apply retroactively.[12]

Open Government Sunset Review Act

The Open Government Sunset Review Act[13] provides for the systematic review of an exemption from the Public Records Act in the fifth year after its enactment.[14] The act states that an exemption may be created, revised, or maintained only if it serves an identifiable public purpose and if the exemption is no broader than necessary to meet the public purpose it serves.[15] An identifiable public purpose is served if the exemption meets one of three specified criteria and if the Legislature finds that the purpose is sufficiently compelling to override the strong public policy of open government and cannot be accomplished without the exemption.[16] An exemption meets the statutory criteria if it:

- Allows the state or its political subdivisions to effectively and efficiently administer a governmental program, which administration would be significantly impaired without the exemption;
- Protects information of a sensitive personal nature concerning individuals, the release of which would be defamatory or cause unwarranted damage to the good name or reputation of such individuals or would jeopardize the safety of such individuals; or
- Protects information of a confidential nature concerning entities, including, but not limited to, a formula, pattern, device, combination of devices, or compilation of information which is used to protect or further a business advantage over those who do not know or use it, the disclosure of which would injure the affected entity in the marketplace.[17]

The act also requires the Legislature to consider the following six questions that go to the scope, public purpose, and necessity of the exemption:[18]

- What specific records or meetings are affected by the exemption?
- Whom does the exemption uniquely affect, as opposed to the general public?
- What is the identifiable public purpose or goal of the exemption?
- Can the information contained in the records or discussed in the meeting be readily obtained by alternative means? If so, how?

[9] Attorney General Opinion 85-62, August 1, 1985.
[10] *Williams v. City of Minneola*, 575 So. 2d 683, 687 (Fla. 5th DCA), *review denied*, 589 So. 2d 289 (Fla. 1991).
[11] *Memorial Hospital-West Volusia, Inc. v. News-Journal Corporation*, 784 So. 2d 438 (Fla. 2001).
[12] *Id.*
[13] Section 119.15, F.S.
[14] Section 119.15(4)(b), F.S., provides that an existing exemption may be considered a substantially amended exemption if the exemption is expanded to cover additional records. As with a new exemption, a substantially amended exemption is also subject to the 5-year review.
[15] Section 119.15(6)(b), F.S.
[16] *Id.*
[17] *Id.*
[18] Section 119.15(6)(a), F.S.

- Is the record or meeting protected by another exemption?
- Are there multiple exemptions for the same type of record or meeting that it would be appropriate to merge?

If, and only if, in reenacting an exemption that will repeal, the exemption is expanded (essentially creating a new exemption), then a public necessity statement and a two-thirds vote for passage are required.[19] If the exemption is reenacted with grammatical or stylistic changes that do not expand the exemption, if the exemption is narrowed, or if an exception to the exemption is created,[20] then a public necessity statement and a two-thirds vote for passage are not required.[21]

Brain Tumors

Malignant brain tumors are one of the most virulent forms of cancer. Brain tumors can be either primary – those that start in the brain and generally stay there, or metastatic – those that begin as a cancer elsewhere in the body and spread to the brain.[22] Some tumors are not cancer but can cause disability and death because of their location in the brain.[23] They can press on sensitive areas and cause serious health problems and surgery to remove them has risks.

Brain tumors are the:
- Second leading cause of cancer-related deaths in children under age 20 (leukemia is the first),
- Second leading cause of cancer-related deaths in males up to age 39,
- Second leading cause of cancer-related deaths in females under age 20, and
- Fifth leading cause of cancer-related deaths in females ages 20–39.6[24]

An estimated 62,930 new cases of primary brain tumors are expected to be diagnosed in 2010 and includes both malignant (23,720) and non-malignant (39,210) brain tumors.[25]

Patients with moderately severe malignant tumors typically survive for two to 5 years, whereas those with severe forms live only 12 to 15 months on average, even with optimal treatment.[26] The normal course of treatment for malignant tumors is surgery followed by a combination of chemotherapy and radiation.

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[19] *Supra* fn. 6.
[20] An example of an exception to a public records exemption would be allowing another agency access to confidential or exempt records.
[21] *Cf., State v. Knight*, 661 So. 2d 344 (Fla. 4th DCA 1995).
[22] National Brain Tumor Society, *Brain Tumor FAQ*, available at: http://www.braintumor.org/patients-family-friends/about-brain-tumors/brain-tumor-faq.html (Last visited on January 4, 2011).
[23] *Id.*
[24] American Brain Tumor Association: *Facts and Statistics, 2010*, available at: http://www.abta.org/sitefiles/pdflibrary/ABTA-FactsandStatistics2010v3.pdf (Last visited on January 4, 2011) (citing Ahmedin Jemal et al.; *Cancer Statistics, 2009*; CA: A Cancer Journal for Clinicians; American Cancer Society; May 2009).
[25] *Id.*
[26] The Florida Center for Brain Tumor Research, Annual Report January 2009 – December 2009, citing Patrick Y. Wen and Santosh Kesari, "Malignant Gliomas in Adults," *The New England Journal of Medicine* 2008; 359: 492-507. (A copy of the report is on file with the Florida Senate Committee on Health Regulation).

The Florida Center for Brain Tumor Research

The Florida Legislature established the FCBTR within the Evelyn F. and William L. McKnight Brain Institute of the University of Florida on July 1, 2006.[27] The Legislature initially appropriated $500,000 for the FCBTR.[28] In 2009 and 2010, the Legislature appropriated $500,000 to the FCBTR.[29]

The purpose of the FCBTR is to find cures for brain tumors by:

- Establishing a coordinated effort among the state's public and private universities and hospitals and the biomedical industry to discover brain tumor cures and develop brain tumor treatment modalities;
- Expanding the state's economy by attracting biomedical researchers and research companies to the state;
- Developing and maintaining a brain tumor registry that is an automated, electronic, and centralized database of individuals with brain tumors; and
- Fostering collaboration with brain cancer research organizations and other institutions, providing a central repository for brain tumor biopsies from individuals throughout the state, improving and monitoring brain tumor biomedical research programs within the state, facilitating funding opportunities, and fostering improved technology transfer of brain tumor research findings into clinical trials and widespread public use.[30]

A Scientific Advisory Council (The Council) is established within the FCBTR.[31] The Council is required to meet at least annually, however it generally meets twice per year.[32] The Council consists of members from the University of Florida, the Scripps Research Institute Florida, Cleveland Clinic in Florida, M.D. Anderson Cancer Center Orlando, Mayo Clinic in Jacksonville, H. Lee Moffitt Cancer Center and Research Institute, the University of Miami, and a neurosurgeon in private practice.[33]

The Registry

The FCBTR maintains a collaborative, statewide registry of banked cancerous and non-cancerous brain tumor specimens, matched samples of DNA, plasma, serum and cerebrospinal fluid, clinical and demographic information, and quality-of-life assessments obtained from patients.[34]

As of January 5, 2010, 742 patients have contributed tissue to the bank. There are 2,550 brain tumor tissue samples and 2,469 plasma, serum, DNA, and cerebrospinal fluid samples stored in

[27] Section 381.853, F.S., was enacted in ch. 2006-258, Laws of Florida.
[28] The FCBTR is to be funded through private, state, and federal sources. See s. 381.853(4)(g), F.S.
[29] *See* ch. 2009-81 and ch. 2010-152, Laws of Florida.
[30] The Florida Center for Brain Tumor Research, Annual Report January 2009 – December 2009. A copy of this report is on file with the Florida Senate Health Regulation Committee.
[31] Section 381.853(5), F.S.
[32] Response to the Florida House of Representative's questionnaire by the Florida Center for Brain Tumor Research dated September 8, 2010. A copy of this response is on file with the Florida Senate Health Regulation Committee.
[33] *Id. See also* s. 381.853(5)(a), F.S.
[34] *Supra* fn. 26.

the FCBTR bio-repository. One hundred forty-two samples have been distributed from the bio-repository for research purposes.[35]

Patients, located in and outside of Florida, are asked to participate in the FCBTR's bio-repository and registry, which has been approved by an Institutional Review Board,[36] to provide valuable specimens and data for future research.[37] The patient signs an informed consent form to authorize the collection and banking of his or her specimens.[38] The banked materials are made available to researchers in Florida and beyond who are investigating improved treatments and cures for brain tumors.[39]

A web-based database stores demographic, clinical and quality-of-life data, creates a registry of participants, and bar-codes and tracks the samples. This clinical database contains information available (in unidentifiable format) to researchers who study brain tumors.[40] Although the registry receives information that identifies an individual donor, neither the registry nor the FCBTR obtain a copy of the donor's medical record.[41] According to a representative from the FCBTR, no researcher has requested information that identifies an individual donor.[42] However, it is conceivable that certain researchers may need such information to further their research objectives. Currently, the law does not authorize release of this information for research purposes.

Protecting Health Information in Research

The federal Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule establishes national standards, and requires appropriate safeguards, to protect individuals' medical records and other personal health information. [43] The Privacy Rule applies only to "covered entities," which are health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically.[44] The Privacy Rule also gives patients rights over their health information, including rights to examine and obtain a copy of their health records and to request corrections; it also sets limits and conditions on the uses

[35] *Id.*
[36] An Institutional Review Board is any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects to assure the protection of the rights and welfare of the human subjects. *See* 21 C.F.R. Part 56.
[37] *Supra* fn. 26.
[38] Section 381.853(3), F.S., provides for a patient to sign a form to opt-out of participation in the registry; however the FCBTR requires an informed consent to participate in the registry.
[39] *Supra* fn. 26.
[40] *Id.*
[41] Email received by professional staff of the Florida Senate Health Regulation Committee from a representative of the FCBTR on July 27, 2010. A copy of the email is on file with the committee.
[42] *Id.*
[43] U.S. Department of Health and Human Services, *Health Information Privacy: The Privacy Rule*, available at http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html (Last visited on January 5, 2011).
[44] *Id. See also* U.S. Department of Health and Human Services, *HIPAA Privacy Rule: To Whom Does the Privacy Rule Apply and Whom Will It Affect?*, available at http://privacyruleandresearch.nih.gov/pr_06.asp (Last visited January 5, 2011).

and disclosures that may be made of such information without patient authorization.[45] The Privacy Rule supplements other federal protections for research involving human subjects.[46]

Many organizations, institutions, and researchers that use, collect, access, and disclose individually identifiable health information are not covered entities.[47] To gain access for research purposes to protected health information created or maintained by covered entities, the researcher or other organization may have to provide supporting documentation on which the covered entity may rely in meeting the requirements, conditions, and limitations of the Privacy Rule.[48]

In 2009, the Institute of Medicine's Committee on Health Research and the Privacy of Health Information issued a report concluding that the HIPAA Privacy Rule does not adequately protect the privacy of people's personal health information and hinders important health research discoveries.[49]

The FCBTR also has a Certificate of Confidentiality from the National Institutes of Health.[50] Certificates of Confidentiality offer an important protection for the privacy of research study participants by protecting identifiable research information from forced disclosure (e.g., through a subpoena or court order).[51] The HIPPA Privacy Rule does not protect against all forced disclosure since it permits disclosures required by law, for example. Various Federal agencies may grant a Certificate of Confidentiality for studies that collect information that, if disclosed, could damage subjects' financial standing, employability, insurability, or reputation, or have other adverse consequences. By protecting research and institutions from forced disclosure of such information, Certificates of Confidentiality help achieve research objectives and promote participation in research studies.[52]

Institutional Review Boards (IRB)

Under federal Food and Drug Administration regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects.[53] An IRB has the authority to approve, require modifications in (to secure

[45] *Supra* fn. 43.
[46] *See e.g.*, The Common Rule, 45 C.F.R. Part 46, Subpart A and the Food and Drug Administration's human subject protections regulations 21 C.F.R. Parts 50 and 56, which primarily address subjects involved in clinical investigations.
[47] U.S. Department of Health and Human Services, *HIPAA Privacy Rule: To Whom Does the Privacy Rule Apply and Whom Will It Affect?*, available at http://privacyruleandresearch.nih.gov/pr_06.asp (Last visited January 5, 2011).
[48] NIH Publication Number 03-5388 Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule, April 2003, available at: http://privacyruleandresearch.nih.gov/pdf/HIPAA_Privacy_Rule_Booklet.pdf, (Last visited on January 5, 2011).
[49] The Institute of Medicine, *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research*. The National Academies' press release announcing the report is available at: http://www.iom.edu/Reports/2009/Beyond-the-HIPAA-Privacy-Rule-Enhancing-Privacy-Improving-Health-Through-Research.aspx, (Last visited on January 5, 2011).
[50] *Supra* fn. 26.
[51] U.S. Department of Health and Human Services, *Certificates of Confidentiality: Background Information*, available at http://grants.nih.gov/grants/policy/coc/background.htm (Last visited on January 5, 2011).
[52] *Id.*
[53] *See supra* fn. 36.

approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.[54]

The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research.[55] To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.[56]

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Public Records Exemption for the FCBTR

Chapter 2006-259, L.O.F., enacted concurrently with the establishment of the FCBTR, made certain information held by the FCBTR confidential and exempt from s. 119.07(1), F.S., and s. 24, Art. I, of the State Constitution.[57]

The exempted information includes an individual's medical records and any information received from an individual from another state or nation or the Federal Government that is otherwise confidential or exempt pursuant to the laws of that state or nation or pursuant to federal law. This law was codified in s. 381.8531, F.S., which is subject to the Open Government Sunset Review Act.[58] Accordingly, it will be repealed automatically on October 2, 2011, unless reviewed and saved from repeal through reenactment by the Legislature.

Exemptions from the public records law must be created by a general law which must specifically state the public necessity justifying the exemption. Further, the exemption must be no broader than necessary to accomplish the stated purpose of the law.[59] The Legislature expressed the reasons supporting the public necessity for making an individual's medical records held by the brain tumor registry confidential and exempt from the public records requirements as follows:

> Matters of personal health are traditionally private and confidential concerns between the patient and the health care provider. The private and confidential nature of personal health matters pervades both the public and private health care sectors. For these reasons, the individual's expectation of and right to privacy in all matters regarding his or her personal health necessitates this exemption. [In addition], …the release of such record

[54] U.S. Food and Drug Administration, *Institutional Review Boards Frequently Asked Questions-Information Sheet*, available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm (Last visited on January 5, 2011).
[55] *Id.*
[56] *Id.*
[57] The FCBTR also operates under the public records exemptions in s. 760.40, F.S., related to genetic testing and DNA analysis. DNA analysis is defined in s. 760.40, F.S., to mean the medical and biological examination and analysis of a person to identify the presence and composition of genes in that person's body. The term includes DNA typing and genetic testing. Results of a DNA analysis are confidential and exempt from the public records law.
[58] Section 119.15, F.S.
[59] *Supra* fn. 7.

could be defamatory to the patient or could cause unwarranted damage to the name or reputation of that patient.

Research from the review disclosed that the FCBTR does not receive a donor's medical records. However, the FCBTR does receive tissue samples, certain medical information about the donor that is extracted from the donor's medical record, and information which identifies the donor. The FCBTR has requested that the exemption be revised to reflect the practice of the FCBTR.[60] This will help ensure that a potential donor is not discouraged from donating to the repository.

The Legislature expressed the reasons supporting the public necessity for making information received by the brain tumor registry from an individual from another state or nation or the Federal Government that is otherwise exempt or confidential pursuant to the laws of that state or nation or pursuant to federal law confidential and exempt from the Florida public records requirement because without this protection, another state or nation or the Federal Government might be less likely to provide information to the registry in the furtherance of its duties and responsibilities.

Representatives from the FCBTR indicated that they have received information from a person from another state or nation or the Federal Government that is confidential or exempt pursuant to the laws of that state or nation or pursuant to federal law.[61] The representative cited protections under HIPAA and its implementing regulations and state law, as well as the federal Common Rule as the basis for protection from public disclosure in those jurisdictions.[62]

As a part of participating in the Open Government Sunset Review process, the FCBTR requested the authority under Florida's law to release identifying information consistent with federal and another state's laws if applicable when necessary to further the purposes of the research and when additional safeguards are in place to protect that information.[63]

Based on research conducted as part of the Open Government Sunset Review Act as required by s. 381.8531(2), F.S., professional staff in the Senate Committee on Health Regulation recommends that the Legislature:

- Re-enact and modify the public records exemption in s. 381.8531, F.S., to delete the exemption for an individual's medical record and instead exempt any personal identifying information pertaining to a donor to the registry and repository. This exemption reflects the practice of the FCBTR, furthers the purpose of the FCBTR to foster research objectives, and complies with the statutory requirements for an exemption because it protects information of a personal nature;
- Authorize the release of identifying information when it is specifically needed to further a particular medical or scientific research project related to brain tumors and when additional privacy safeguards are in place; and

[60] *Supra* fn. 41.
[61] *Supra* fn. 32.
[62] *Id. See supra* fn. 46 for information regarding the Common Rule.
[63] *Supra* fn. 41.

- Re-enact the exemption related to information received by the brain tumor registry from an individual from another state or nation. Continuing the exemption promotes donations from persons in other jurisdictions which, in turn, will further the purposes of the FCBTR.

III. Effect of Proposed Changes:

The bill exempts information held by the FCBTR before, on, or after July 1, 2011,[64] which identifies an individual who has donated specimens or information to the brain tumor registry and repository from public disclosure. This information is made confidential and exempt from s. 119.07(1), F.S., and s. 24, Art. I, of the State Constitution. The bill eliminates the exemption from public disclosure for an individual's medical record because the FCBTR does not receive or maintain an individual's medical record.

The bill provides for disclosure of a donor's personal identifying information or any information that is received from an individual from another state or nation or the Federal Government that is confidential or exempt pursuant to the laws of that state or nation or pursuant to federal law when the research cannot otherwise be conducted without that information. Specific conditions for such release are included in the bill. The confidential and exempt information may only be disclosed to a person engaged in bona fide research if the researcher agrees to:

- Submit to the FCBTR a research plan that has been approved by an institutional review board and that specifies the exact nature of the information requested, the intended use of the information, and the reason that the research could not practicably be conducted without the information;
- Sign a confidentiality agreement with the FCBTR;
- Maintain the confidentiality of the personal identifying information or otherwise confidential or exempt information; and
- To the extent permitted by law and after the research is concluded, destroy any confidential records or information obtained.

Notwithstanding the authorization in state law for such release of identifying information, the disclosure must comply with applicable federal law.

Because the exemption from the public records law is modified and broadens the scope of the exemption, a statement pertaining to the public necessity for the exemption is provided and a two-thirds vote of each house is required to enact the bill. Additionally, the law must be scheduled for review again under the Open Government Sunset Review Act. Accordingly, the proposed committee bill provides for repeal of this law on October 2, 2016, if not reviewed and saved from repeal through reenactment by the Legislature.

The act will take effect on July 1, 2011.

[64] The phrase "before, on, or after July 1, 2011" provides a clear legislative intent that the law should apply retroactively. As mentioned previously in the analysis, there must be a clear legislative intent for a statute affecting substantive rights to apply retroactively. *See supra* fn. 11, 12.

Other Potential Implications:

If the Legislature chooses not to retain or modify the public records exemption for the FCBTR repository and registry, the exemption will expire on October 2, 2011. Without the exemption, certain information in the repository and registry of the FCBTR might become public, deter donations, and impede the timely discovery of treatments or cures for brain tumors.

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 s. 18, Art. VII, of the State Constitution.

B. Public Records/Open Meetings Issues:

The bill reenacts and amends an existing public records exemption in s. 381.8531, F.S. Because the bill expands the exemption, it contains a constitutionally required statement of public necessity for the expansion. Additionally, this bill is subject to a two-thirds vote of each house of the Legislature for enactment as required by s. 24(c), Art. I, of the State Constitution because it expands the public records exemption.

C. Trust Funds Restrictions:

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

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

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.)

None.

B. Amendments:

None.