The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH REGULATION
Senator Garcia, Chair
Senator Sobel, Vice Chair

MEETING DATE: Tuesday, January 11, 2011
TIME: 1:45 —3:45 p.m.
PLACE: *Pat Thomas Committee Room,* 412 Knott Building

MEMBERS: Senator Garcia, Chair; Senator Sobel, Vice Chair; Senators Altman, Bennett, Diaz de la Portilla, Fasano, Gaetz, Gardiner, Jones, Latvala, Norman, and Ring

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	**SB 94** Gaetz	Blood Establishments; Defines the term "volunteer donor." Prohibits local governments from restricting access to public facilities or infrastructure for certain activities based on whether a blood establishment is operating as a for-profit organization or not-for-profit organization. Requires that certain blood establishments disclose specified information on the Internet, etc. HR 01/11/2011 CA BC	
2	**SB 96** Ring (Identical H 25)	Mammogram Reports; Requires that all mammography reports include information and a notice about breast density. HR 01/11/2011 BI BC	
3	Consideration of proposed committee bill:		
7	**SPB 7000**	OGSR/Donor Personal Identifying Information; Provides that personal identifying information pertaining to a donor to the central repository for brain tumor biopsies or the brain tumor registry of the Florida Center for Brain Tumor Research is confidential and exempt from public records requirements. Provides an exception under certain conditions for information disclosed to a person engaged in bona fide research. Provides for future legislative review and repeal of the exemption under the Open Government Sunset Review Act. Provides a finding of public necessity.	
4	Presentation on Medicaid Fraud Prevention by Roy Schultheis, XTec		
5	**Interim Project 2011-125** (Review the Moratorium on Nursing Home Certificates of Need) Presentation		

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
6		Status report on implementation of the regulation of pain management clinics and the prescription drug monitoring database	

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:	SB 94
INTRODUCER:	Senator Gaetz
SUBJECT:	Blood Establishments
DATE:	January 6, 2011 REVISED:

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

I. Summary:

Senate Bill 94:

- Defines a "volunteer donor" for purposes of blood donations;
- Prohibits local governments from restricting access to public facilities or infrastructure for volunteer blood drives based on the tax status of a blood establishment conducting the blood drive;
- Prohibits a blood establishment from considering the tax status of certain customers when determining the price at which to sell blood or a blood component that was obtained from volunteer donors;
- Requires a blood establishment that collects blood or blood components from volunteer donors, except a hospital that uses the blood or blood components that the hospital collects, to disclose information on its Internet website concerning: a description of the activities of the blood establishment related to collecting, processing, and distributing volunteer blood donations; the number of units by component that are produced, obtained from other sources, and distributed; policies related to corporate conduct and executive compensation; and financial-related data. Failing to disclose this information as required in the bill subjects the blood establishment's clinical laboratory license to disciplinary action in the form of an administrative fine;
- Clarifies that a blood establishment may be a health care entity and engage in the wholesale distribution of certain prescription drugs;
- Exempts a blood establishment that manufactures blood and blood components from the requirement to be permitted as a prescription drug manufacturer and register products;

- Authorizes certain blood establishments to obtain a restricted prescription drug distributor permit to engage in the wholesale distribution of certain prescription drugs to health care entities; and
- Authorizes the Department of Health (DOH) to adopt rules related to certain activities with prescription drugs by blood establishments.

This bill substantially amends the following sections of the Florida Statutes: 381.06014, 483.201, 499.003, 499.005, and 499.01.

II. Present Situation:

Regulatory Background

A blood establishment is defined in s. 381.06014, F.S., to mean any person, entity, or organization, operating within Florida, which examines an individual for the purpose of blood donation or which collects, processes, stores, tests, or distributes blood or blood components collected from the human body for the purpose of transfusion, for any other medical purpose, or for the production of any biological product.

The state of Florida does not issue a specific license as a blood establishment. Florida law[1] requires a blood establishment operating in Florida to operate in a manner consistent with the provisions of federal law in Title 21 Code of Federal Regulations (C.F.R.) parts 211 and 600-640, relating to the manufacture and regulation of blood and blood components. If the blood establishment does not operate accordingly and is operating in a manner that constitutes a danger to the health or well-being of blood donors or recipients, the Agency for Health Care Administration (Agency) or any state attorney may bring an action for an injunction to restrain such operations or enjoin the future operation of the establishment.

Federal law classifies blood establishments as follows:[2] community (non-hospital) blood bank (community blood center), hospital blood bank, plasmapheresis center, product testing laboratory, hospital transfusion service, component preparation facility, collection facility, distribution center, broker/warehouse, and other. Community blood centers are primarily engaged in collecting blood and blood components from voluntary donors to make a safe and adequate supply of these products available to hospitals and other health care providers in the community for transfusion. Blood establishments that focus on the collection of plasma that is not intended for transfusion, but is intended to be sold for the manufacture of blood derivatives[3] routinely pay donors.

Community blood centers in Florida are licensed as clinical laboratories by the Agency, unless otherwise exempt.[4] As a part of the clinical laboratory license, the facility is inspected at least

[1] Section 381.06014, F.S.
[2] A description of these classifications may be found at: http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/BloodEstablishmentRegistration/ucm055484.htm (Last visited on January 6, 2011).
[3] Blood derivatives are classified as prescription drugs. *See* s. 499.003(43), F.S. and s. 503(b) of the Federal Food, Drug, and Cosmetic Act.
[4] *See* ch. 59A-7.019, F.A.C., and part I of ch. 483, F.S., related to Health Testing Services.

every 2 years.[5] The Agency may accept surveys or inspections conducted by a private accrediting organization in lieu of conducting its own inspection.[6] The clinical laboratory personnel are required to maintain professional licensure by the DOH. Community blood centers must also have appropriate licenses issued by the DOH and must comply with laws related to biomedical waste[7] and radiation services.[8]

Blood and Blood Components

Blood may be transfused to patients as whole blood or as one of its primary components: red blood cells (RBCs), plasma, platelets, and cryoprecipitated antihemophilic factor (AHF).[9]

- RBCs are prepared from whole blood by removing the plasma, and are given to surgery and trauma patients, along with patients with blood disorders like anemia and sickle cell disease. RBCs have a shelf life of 42 days, or they may be treated and frozen for storage of up to 10 years.
- Leukoreduced RBCs are filtered to contain a lesser amount of white blood cells than would normally be present in whole blood or RBC units. Leukoreduction is recommended to improve the safety of blood transfusions by reducing the possibility of post-transfusion infection or reaction that may result from pathogens concentrated in white blood cells.
- Plasma is the liquid portion of the blood that carries clotting factors and nutrients. It may be obtained through apheresis[10] or separated from whole blood, which is referred to as recovered plasma. It is given to trauma patients, organ transplant recipients, newborns and patients with clotting disorders. Fresh frozen plasma (FFP) is plasma frozen within hours after donation in order to preserve clotting factors and may be stored up to 7 years. It is thawed before it is transfused.
- Cryoprecipitated AHF is the portion of plasma that is rich in certain clotting factors. It is removed from plasma by freezing and then slowly thawing the plasma. Cryoprecipitated AHF is used to prevent or control bleeding in individuals with hemophilia and von Willebrand disease.
- Platelets control blood clotting in the body, and are used to stop bleeding associated with cancer and surgery. Units of platelets are prepared by using a centrifuge to separate the platelet-rich plasma from the donated unit of whole blood. Platelets also may be obtained from a donor by the process of apheresis, which results in about six times as many platelets as a unit of platelets obtained from the whole blood. Platelets are stored at room temperature for up to 5 days.

[5] Section 483.061(1), F.S.
[6] Section 483.061(4), F.S.
[7] *See* ch. 64E-16, F.A.C., Biomedical Waste, and s. 381.0098, F.S.
[8] *See* ch. 64E-5, F.A.C., Control of Radiation Hazards. If a blood center irradiates blood products using radioactive materials, the location in which this occurs must be licensed. If a blood center irradiates blood products using a machine, then the community blood center must register the machine.
[9] Blood component definitions from: AABB, *Whole Blood and Blood Components*, available at: http://www.aabb.org/resources/bct/bloodfacts/Pages/fabloodwhole.aspx (Last visited on January 6, 2011).
[10] *Ibid.* Apheresis is a process in which blood is drawn from the donor into an apheresis instrument that separates the blood into its components, retains the desired component, and returns the remainder of the blood to the donor.

Community Blood Centers

Currently, there are six not-for-profit corporations[11] and one for-profit corporation[12] that operate community blood centers in Florida.[13] Several hospital-owned blood centers operate in this state as well, primarily collecting blood or blood components to be used in each hospital's own facilities. At least one community blood center that does not have a fixed location in Florida collects blood and blood components from volunteer donors by using a mobile blood-collection vehicle and distributes blood and blood components to health care providers in Florida.

Recently, the for-profit community blood center received notification of a policy that impairs its ability to engage in blood collection activities and compete with the not-for-profit community blood centers. According to correspondence dated October 13, 2009, between officials within the Miami Parking Authority, that policy statement provides, "Meter rentals for blood mobile agencies will only be granted to non-profit companies conducting a blood drive ..."[14]

Pricing

The cost of blood and blood components is primarily based on the cost of labor and required testing, which ensures the safety of the blood collected. In addition to screening, collecting, processing (separation), and testing, blood centers must ensure that they implement procedures for labeling, including expiration dating; tracking and tracing the donation; deferral; public health reporting and donor follow-up as applicable; blood component quarantining in temperature-controlled environments until testing indicates the unit may be released for use; continued storage in temperature-controlled environments for released units; transportation and handling; and environmentally appropriate disposal of supplies and unusable units.[15]

Generally, the median fees charged by community blood centers in Florida are at or near the lowest median fees nationally.[16] As a part of The Florida Senate Committee on Health Regulation Interim Report 2010-119, Review of the Regulation of Blood Banks, professional

[11] The not-for-profit corporations include: Community Blood Centers of South Florida, Florida Blood Services, Florida's Blood Centers, LifeSouth Community Blood Centers, Suncoast Communities Blood Bank, and The Blood Alliance.
[12] The for-profit corporation is the United States Blood Bank (USBB).
[13] However, on November 18, 2010, the Community Blood Centers of Florida, Florida's Blood Centers, and Florida Blood Services announced they had received approval from each of their Boards to pursue a merger. A copy of the press release and a video of the announcement are available at http://www.floridasbloodcenters.org/news/news.stml?portalProcess_dd_0_1_1=showPublicPosting&calendar_entry_id=744 (Last visited on January 6, 2011).
[14] A copy of the correspondence is on file with the Florida Senate Health Regulation Committee. A representative from the Miami Parking Authority indicated in a telephone conversation with professional committee staff that they had received complaints concerning staff from blood centers standing in the middle of the street harassing people to donate and blood drives that were not conducted in cooperation with a business in the vicinity.
[15] AABB, *Blood FAQ: What fees are associated with blood?*, available at http://www.aabb.org/resources/bct/Pages/bloodfaq.aspx#a11 (Last visited on January 6, 2011). *See also* 21 C.F.R. Part 606, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=606&showFR=1&subpartNode=21:7.0.1.1.3.6 (Last visited on January 6, 2011).
[16] *See* The Florida Senate Committee on Health Regulation Interim Report 2010-119, Review of the Regulation of Blood Banks, found at: http://www.flsenate.gov/data/Publications/2010/Senate/reports/interim_reports/pdf/2010-119hr.pdf (Last visited on January 6, 2011).

staff surveyed a small sample of for-profit and not-for-profit hospitals. Based on responses to the committee's survey question requesting the average cost of a unit of specified blood components paid by the hospital over the last 12 months, it appeared that for-profit hospitals and not-for-profit hospitals were not paying an equivalent price for blood and blood components.[17]

Licensure to handle prescription drugs

Human blood and blood products are characterized as both "biologics,"[18] for purposes of regulation under the federal Public Health Service Act, as amended, and also as "drugs," subject to regulation under applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act).[19] Some of the community blood centers are licensed by the DOH as a prescription drug wholesaler since they purchase and distribute prescription drugs, such as blood, blood components, blood derivatives, and other prescription drugs used in the collection, processing, and therapeutic activities conducted by the community blood centers.[20]

The Florida Drug and Cosmetic Act (the Act),[21] as well as federal law,[22] prohibits the sale, purchase, or trade (wholesale distribution) of a prescription drug that was purchased by a health care entity or donated or supplied at a reduced price to a charitable organization. A community blood center is a health care entity[23] and the not-for-profit community blood centers are charitable organizations.[24] However, some of the community blood centers in this state are licensed as prescription drug wholesalers in order to purchase and distribute certain prescription drugs that are needed by community blood centers and hospitals to deliver health care services that are traditionally performed by, or in cooperation with, community blood centers. For example, some community blood centers offer hospitals the full range of blood-related products, such as albumin (to replace fluid), Rh Immune Globulin (to prevent incompatible maternal-fetal blood admixture), and erythropoietin (to stimulate the production of RBCs), as well as trained personnel and expertise in handling those products. The DOH has denied requests by blood establishments to renew the prescription drug wholesaler permits and has provided denial notices

[17] *Ibid.*

[18] The term "biologics" or "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, applicable to the prevention, treatment, or cure of a disease or condition of human beings.
See http://www.law.cornell.edu/uscode/42/usc_sec_42_00000262----000-.html (Last visited on January 6, 2011).

[19] The FDA, *Inspections, Compliance, Enforcement, and Criminal Investigations: CPG 230.120 – Human Blood and Blood Products as Drugs*, available at:
http://www.fda.gov/ICECI/ComplianceManuals/ComplianceProgramManual/ucm073863.htm (Last visited on January 6, 2011). Blood and blood components intended for further manufacture into products that meet the device definition are biological devices.

[20] Part I, ch. 499, F.S., related to Drugs, Devices, and Cosmetics.

[21] Section 499.005(21), F.S.

[22] 21 U.S.C. 353(c)(3)(A)(ii)(I) (Section 503(c)(3)(A)(ii)(I) of the FD&C Act).

[23] A "health care entity" is defined as a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. *See* s. 499.003(23), F.S. The federal definition, found at 21 C.F.R. § 203.3(q), is similar.

[24] *See* Internal Revenue Service, *Exemption Requirements - Section 501(c)(3) Organizations*, updated November 15, 2010, available at http://www.irs.gov/charities/charitable/article/0,,id=96099,00.html (Last visited on January 6, 2011).

to those blood establishments that have sought a renewal.[25] The Act and licensure of community blood centers under the Act are at odds with providing critical health care services by community blood centers.[26]

In November 2008, the FDA's rule to address this dilemma in federal law became effective.[27] That rule provides for exceptions to authorize a registered blood establishment that qualifies as a health care entity to sell, purchase, or trade certain prescription drugs that would otherwise be prohibited. The DOH suggested that the authorizations in the federal rule should be included in the Act, but could be more narrowly crafted to limit the sale, purchase, or trade of these prescription drugs *to a health care entity* to avoid unintended consequences or the opportunity for community blood centers to compete in the marketplace as a prescription drug wholesaler.

The DOH recently noted that blood establishments have not been permitted under the Act as a prescription drug manufacturer and have not registered the prescription drugs that they manufacture (the blood and blood components) with the DOH, notwithstanding the fact that blood establishments are considered manufacturers of prescription drugs under federal law. The distribution of the prescription drugs that blood establishments manufacture have been exempted from the definition of wholesale distribution under s. 499.003(54)(d), F.S., for years. This situation applies to the community blood centers as well as other types of blood establishments, such as the establishments that collect plasma from paid donors.

Restricted Prescription Drug Distributor Permit

The Florida Drug and Cosmetic Act is found in part I of ch. 499, F.S. The DOH is responsible for administering and enforcing efforts to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.[28] The DOH issues 20 different types of permits to persons (defined to also include business entities) who qualify to engage in activity regulated under the Act. The regulatory structure provides for prescription drugs to be under the responsibility of a permit at all times, until a prescription drug is dispensed to a patient, in which case the prescription from the practitioner represents the authority for the patient to possess the prescription drug.[29]

One of the permits issued by the DOH under the Act is the Restricted Prescription Drug Distributor (RPDD) Permit.[30] The biennial fee for the RPDD permit is $600 and the permit is valid for 2 years, unless suspended or revoked.[31]

[25] Information obtained by Florida Senate Health Regulation Committee staff via a telephone conference with representatives from the DOH on January 5, 2011.
[26] The DOH indicated in an email to Florida Senate Health Regulation Committee staff, dated November 12, 2009, that at the present time, they are not aware of any serious abuses or action by the licensed community blood centers that may pose a public health threat.
[27] The final rule in Vol. 73, No. 197 of the Federal Register on page 59496, published on October 9, 2008, is available at: http://edocket.access.gpo.gov/2008/pdf/E8-24050.pdf (Last visited on January 6, 2011).
[28] Section 499.002, F.S.
[29] Section 499.03(1), F.S.
[30] Section 499.01(2)(g), F.S.
[31] Chapter 64F-12.018, F.A.C., Fees.

A RPDD permit is required for any person that engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution."[32] The DOH issues different types of RPDD permits to eligible persons, including certain health care entities, for limited distributions of prescription drugs that are authorized under the Act.

Senate Interim Project Report 2010-119

During the 2009-2010 interim, professional staff of the Senate Committee on Health Regulation reviewed the regulation of blood banks (a.k.a. community blood centers). The recommendations concerning legislative action in the resulting report were to: prohibit public agencies from restricting the access to, or use of, public facilities or infrastructure for the collection of blood and blood components based on the tax status of the community blood center; prohibit a community blood center from using the tax status of a hospital or other health care facility as the sole factor when determining the price at which it offers to sell or sells blood or blood components to the hospital or other health care facility; and address the statutory obstacle in Florida law concerning a community blood center distributing prescription drugs in a manner that is consistent with federally authorized distributions, with certain additional safeguards.

In the 2010 general legislative session, SB 1818 sought to implement the committee staff's recommendations as well as additional provisions to increase transparency in the activities of community blood centers and address other glitches in Florida law related to the permitting of blood establishments. SB 1818 was voted favorably by each of its assigned committees. The bill was substituted by CS/CS/HB 509 and voted favorably on the Senate Floor. However, it died in returning messages to the House.

III. Effect of Proposed Changes:

Section 1 amends s. 381.06014, F.S., to define a volunteer donor as a person who does not receive remuneration, other than an incentive, for a blood donation intended for transfusion and the product container of the donation from the person qualifies for labeling with the statement "volunteer donor" under federal regulations.

The bill prohibits a local government from restricting access to, or use of, a public facility or public infrastructure for collecting blood or blood components from voluntary donors based on whether the blood establishment is a for-profit or not-for-profit corporation. Additionally, the bill prohibits a blood establishment from using as the sole factor whether a hospital or other health care entity is a for-profit or not-for-profit corporation when the blood establishment sets the service fee (price) at which it will sell blood and blood components collected from voluntary donors to the hospital or other health care entity.

The bill requires a blood establishment that collects blood or blood components from volunteer donors to disclose information on its Internet website concerning its activities. A hospital that collects blood or blood components from volunteer donors for use in its own facilities is not required to disclose this information. The disclosures may be cumulative for all blood

[32] Under s. 499.003(54)(a), F.S., the sale, purchase, or trade of blood and blood components intended for transfusion are specifically excluded from the definition of wholesale distribution.

establishments (branches) within the business entity. The information required to be disclosed includes:

- A description of the activities of the blood establishment related to collecting, processing, and distributing volunteer blood donations. This information is to be presented in a manner that is appropriate for the donating public;
- The number of units by component (whole blood, red blood cells, leukoreduced red blood cells, fresh frozen plasma or equivalent, recovered plasma, platelets, and cryoprecipitated AHF) that the blood establishment:
  - Produced (such as units that passed quality control and are available for use),
  - Obtained from other sources,
  - Distributed to health care providers that are located outside the state. However, if the blood center collects donations in a county outside Florida and distributes to health care providers in that county, then the distributions made to that county must be excluded. This distribution information must be the aggregate of health care providers that are located within the United States and its territories or outside the United States and its territories, and
  - Distributed to entities that are not health care providers. This information must be the aggregate of purchasers that are located within the United States and its territories or outside the United States and its territories.

  This information must be on the establishment's website by March 1 of each year reflecting data from the preceding calendar year;
- The blood establishment's policies pertaining to conflicts of interest, related-party transactions, and determining executive compensation. If any changes are made to any of these policies, the revised document must be on the blood establishment's website by the following March 1; and
- Either the most recent 3 years of a not-for-profit blood establishment's Form 990 that have been reported to the Internal Revenue Services, which must be posted within 30 calendar days after filing, or an audited or reviewed balance sheet, income statement, and statement of changes in cash flow, along with the expression of opinion on these statements from an independent certified public accountant, which must be posted within 120 days following the end of the fiscal year for a for-profit blood establishment and which must remain on the website for 36 months.

The clinical laboratory license of a blood establishment that fails to disclose this information is subject to an administrative fine as provided in section 2 of the bill.

Section 2 amends s. 483.201, F.S., to add the failure of a blood establishment that collects blood or blood components from volunteer donors to disclose the information required by s. 381.06014, F.S., regarding the blood establishment's activities to the grounds for which disciplinary action may be taken against a blood establishment's clinical laboratory license. If multiple blood establishments are operated by the blood establishment, the fines may be assessed against only one of the clinical laboratory licenses of the business entity. A $1,000 fine may be assessed for each day for which the disclosure is not made, up to a maximum amount of $10,000 for each annual reporting period.

Section 3 amends s. 499.003, F.S., to revise the definition of a health care entity to authorize a blood establishment that collects blood or blood components from volunteer donors to be a

health care entity and engage in the wholesale distribution of prescription drugs in accordance with the requirements contained in section 5 of the bill related to the restricted prescription drug distributor permit for a blood establishment.

Section 4 amends s. 499.005, F.S., to remove the prohibition against the wholesale distribution of prescription drugs by a blood establishment that collects blood or blood components from volunteer donors if the blood establishment is operating in compliance with the requirements contained in section 5 of the bill related to the restricted prescription drug distributor permit for a blood establishment.

Section 5 amends s. 499.01, F.S., to exempt a blood establishment that only manufactures blood and blood components from the requirements to be permitted as a prescription drug manufacturer and register the products it manufactures.

The bill also requires certain blood establishments to obtain a permit as a restricted prescription drug distributor in order to lawfully sell and distribute prescription drugs to another health care entity. The bill provides for certain restrictions on this authorization, including:

- The permit may be issued only to a blood establishment that is located in Florida;
- The permit may be issued to a blood establishment that collects blood and blood components from volunteer donors only or pursuant to an authorized practitioner's order for medical treatment or therapy;
- The distributions may be made only to a health care entity that is licensed as a closed pharmacy or provides health care services at the location where the health care entity receives the prescription drugs;
- The prescription drugs that may be distributed pursuant to the restricted prescription drug distributor permit are limited to:
  - A prescription drug that is indicated for a bleeding disorder, clotting disorder, or anemia;
  - A blood collection container that is approved under s. 505 of the federal FD&C Act related to new drugs;
  - A drug that is a blood derivative, or a recombinant or synthetic form of a blood derivative; or
  - A prescription drug that is essential to services performed or provided by blood establishments and is authorized for distribution by blood establishments under federal law if it is identified in rules adopted by the DOH; and
- The blood establishment may only provide health care services that:
  - Are related to its activities as an FDA-registered blood establishment;
  - Consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells; or
  - Consist of performing diagnostic testing of specimens if these specimens are tested together with specimens undergoing routine donor testing.

In addition, the bill provides that a blood establishment that is permitted as a restricted prescription drug distributor must comply with all the storage, handling, and recordkeeping

requirements with which a prescription drug wholesale distributor must comply. This includes providing pedigree papers[33] upon the wholesale distribution of these prescription drugs.

The DOH is authorized to adopt rules related to the distribution, transportation, storage, and recordkeeping of prescription drugs by blood establishments. These rules may include requirements for the use of prescription drugs in mobile blood-collection vehicles.

Section 6 provides an effective date of July 1, 2011.

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 the 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. Fiscal Impact Statement:

A. Tax/Fee Issues:

Instead of paying $800 annually for a prescription drug wholesale distributor permit and a $150 fee for certification of a designated representative, a community blood center that intends to engage in the wholesale distribution of certain prescription drugs in order to provide healthcare services typically provided by blood establishments will pay a $600 fee biennially for a restricted prescription drug distributor permit.[34]

B. Private Sector Impact:

Community blood centers that collect donations of blood and blood components from volunteer donors will need to ensure that pricing considerations for the sale of blood and blood components are not based solely on the whether the customer is a for-profit corporation or not-for-profit corporation.

[33] A pedigree paper contains information required by s. 499.01212, F.S., regarding the sale and distribution of a prescription drug.
[34] *See* ch. 64F-12.018, F.A.C., Fees.

A community blood center that collects donations of blood and blood components from volunteer donors, except hospitals, will be required to post certain information concerning its activities on its Internet website.

A community blood center that chooses to engage in the wholesale distribution of certain prescription drugs may lawfully do so if it is permitted as a restricted prescription drug distributor and complies with the requirements of that permit.

C. Government Sector Impact:

Governmental agencies may not limit the use of public infrastructure for the purpose of collecting voluntary donations of blood or blood components solely upon whether the corporation collecting the blood is for-profit or not-for-profit.

The DOH will need to adopt rules related to the permitting of a blood establishment as a restricted prescription drug distributor and other activities of blood establishments that are regulated under the Act.

VI. Technical Deficiencies:

On lines 116 and 123 of the bill, the term "calendar" prior to the term "year" has been unintentionally omitted.

If it is the Legislature's intent, line 181 of the bill should be clarified to state that a blood establishment "is" a health care entity that "may" engage in the wholesale distribution of certain prescription drugs specified in the bill. Currently line 181 of the bill states that a blood establishment "may" be a health care entity without providing any parameters as to when a blood establishment would not be considered a health care entity.

VII. Related Issues:

Lines 93 through 96 of the bill require a blood establishment that collects blood or blood components from volunteer donors to disclose on the Internet information to educate and inform donors and the public about the blood establishment's activities. This requirement may be interpreted to require blood establishments to disclose more information than what is specifically required to be disclosed by blood establishments in lines 112 through 153 of the bill.

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.

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Gaetz) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Section 381.06014, Florida Statutes, is amended to read:

381.06014 Blood establishments.—

(1) As used in this section, the term:

(a) "Blood establishment" means any person, entity, or organization, operating within the state, which examines an individual for the purpose of blood donation or which collects,

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processes, stores, tests, or distributes blood or blood components collected from the human body for the purpose of transfusion, for any other medical purpose, or for the production of any biological product. A person, entity, or organization that uses a mobile unit to conduct such activities within the state is also a blood establishment.

(b) "Volunteer donor" means a person who does not receive remuneration, other than an incentive, for a blood donation intended for transfusion, and the product container of the donation from the person qualifies for labeling with the statement "volunteer donor" under 21 C.F.R. s. 606.121.

(2) Any blood establishment operating in the state may not conduct any activity defined in paragraph (1)(a) ~~subsection (1)~~ unless that blood establishment is operated in a manner consistent with the provisions of Title 21 C.F.R. parts 211 and 600-640~~, Code of Federal Regulations~~.

(3) Any blood establishment determined to be operating in the state in a manner not consistent with the provisions of Title 21 C.F.R. parts 211 and 600-640~~, Code of Federal Regulations,~~ and in a manner that constitutes a danger to the health or well-being of donors or recipients as evidenced by the federal Food and Drug Administration's inspection reports and the revocation of the blood establishment's license or registration is ~~shall be~~ in violation of this chapter and must ~~shall~~ immediately cease all operations in the state.

(4) The operation of a blood establishment in a manner not consistent with the provisions of Title 21 C.F.R. parts 211 and 600-640~~, Code of Federal Regulations,~~ and in a manner that constitutes a danger to the health or well-being of blood donors

or recipients as evidenced by the federal Food and Drug Administration's inspection process is declared a nuisance and inimical to the public health, welfare, and safety. The Agency for Health Care Administration or any state attorney may bring an action for an injunction to restrain such operations or enjoin the future operation of the blood establishment.

(5) A local government may not restrict the access to or use of any public facility or infrastructure for the collection of blood or blood components from volunteer donors based on whether the blood establishment is operating as a for-profit organization or not-for-profit organization.

(6) In determining the service fee of blood or blood components received from volunteer donors and sold to hospitals or other health care providers, a blood establishment may not base the service fee of the blood or blood component solely on whether the purchasing entity is a for-profit organization or not-for-profit organization.

(7) A blood establishment that collects blood or blood components from volunteer donors must disclose on the Internet the information required under this subsection to educate and inform donors and the public about the blood establishment's activities. A hospital that collects blood or blood components to be used only by that hospital's licensed facilities or by a health care provider that is a part of the hospital's business entity is exempt from the disclosure requirements in this subsection. The information required to be disclosed under this subsection may be cumulative for all blood establishments within a business entity. A blood establishment must disclose on its website all of the following information:

(a) A description of the steps involved in collecting, processing, and distributing volunteer donations.

(b) By March 1 of each year, the number of units of blood components which were:

1. Produced by the blood establishment during the preceding calendar year;

2. Obtained from other sources during the preceding calendar year;

3. Distributed during the preceding calendar year to health care providers located outside this state. However, if the blood establishment collects donations in a county outside this state, distributions to health care providers in that county shall be excluded. Such information shall be reported in the aggregate for health care providers located within the United States and its territories or outside the United States and its territories; and

4. Distributed during the preceding calendar year to entities that are not health care providers. Such information shall be reported in the aggregate for purchasers located within the United States and its territories or outside the United States and its territories.

(c) The blood establishment’s conflict-of-interest policy, policy concerning related-party transactions, whistleblower policy, and policy for determining executive compensation. If a change occurs to any of these documents, the revised document must be available on the blood establishment’s website by the following March 1.

(d) Except for a hospital that collects blood or blood components from volunteer donors:

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1. The most recent 3 years of the Return of Organization Exempt from Income Tax, Internal Revenue Service Form 990, if the business entity for the blood establishment is eligible to file such return. The Form 990 must be available on the blood establishment's website within 60 calendar days after it is filed with the Internal Revenue Service; or

2. If the business entity for the blood establishment is not eligible to file the Form 990 return, a balance sheet, income statement, and statement of changes in cash flow, along with the expression of an opinion thereon by an independent certified public accountant who audited or reviewed such financial statements. Such documents must be available on the blood establishment's website within 120 days after the end of the blood establishment's fiscal year and must remain on the blood establishment's website for at least 36 months.

(8) A blood establishment is liable for a civil penalty for failing to make the disclosures required under subsection (7). The Department of Legal Affairs may assess the civil penalty against the blood establishment for each day that it fails to make such required disclosures, but the penalty may not exceed $10,000 per year. If multiple blood establishments operated by a single business entity fail to meet such disclosure requirements, the civil penalty may be assessed against only one of the business entity's blood establishments. The Department of Legal Affairs may terminate an action if the blood establishment agrees to pay a stipulated civil penalty. A civil penalty so collected accrues to the state and shall be deposited as received into the General Revenue Fund unallocated. The Department of Legal Affairs may terminate the action and waive

the civil penalty upon a showing of good cause by the blood establishment as to why the required disclosures were not made.

Section 2. Subsection (23) of section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(23) "Health care entity" means a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. However, a blood establishment is a health care entity that may engage in the wholesale distribution of prescription drugs under s. 499.01(2)(g)1.c.

Section 3. Subsection (21) of section 499.005, Florida Statutes, is amended to read:

499.005 Prohibited acts.—It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(21) The wholesale distribution of any prescription drug that was:

(a) Purchased by a public or private hospital or other health care entity; or

(b) Donated or supplied at a reduced price to a charitable organization,

unless the wholesale distribution of the prescription drug is authorized in s. 499.01(2)(g)1.c.

Section 4. Paragraphs (a) and (g) of subsection (2) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits.—

(2) The following permits are established:

(a) *Prescription drug manufacturer permit.*—A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.

1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in wholesale distribution of prescription drugs manufactured at that establishment and must comply with all of the provisions of this part, except s. 499.01212, and the rules adopted under this part, except s. 499.01212, which ~~that~~ apply to a wholesale distributor.

2. A prescription drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

3. A blood establishment, as defined in s. 381.06014, operating in a manner consistent with the provisions of Title 21 C.F.R. parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(54)(d) is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.

(g) *Restricted prescription drug distributor permit.*—

1. A restricted prescription drug distributor permit is required for:

a. Any person located in this state that engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(54)(a).

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b.~~1.~~ Any ~~A~~ person located in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction ~~must obtain a permit as a restricted prescription drug distributor~~ if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.

c. A blood establishment located in this state which collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized practitioner's order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(54)(d) to a health care entity. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment. The blood establishment must operate in accordance with s. 381.06014 and may distribute only:

(I) Prescription drugs indicated for a bleeding or clotting disorder or anemia;

(II) Blood-collection containers approved under s. 505 of the federal act;

(III) Drugs that are blood derivatives, or a recombinant or synthetic form of a blood derivative;

(IV) Prescription drugs that are identified in rules adopted by the department and that are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law; or

(V) To the extent authorized by federal law, drugs

necessary to collect blood or blood components from volunteer blood donors; for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a licensed physician; and to diagnose, treat, manage, and prevent any reaction of either a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician,

as long as all of the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimens if such specimens are tested together with specimens undergoing routine donor testing.

2. Storage, handling, and recordkeeping of these distributions by a person required to be permitted as a restricted prescription drug distributor must comply with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212 if the distribution occurs pursuant to sub-subparagraph 1.a. or sub-subparagraph 1.b.

3. A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

4. The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, ~~or~~ other persons not involved in wholesale distribution, and blood establishments,

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which rules are necessary for the protection of the public health, safety, and welfare.

Section 5. This act shall take effect July 1, 2011.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to blood establishments; amending s. 381.06014, F.S.; redefining the term "blood establishment" and defining the term "volunteer donor"; prohibiting local governments from restricting access to public facilities or infrastructure for certain activities based on whether a blood establishment is operating as a for-profit organization or not-for-profit organization; prohibiting a blood establishment from considering whether certain customers are operating as for-profit organizations or not-for-profit organizations when determining service fees for selling blood or blood components; requiring that certain blood establishments disclose specified information on the Internet; authorizing the Department of Legal Affairs to assess a civil penalty against a blood establishment that fails to disclose specified information on the Internet; providing that the civil penalty accrues to the state and requiring that it be deposited as received into the General Revenue Fund;

amending s. 499.003, F.S.; redefining the term "health care entity" to clarify that a blood establishment is a health care entity that may engage in certain activities; amending s. 499.005, F.S.; clarifying provisions that prohibit the unauthorized wholesale distribution of a prescription drug that was purchased by a hospital or other health care entity or donated or supplied at a reduced price to a charitable organization, to conform to changes made by the act; amending s. 499.01, F.S.; exempting certain blood establishments from the requirements to be permitted as a prescription drug manufacturer and register products; requiring that certain blood establishments obtain a restricted prescription drug distributor permit under specified conditions; limiting the prescription drugs that a blood establishment may distribute under a restricted prescription drug distributor permit; authorizing the Department of Health to adopt rules regarding the distribution of prescription drugs by blood establishments; providing an effective date.

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: SB 96

INTRODUCER: Senator Ring

SUBJECT: Mammogram Reports

DATE: January 7, 2011 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Brown	Stovall	HR	**Pre-meeting**
2.			BI	
3.			BC	
4.				
5.				
6.				

I. Summary:

The bill amends three sections of Florida Statutes related to health insurance policies and health maintenance contracts to require that mammography reports provided to patients include information about breast density.

The effective date of the bill is October 1, 2011.

This bill substantially amends the following sections of the Florida Statutes: 627.6418, 627.6613, and 641.31095.

II. Present Situation:

A mammogram is an X-ray of the breast. Mammograms known as screening mammograms may be routinely performed periodically as a tool to screen for breast cancer in patients who have no symptoms. Mammograms are also performed with patients who have symptoms, such as a lump or pain, or who have a suspicious change seen on a screening mammogram, and are known as diagnostic mammograms.[1]

Florida Insurance Mandates

Sections 627.6418, 627.6613, and 641.31095, F.S., currently contain mandates for accident or health insurance policies, group, blanket, or franchise accident or health insurance policies, and health maintenance contracts, respectively, to cover mammograms under certain parameters and requirements. Those parameters and requirements include coverage of a baseline mammogram

[1] American Cancer Society, *Mammograms and Other Breast Imaging Procedures,* p. 1.

and coverage of mammograms performed annually, biennially, or on a more frequent basis, depending on the age of the patient, recommendations of the patient's physician, and the patient's risk of breast cancer as determined by personal or family history.

These statutes also allow copayments and deductibles to be applied to mammogram services while requiring health insurers and HMOs to make mammogram coverage available, as part of the application for coverage and for an appropriate additional premium, without mammogram services being subject to copayments and deductibles.[2]

Sections 627.6418, 627.6613, and 641.31095, F.S., do not require mammogram reports to be provided to patients, nor do other provisions of Florida Statutes. The Agency for Health Care Administration and the Department of Health do not regulate health care providers or facilities regarding the issuance of mammogram reports, deferring to federal regulations and accreditation requirements, except to the extent that the Florida Board of Medicine has acted upon complaints and disciplined physicians who failed to contact patients about suspicious mammogram reports.[3] The Board has treated this type of violation as a standard of care or malpractice matter pursuant to s. 458.331(1)(t), F.S.

Federal Regulations

The federal Mammography Quality Standards Act (MQSA)[4] contains requirements related to the accreditation and operation of mammogram facilities. Such a facility is defined as a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: operation of equipment to produce a mammogram, processing of the mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation. The term does not include a facility of the Department of Veterans Affairs.[5]

A certificate issued by the Food and Drug Administration is required for lawful operation of all mammogram facilities subject to the provisions of the MQSA. To obtain a certificate, facilities are required to meet various quality standards set forth in federal regulations, including the requirement to communicate mammography results to patients and health care providers.[6]

Mammogram facilities are required to send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are "suspicious" or "highly suggestive of malignancy," the facility must make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.[7] Facilities are not required to include specific information about breast tissue density in the report summary sent to patients.

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[2] The federal Patient Protection and Affordable Care Act prohibits copayments and deductibles for preventive services, including breast cancer mammography screenings every 1 to 2 years for women over age 40, as of September 23, 2010.
[3] Email from the Florida Department of Health to staff in the Florida Senate Committee on Health Regulation, January 6, 2011, 9:47 am EST (on file with committee staff).
[4] *See* 42 USC 263b.
[5] *See* 21 CFR § 900.2(q).
[6] See 21 CFR § 900.11(a).
[7] *See* 21 CFR § 900.12(c)(2),(3).

Scientific Research

Recent medical research has produced findings about breast tissue density as it relates to breast cancer screening via mammography and the risk of developing breast cancer. Breasts contain both dense tissue (glandular tissue and connective tissue, collectively known as fibroglandular tissue) as well as fatty tissue that is much less dense. Fatty tissue appears dark on a mammogram, whereas dense tissue and tumors appear as white areas. Because fibroglandular tissue and tumors have similar density and can have a similar appearance on mammograms, tumors can be more difficult to detect in women with denser breast tissue.[8]

Women with denser breast tissue are also more likely to develop breast cancer. Women with dense tissue in 75 percent or more of the breast have a risk of breast cancer four to six times as great as the risk among women with little or no dense breast tissue.[9]

Younger women are more likely than older women to have dense breast tissue. As a woman ages, her breasts usually become more fatty as glandular tissue atrophies.[10] Breast glands that produce milk form small lobes called breast lobules. Age-related atrophy of breast lobules is called lobular involution. Normal lobular involution is inversely associated with breast cancer risk. Having no or partial lobular involution is associated with a higher risk of breast cancer than having complete involution. Having a combination of no involution and dense breast tissue is associated with higher risk of breast cancer than having complete involution and non-dense breast tissue. Those two factors are independently associated with breast cancer incidence; combined, they are associated with an even greater risk.[11]

Mammography

The National Cancer Institute (NCI) recommends that women age 40 and older should have screening mammograms every 1 to 2 years and that women who are at higher than average risk of breast cancer should talk with their health care providers about whether to have mammograms before age 40 and how often to have them.[12]

There are two methods for recording and storing images produced by mammograms: conventional and digital. Both use X-rays to produce an image of the breast; however, in conventional mammography, the image is stored directly on film, whereas in digital mammography, an electronic image of the breast is stored as a computer file. This digital information can be enhanced, magnified, or manipulated for further evaluation more easily than information stored on film. Except for the difference in how the image is recorded and stored, there is no other difference between the two types of mammography.[13]

Early detection of breast cancer with screening mammography means that treatment can be started earlier in the course of the disease, possibly before it has spread. Results from

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[8] National Cancer Institute, *Mammogram Fact Sheet,* September 22, 2010.
[9] Boyd, et al., Mammographic Density and the Risk and Detection of Breast Cancer, *The New England Journal of Medicine,* January 18, 2007, p. 228.
[10] Supra, note 8.
[11] Ghosh, et al., Independent Association of Lobular Involution and Mammographic Breast Density With Breast Cancer Risk, *Journal of the National Cancer Institute,* November 17, 2010, p. 1716.
[12] Supra, note 8.
[13] Supra, note 8.

randomized clinical trials and other studies show that screening mammography can help reduce the number of deaths from breast cancer among women ages 40 to 74, especially for those over age 50.[14] However, studies conducted to date have not shown a benefit from regular screening mammography in women under age 40 or from baseline screening mammograms (mammograms used for comparison) taken before age 40.[15]

Magnetic Resonance Imaging (MRI)

MRI is a technology that uses magnets and radio waves to produce detailed cross-sectional images of breast tissue and other internal body structures. MRI does not use X-rays.

Breast MRI is not recommended as a routine breast cancer screening tool for women at average risk for breast cancer. However, it is recommended for screening women who are at higher risk. The American Cancer Society (ACS) recommends that women at high risk of breast cancer (about 20 percent or greater lifetime risk based on a detailed family history or a history of radiation treatments at a young age), should get an MRI and a mammogram every year beginning at age 30. The ACS further recommends that women at moderately increased risk (15 percent to 20 percent lifetime risk) should discuss with their health care providers the benefits and limitations of adding MRI screening to a yearly mammogram, and this group includes women with extremely dense breast tissue.[16]

Ultrasound

Also known as sonography, ultrasound uses high-frequency sound waves to look inside a part of the body. Echoes from the sound waves are detected and translated by a computer into a black and white image shown on a computer screen. Ultrasound does not use X-rays. Breast ultrasound is sometimes used to evaluate breast problems that are found during a screening or diagnostic mammogram or during physical exam. Breast ultrasound is not routinely used for screening. Ultrasound is useful for examining some breast masses and it is the only way to tell if a suspicious area is a cyst without putting a needle into the area to remove fluid. Breast ultrasound may also be used to help doctors guide a biopsy needle into some breast lesions or areas of concern.[17]

The American College of Radiology (ACR) has stated that appropriate indications for breast sonography include evaluation of breasts with areas suspicious for malignancy or highly suggestive of malignancy in a setting of dense fibroglandular tissue. In such cases, sonography may be used for detection of an underlying mass that may be obscured on a mammogram.[18]

Breast Imaging Reporting and Database System (BI-RADS)

BI-RADS® is a quality assurance guide, produced by the ACR, designed to standardize breast imaging reporting and facilitate outcome monitoring. BI-RADS® serves as a comprehensive guide providing standardized breast imaging terminology, report organization, and assessment

[14] National Cancer Institute, *Breast Cancer Screening (PDQ®),* September 3, 2010.
[15] Supra, note 8.
[16] Supra, note 1, pp. 4-5.
[17] Supra, note 1, p. 20.
[18] American College of Radiology, *ACR Practice Guideline for the Performance of a Breast Ultrasound Examination,* pp. 1-2.

structure, as well as a classification system for mammography, ultrasound, and MRI of the breast.[19]

The ACR indicates it is appropriate for mammography reports to include a statement regarding extremely dense breast tissue and that, for consistency, breast composition should be described for all patients using the following patterns:

1. The breast is almost entirely fat (less than 25 percent glandular)
2. There are scattered fibroglandular densities (approximately 25 percent to 50 percent glandular)
3. The breast tissue is heterogeneously dense, which could obscure detection of small masses (approximately 51 percent to 75 percent glandular)
4. The breast tissue is extremely dense. This may lower the sensitivity of mammography (greater than 75 percent glandular)[20]

III. Effect of Proposed Changes:

The bill would amend three statutory mandates that currently require the coverage of mammography by health insurers and health maintenance organizations. Under the bill, the statutory language for those mandates would also contain two requirements related to mammography reports:

1. Each mammography report provided to a patient would have to include information about breast density based on the BI-RADS®, and
2. Where applicable, such a report would be required to include the following notice:

   "If your mammogram demonstrates that you have dense breast tissue, which could hide small abnormalities, you might benefit from supplementary screening tests, including a breast ultrasound screening or a breast MRI examination, or both, depending on your individual risk factors. A report of your mammography results, which contains information about your breast density, has been sent to your physician's office and you should contact your physician if you have any questions or concerns about this report."

The effective date of the bill is October 1, 2011.

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.

[19] American College of Radiology, *The American College of Radiology BI-RADS® Atlas and MQSA: Frequently Asked Questions,* December 20, 2010, p. 1.
[20] Ibid, p. 3.

B. Public Records/Open Meetings Issues:

The provisions of the 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. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The cost to private sector entities to include the required information in mammography reports is indeterminate.

C. Government Sector Impact:

The cost for government sector entities to include the required information in mammography reports is indeterminate. The legislation has no fiscal impact on the government sector in a regulatory sense.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill references mammography reports and the contents they must include, but the bill requires neither insurance carriers nor health care providers to actually issue mammography reports. Mammogram facilities are required to issue reports by federal law, not Florida law.

Under requirement 1 (see Section III. Effect of Proposed Changes), it is not clear exactly what information about breast density would have to be communicated to patients. This lack of clarity could lead to wide variance in the content of information relating to breast density included in mammography reports provided to patients.

Under requirement 2, it is not clear what circumstances would satisfy the "where applicable" condition and require the inclusion of the specified notice, which could lead to wide variance as to whether mammography reports provided to patients actually contain the notice.

The Office of Insurance Regulation (OIR) suggests that the amendment might be more appropriate in laws that govern medical practice, since mammogram facilities are required to provide mammography reports to patients while insurance carriers are not.

In addition, the OIR notes that the legislation applies only to those mammograms administered to an insured health plan participant and would not necessarily affect a significant number of women who are participants in public medical service programs, are covered by an employer's self-insured plan, or who may self-pay for the mammogram test without health care coverage.

The OIR further notes that while the bill's required notice language makes reference to supplemental tests (ultrasound, MRI, or both), the bill does not specifically require coverage for such procedures as the statutes currently require for mammograms.

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.

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.

Medicaid Reform

Fraud Prevention Solution

Authentication and Security Solutions you can trust.SM

XTEC

The Problem

- Among the many types of Medicaid fraud,
  - Phantom billing, which is primarily based on ID theft.
  - Home health care. May involve collusion between the patient and provider, in which providers bill for services not performed.
  - Pharmacy claims. Billing for prescription medication never dispensed to Patients.
- It has been estimated by the Legislature Policy Research office that Medicaid fraud may exceed $2 billion out of a total of a $20 billion spent on Medicaid. This represents 10% of the funds not going to provide services for those in need.

XTEC

The Industry Leader

Founded in 1992, XTec is an independent developer, producer, and licensor of Credential Management, Access Control Systems and Security Solutions.
XTec was one of the first companies to be certified as a GSA-FIPS 201 “End-to-End” solution provider.
We are forensic experts in financial fraud for the United States Secret Service (USSS) and other governments as mediated by Interpol.

XTec has delivered FIPS-201 and HSPD-12 compliant solutions to over 15 Federal Agencies for use nationwide.


GSA

General Services Administration

Certificate of Completion

GSA

For

HSPD-12 SIN 132-62 Vendor Evaluation

is hereby granted to

X-Tec

This Certificate certifies that X-Tec has passed the SIN 132-62 Evaluation for:
Activation and Finalization Services and Products,
Card Management and Production Services and products,
Enrollment and Registration Services and Products,
Systems Infrastructures Services and Products,
Systems Integration Services and Products

Michael R. Brooks June 28, 2006

Director, Center for Smartcard Solutions

XTEC

XTEC HSPD-12 Federal Customers

Over 40% of FIPS201 PIV cards issued by the Federal Government are issued with XTec solutions, including the agencies listed below.

- Department of Homeland Security – Headquarters (DHS)
- Department of State (DOS)
- Department of Defense (DOD – Navy, Air Force, Army)
- General Services Administration (GSA)
- Department of Labor (DOL)
- Federal Emergency Management Agency (FEMA)
- USAID
- Peace Corps
- Millennium Challenge Corporation
- National Science Foundation
- International Broadcasting Bureau (IBB)
- Smithsonian Institute
- Department of Education
- Railroad Retirement Board
- Department of Energy (DOE)
- Maritime Administration
- Department of Justice (BOP)

The Solution

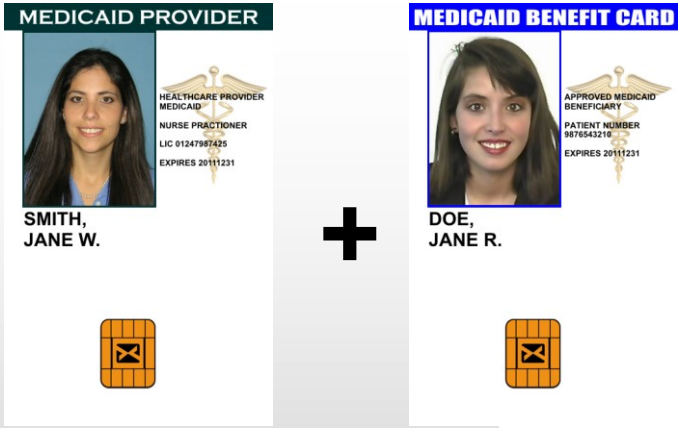
- The most cost-effective way to address Medicaid fraud is to **prevent it** rather having to detect it after the fact. The recovery of a $1,000 fraudulent transaction may cost many times that amount to recover in a future audit.
- The Medicaid system is fundamentally flawed because there is no mechanism to authenticate patients or providers, or to generate validated transactions. XTec would propose leveraging our Federal HSPD12 / PIV-*i* based technology and infrastructure to solve the problem.
- Establishing the identity of all of your involved parties within the Medicaid system is paramount for eliminating current misuse and abuse.

The Implementation

- This solution prevents the basic types of fraud by ***authenticating the entire transaction*** between patients and providers.
- The solution is based on the Federal government-mandated FIPS201 standard for security.
- By using this solution the State of Florida immediately lowers the cost of fraud prevention and provides a vetted, reliable and compatible solution for other areas.
- Instead of only relying on expensive audits to detect fraud, this solution virtually eliminates it at the point of interaction by authenticating the patient, authenticating the provider, which results in a digitally-signed unique transaction approval code.
- Requires minimal or no changes in current Medicaid accounting systems.

A Secure Medicaid Transaction

A unique approval code is generated that validates and authenticates the total transaction between the patient and provider.



Transaction Approval Process

TX Number	Approval Code	
001	998796436	?
002	987247364	?
003	897566317	?
004	489766314	?

TX Number	Approval Code	
001	998796436	✓
002	987247364	✘
003	897566317	✓
004	489766314	✓

Billing: Eliminates fraudulent transactions via unique ID
Audit: Provides audit trail, although prevention is the strong point
Reporting: Various system reports available depending on the metrics required

Process Guarantees

- XTec guarantees the State of Florida the integrity and security of the card issuance process in conformance with current and future Federal Standards for Personal Identity Verification cards or tokens.
- XTec guarantees the integrity of the cryptographic process that generates a unique digest for each transaction.
- XTec guarantees the ability to electronically authenticate cards and detect fraudulent tokens.
- XTec guarantees the integrity and security of the responding authentication and transactional servers.
- XTec guarantees the State's investment in a mutually agreed deployment of the system.

Additional Transaction Analysis

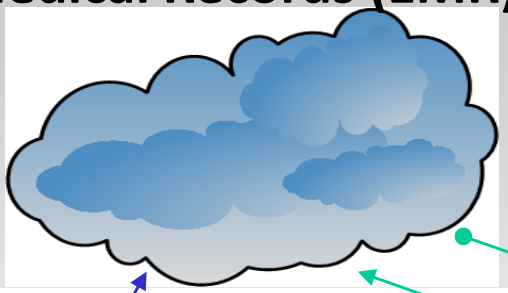
- Based on the authentication of the patient and providers, additional transactional analysis can be performed to prevent fraudulent claims. Algorithms can be implemented that will detect fraudulent claims being submitted for patients based on velocity patterns similar to those used in the financial transaction industry.
- Parameters established by Medicaid for allowable mix of procedures, number of procedures and historical transaction profiles can be implemented to detect fraud.

Additional PIV Card capabilities

Electronic Medical Records

- PIV cards and the Public Key Infrastructure (PKI) that supports it is the ideal mechanism to effect the secure transfer of EMR from one Provider to another.
- Electronic Medical Records is an initiative designed to expedite and improve medical care for patients and providers.
- EMR that can be efficiently shared by providers will assist in reducing duplicity of medical procedures and tests creating a cost savings to the Program.
- Privacy issues with sensitive medical records are a concern to both Provider and Beneficiary.
- EMRs can be securely transferred over the open internet using available encryption mechanisms that rely on the cryptographic keys resident on the beneficiary's PIV card.

Electronic Medical Records (EMR) Repository



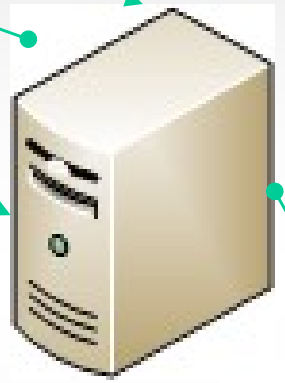
Sending Provider is authenticated

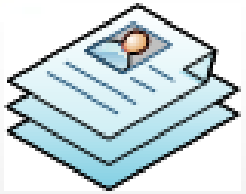
Sending Provider

Receiving Provider

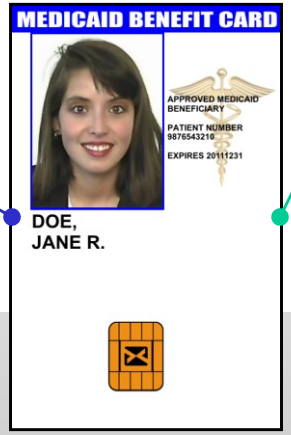
Encrypts EMR file

Decrypts EMR file





Patient Authorizes release of EMR with PIV card



Patient presents PIV card to Receiving Provider which authorizes Provider to decrypt medical records

Patient Benefit Card

Electronic Medical Record Transfers

- Patient electronically authorizes Medical Records to be transferred to another Provider using the PIV card.
- Sending provider encrypts EMR file and uploads to EMR repository server.
- Data is securely stored and organized in the repository protected by the Patient's PIV card cryptographic keys.
- Electronic notification is send to Receiving Provider that EMR are available for retrieval.
- Receiving Provider is authenticated electronically and allowed to retrieve the specific file from the repository.
- File is decrypted and available for viewing.

Electronic Medical Records Audit Capabilities

- EMR transfer capabilities can also be used to securely request and transfer records from Providers for audit and fraud control purposes.
- Transactions that are not authenticated electronically can be audited prior to disbursing payments.

Pricing Models

- Estimated costs are based on XTec's experience with deployments of authentication frameworks in the Federal Government.
- For purposes of providing a Rough Order of Magnitude, the population of Florida Medicaid beneficiaries will be assumed to be 2.9 million with 89,000 providers.
- Pricing is based on centralized issuance and distribution of PIV cards for the population. It is assumed that the State will piggyback on the infrastructure and systems already developed for Federal government, with modifications to meet specific needs of the Medicaid program.
- Annual cost for deployment and sustainment of similar infrastructure and population is approximately $30 million, including FIPS 201 compliant smart cards
- Other pricing models can be negotiated based on more precise information.

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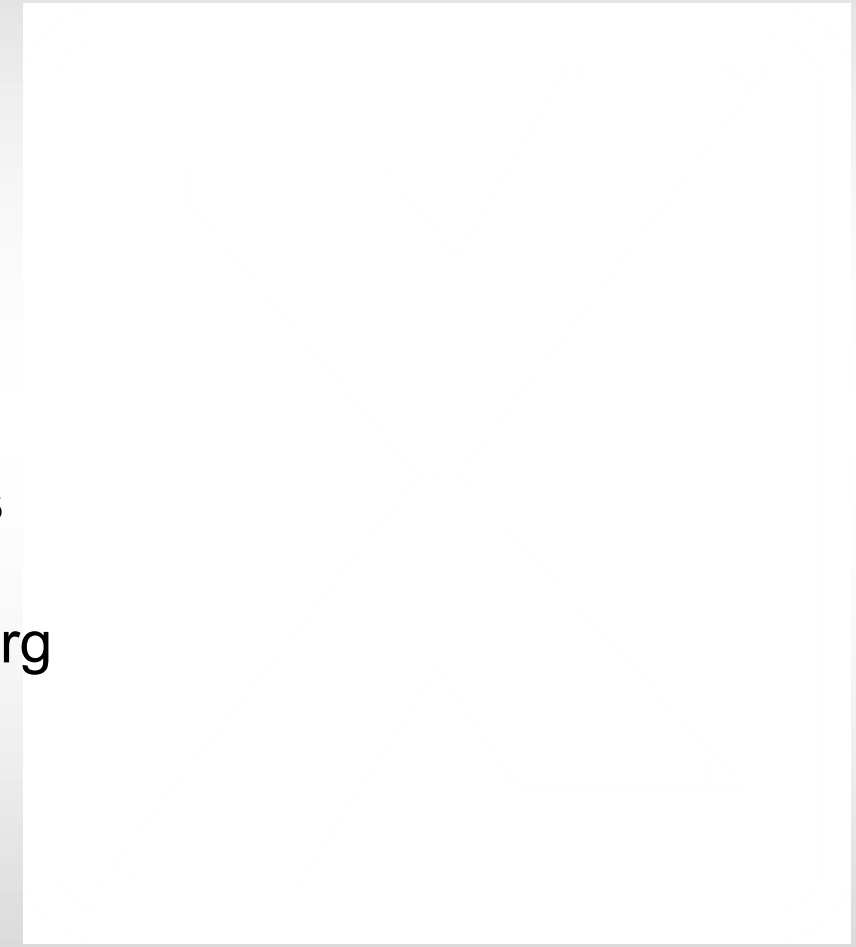

The Florida Senate

Interim Report 2011-125 *October 2010*

Committee on Health Regulation

REVIEW THE MORATORIUM ON NURSING HOME CERTIFICATES OF NEED

Issue Description

Florida regulates the entry of nursing homes into the market and the expansion of nursing home beds through the certificate of need (CON) process. Currently a moratorium is imposed on the issuance of a CON for additional nursing home beds, with certain exceptions, until July 1, 2011. The moratorium has been in place since 2001, after reenactment with modifications by the Legislature in 2006. The purpose of the moratorium is to contain nursing home placements and encourage other forms of assistance in a manner that is both more cost-effective and more in keeping with the wishes of elderly residents in this state. This report examines factors impacting an extension of the moratorium and recommends a legislative extension of the moratorium on the issuance of CONs for additional nursing home beds.

Background

Certificates of Need

A CON is a written statement issued by the Agency for Health Care Administration (Agency) evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility, health service, or hospice.[1] Under this regulatory program, the Agency must provide approval through the CON review and approval process prior to a provider establishing a new nursing home or adding nursing home beds.

The Florida CON program has three levels of review: full, expedited, and the granting of an exemption.[2] The nursing home projects addressed in s. 408.036, F.S., related to CONs are as follows:

Projects Subject to Full Comparative Review

- Adding beds in community nursing homes and
- Constructing or establishing new health care facilities, which include skilled nursing facilities (SNFs).[3]

Projects Subject to Expedited Review

- Replacing a nursing home within the same district and
- Relocating a portion of a nursing home's licensed beds to a facility within the same district.

Exemptions from CON Review

- Converting licensed acute care hospital beds to Medicare and Medicaid certified skilled nursing beds in a rural hospital;
- Adding nursing home beds at a SNF that is part of a retirement community which had been in operation on or before July 1, 1949 for the exclusive use of the community residents;

[1] s. 408.032(3), F.S.
[2] s. 408.036, F.S.
[3] Section 408.032(16), F.S., defines a SNF as an institution, or a distinct part of an institution, which is primarily engaged in providing, to inpatients, skilled nursing care and related services for patients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

- Combining licensed beds from two or more licensed nursing homes within a district into a single nursing home within that district if 50 percent of the beds are transferred from the only nursing home in a county and that nursing home had less than a 75 percent occupancy rate;[4]
- State veteran's nursing homes operated by or on behalf of the Florida Department of Veterans' Affairs;
- Combining into one nursing home, the beds or services authorized by two or more CONs issued in the same planning subdistrict;
- Separating into two or more nursing homes in the subdistrict, the beds or services that are authorized by one CON;
- Adding no more than 10 total beds or 10 percent of the licensed nursing home beds of that facility, whichever is greater; or if the nursing home is designated as a Gold Seal nursing home, no more than 20 total beds or 10 percent of the licensed nursing home beds of that facility for a facility with a prior 12-month occupancy rate of 96 percent or greater; and
- Replacing a licensed nursing home on the same site, or within 3 miles, if the number of licensed beds does not increase.

The CON program applies to all nursing home beds, regardless of the source of payment for the beds (private funds, insurance, Medicare, Medicaid, or other funding sources).

Determination of Need

A CON is predicated on a determination of need. The future need for community nursing home beds is determined twice a year and published by the agency as a fixed bed need pool for the applicable planning horizon. The planning horizon for CON applications is 3 years. Need determinations are calculated for subdistricts within the Agency's 11 service districts[5] based on estimates of current and projected population as published by the Executive Office of the Governor.

The need formula[6] links the projected subdistrict need to a projected increase in the district need for nursing home beds. The district increase is based on the expected increase in the district population age 65 to 74 and age 75 and over, with the age group 75 and over given 6 times more weight in projecting the population increase. The projected district bed need total is then allocated to its subdistricts. The result for a given subdistrict is adjusted to reflect the current subdistrict occupancy of beds, and a desired standard of 94 percent occupancy. The subdistrict net need is the excess of the allocated beds over the licensed or approved beds in the subdistrict. If current occupancy of licensed beds is less than 85 percent, the net need in the subdistrict is zero regardless of whether the formula otherwise shows a net need.

The Agency is required to issue a CON to the holder of a provisional certificate of authority to construct nursing home beds for the exclusive use of the prospective residents of the proposed continuing care facility under a different bed-need assessment scheme.[7] The Agency is required to approve at least one sheltered nursing home bed[8] for every four proposed residential units. Additional sheltered nursing home beds must be approved based on actual utilization and demand by current residents. Sheltered nursing home beds are not included in the need formula for community nursing home beds.

[4] This exemption is repealed upon the expiration of the moratorium by operation of s. 408.036(3)(f), F.S.
[5] The nursing home subdistricts are set forth in Rule 59C-2.220, F.A.C.
[6] Rule 59C-1.036, F.A.C.
[7] s. 651.118, F.S.
[8] A sheltered nursing home bed is a nursing home bed located within a continuing care facility for which a CON is issued pursuant to s. 651.118(2), F.S. Generally these beds must be used for residents of the continuing care facility. However, the beds may be used for persons who are not residents of the continuing care facility for a period of up to 5 years after the date of issuance of the initial nursing home license. A continuing care community may request an extension of this timeframe for up to 30 percent of the sheltered nursing home beds based on demonstrated financial need.

Application Process

Nursing home bed projects subject to competitive review are included in the batching cycle for "other beds and programs." The review process takes approximately 120 days.[9] The fixed bed need determination is published in the Florida Administrative Weekly. A letter of intent describing the applicant, the project type including the number of beds, and its location must be submitted to the Agency at least 30 days prior to the applicable batching cycle application due date.[10] A grace period after the initial letter of intent deadline provides an opportunity for other applicants to compete with an initial letter of intent. The grace period extends this initial phase by an additional 16 days for the submission of a competitor's letter of intent.

The CON application must be submitted to the Agency by the date published for that batching cycle. The Agency must perform a completeness review of the application within 15 calendar days of the application submission deadline.[11] The applicant has 21 calendar days after receipt of the Agency's request for additional information to provide the requested information, otherwise the application is withdrawn from further consideration. The Agency must determine whether the application is complete or withdrawn within 7 calendar days after receipt of the requested information.

The Agency will conduct public hearings on the applications, if requested and the Agency determines that a proposed project involves issues of great local public interest.[12]

The Agency reviews CON applications for additional nursing home beds in context with the following criteria:[13]

- The need for the health care facilities and health services being proposed. An application for nursing facility beds will not be approved in the absence or insufficiency of a numeric need unless the absence or insufficiency of numeric need is outweighed by other information presented in a CON application showing special circumstances consistent with the additional criteria that follows;[14]
- The availability, quality of care, accessibility, and extent of utilization of existing health care facilities and health services in the service district of the applicant;
- The ability of the applicant to provide quality of care and the applicant's record of providing quality of care;
- The availability of resources, including health personnel, management personnel, and funds for capital and operating expenditures, for project accomplishment and operation;
- The extent to which the proposed services will enhance access to health care for residents of the service district;
- The immediate and long-term financial feasibility of the proposal;
- The extent to which the proposal will foster competition that promotes quality and cost-effectiveness;
- The costs and methods of the proposed construction, including the costs and methods of energy provision and the availability of alternative, less costly, or more effective methods of construction;
- The applicant's past and proposed provision of health care services to Medicaid patients and the medically indigent; and
- The applicant's designation as a Gold Seal Program nursing facility pursuant to s. 400.235, F.S., when the applicant is requesting additional nursing home beds at that facility.

The Agency issues a State Agency Action Report which states the Agency's intent to grant or deny a CON for projects in their entirety or for identifiable portions thereof and states the conditions required, if any, of the CON holder. If there is no challenge to all or any part of the agency decision embodied in the State Agency Action

[9] Presentation by the Agency on Florida CONs to the House Health Innovation Committee on January 8, 2008. A copy of the presentation slides is available from the Senate Committee on Health Regulation.
[10] Rule 59C-1.008, F.A.C.
[11] Rule 59C-1.010, F.A.C.
[12] s. 408.039, F.S.
[13] s. 408.035, F.S.
[14] Rule 59C-1.036, F.A.C.

Report within 21 days after publication in the Florida Administrative Weekly, the decision becomes final and the CON(s) are issued.[15]

Applicants in the same batching cycle and exiting health care facilities in the same district that will be substantially affected by the issuance of any CON may challenge the issuance or denial of a CON. The Division of Administrative Hearings conducts the hearing, which must commence within 60 days after the administrative law judge has been assigned except upon unanimous consent of the parties or pursuant to a motion of continuance granted by the administrative law judge.[16] A party to an administrative hearing for an application for a CON may seek judicial review of the final order issued by the administrative law judge to the District Court of Appeal.

Moratorium on Nursing Home CONs

In 2001, the Legislature enacted the first moratorium on the issuance of CONs for additional community nursing home beds until July 1, 2006.[17] In 2006, the Legislature extended the moratorium until July 1, 2011.[18] In addition, the Legislature provided for additional exceptions to the moratorium to address occupancy needs that might arise.

The Legislature has provided for certain exceptions to the moratorium on CONs as follows:

- Adding sheltered nursing home beds;
- Beds may be added in a county that has no community nursing home beds and the lack of beds is the result of the closure of nursing homes that were licensed on July 1, 2001;[19]
- Adding the greater of no more than 10 total beds or 10 percent of the licensed nursing home beds of a nursing home located in a county having up to 50,000 residents,[20] if:
    - The nursing home has not had any class I or class II deficiencies[21] within the 30 months preceding the request for addition;
    - The prior 12-month average occupancy rate for the nursing home beds at the facility meets or exceeds 94 percent and the facility has not had any class I or class II deficiencies since its initial licensure; or
    - For a facility that has been licensed for less than 24 months, the prior 6-month average occupancy rate for the nursing home beds at the facility meets or exceed 94 percent and the facility has not had any class I or class II deficiencies since its initial licensure; [22] and
- Adding the greater of no more than 10 total beds or 10 percent of the number of licensed nursing home beds if:
    - The facility has not had any class I or class II deficiencies within the 30 months preceding the request for addition;
    - The prior 12-month average occupancy rate for the nursing home beds at the facility meets or exceeds 96 percent;
    - The prior 12-month occupancy rate for the nursing home beds in the subdistrict is 94 percent or greater; and

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[15] *Supra* note 11.
[16] *Supra* note 11.
[17] Ch. 2001-45, L.O.F. s. 52.
[18] Ch. 2006-161, L.O.F.
[19] The request to add beds under this exception to the moratorium is subject to the full competitive review process for CONs.
[20] Twenty-two counties have under 50,000 residents. These counties include: Baker, Bradford, Calhoun, DeSoto, Dixie, Franklin, Gilchrist, Glades, Gulf, Hamilton, Hardee, Hendry, Holmes, Jefferson, Lafayette, Levy, Liberty, Madison, Okeechobee, Taylor, Union, and Wakulla. Source: The Florida Legislature Office of Demographic and Economic Research as of August 9, 2010, available at: <http://edr.state.fl.us/>, (Last visited on September 21, 2010).
[21] Deficiencies in nursing homes are classified according to the nature and scope of the deficiency. A class I deficiency is a deficiency that the Agency determines presents a situation in which immediate corrective action is necessary because the facility's noncompliance has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident receiving care in a facility. A class II deficiency is a deficiency that the Agency determines has compromised a resident's ability to maintain or reach his or her highest practicable physical, mental, and psychosocial well-being, as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. (See s. 400.23(8), F.S.)
[22] The requirement that the facility not have had any class I or class II deficiencies within the three timeframes is unclear, especially within the first two provisions. This language could be clarified.

- Any beds authorized for the facility under this exception in a prior request have been licensed and operational for at least 12 months.[23]

Findings and/or Conclusions

Nursing Home Occupancy Levels

There are 671 licensed nursing homes in Florida.[24] As of March 1, 2010, there were 82,598 licensed nursing home beds, with an additional 1,024 CON-approved beds that are not licensed currently. Of the licensed beds, 79,437 were community beds, 2,496 were sheltered nursing home beds, 600 were beds in Veteran's nursing homes and 65 beds were dedicated to pediatric residents.[25]

Over the last 10 years, the average nursing home occupancy level in Florida has remained below 90 percent and has been declining steadily. As might be expected, there are some subdistricts that exceed the 94 percent standard occupancy level. Specifically, since the moratorium was reenacted in 2006, the Leon and Okeechobee subdistricts have exceeded slightly the 94 percent occupancy level. The number of resident days for persons aged 65 and older has been declining steadily. The annual statewide nursing home occupancy levels are presented below:[26]

Year	Occupancy Level	Number of resident days per 1000 population aged 65+
2000	85.29 %	8849
2001	85.07 %	8679
2002	86.75 %	8639
2003	87.67 %	8655
2004	88.12 %	8445
2005	87.17 %	8346
2006	88.22 %	8094
2007	88.05 %	7942
2008	87.35 %	7756
2009	86.92 %	7618

The Agency projected the nursing home occupancy levels and need projections for January 2016 for purposes of the July 2012 planning horizon. Based on this calculation, the statewide occupancy level is projected at 86.55 percent. However, three subdistricts will exceed the desired standard of 94 percent occupancy based on the Agency's projection. This calculation projects additional nursing home beds will be needed in the following rural subdistricts: Okeechobee will need 16 additional nursing home beds (currently it has 180 licensed beds), Columbia/ Hamilton/ Suwannee will need 86 additional nursing home beds (currently it has 766 licensed beds), and Putnam will need 39 additional nursing home beds (currently it has 337 licensed beds).[27] Exceptions to the moratorium currently authorized in law will enable nursing homes which have not been poor performers that are located in these areas to incrementally expand to meet increased demand if it materializes as projected.

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[23] The request to add beds under the exception to the moratorium is subject to the procedures related to an exemption to the CON requirements.

[24] Source: Agency for Health Care Administration, as of On September 2, 2010. Data available at: <http://www.fdhc.state.fl.us/MCHQ/Long_Term_Care/FDAU/docs/SummaryAllActive.pdf>, (Last visited on September 21, 2010).

[25] Source: Agency for Health Care Administration report provided to professional staff of the Florida Senate Health Regulation Committee on July 28, 2010, a copy of which is available upon request from the Senate Health Regulation Committee.

[26] *Id.*

[27] *Id.*

Demographic Trends

The older population will burgeon between the years 2010 and 2030 when the "baby boom" generation[28] reaches age 65. On a national level, the population 65 and over will increase from 40 million in 2010 to 55 million in 2020. By 2030, there will be about 72.1 million older persons, almost twice their number in 2008. People 65 and over represented 12.8 percent of the population in the year 2008 but are expected to grow to be 19.3 percent of the population by 2030.[29] Most of the growth, especially over the next 10 to 15 years, will be among the young old (age 65-74) because of the aging of the baby boomers.[30] Within Florida, the population 65 and over will increase from 3.3 million in 2010 to 4.5 million in 2020, and to 6.2 million in 2030.[31] Nearly one in five U.S. residents will be aged 65 and older in 2030.

A better barometer for the potential demand for long-term care services is the growth in the 85 and over population (referred to as the "oldest-old"), not only because they have much higher rates of disability, but they also are much more likely to be widowed and without someone to provide assistance with daily activities.[32] Nationally, the population of the oldest old is projected to increase from 5.8 million in 2010, to 6.6 million in 2020, and to 8.7 million in 2030.[33] In Florida, the population of the oldest-old is projected to increase from 537,926 in 2010, to 739,069 in 2020, and to just over 1 million in 2030.[34] The baby boomers will begin to turn age 85 in 2031.[35]

Trends and Conditions In Long-Term Care

The term long-term care refers to a variety of services which includes medical and non-medical care for people who have a chronic illness or disability. Long-term care helps meet health or personal needs. Most long-term care is to assist people with support services such as activities of daily living like dressing, bathing, and using the bathroom. Long-term care can be provided at home, in the community, in assisted living facilities (ALFs) or in nursing homes.[36]

The majority of Americans age 50 and over (89 percent) want to stay in their homes for as long as they can.[37] The average age of residents in nursing homes in Florida in 2007 was 80.21 years of age.[38] Nursing facility residents, beds, and occupancy rates have remained nearly constant over the last 5 years, despite an increase in the older population.[39] The stabilization of the nursing home population in Florida can at least partially be attributed to expanding home and community-based services,[40] including services available in ALFs.[41]

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[28] The baby boomer generation consists of people born between 1946 and 1964.
[29] A Profile of Older Americans: 2009, U.S. Department of Health and Human Services, Administration on Aging, available at: <http://www.aoa.gov/AoARoot/Aging_Statistics/Profile/2009/docs/2009profile_508.pdf>, (Last visited on September 21, 2010). (page 5)
[30] AARP Across the States, Profiles of Long-Term Care and Independent Living, Eighth Edition, 2009 available at: <http://www.aarp.org/home-garden/livable-communities/info-03-2009/across_the_states_2009__profiles_of_long-term_care_and_independent_living.html>, (Last visited on September 21, 2010).
[31] The Office of Economic and Demographic Research, The Florida Legislature, available at: <http://edr.state.fl.us/population/Pop_Census_Day.pdf>, (Last visited on September 21, 2010).
[32] *Supra* note 30.
[33] *Supra* note 29, and THE NEXT FOUR DECADES The Older Population in the United States: 2010 to 2050, US Census Bureau, Issued May 2010, available at: <http://www.census.gov/prod/2010pubs/p25-1138.pdf>, (Last visited on September 21, 2010).
[34] *Supra* note 31.
[35] *Supra* note 30.
[36] Definition from Medicare.gov, found at:< http://www.medicare.gov/longtermcare/static/home.asp>, (Last visited on September 21, 2010).
[37] Providing More Long-term Support and Services at Home: Why It's Critical for Health Reform. AARP Public Policy Institute, June 2009, available at: http://www.aarp.org/health/health-care-reform/info-06-2009/fs_hcbs_hcr.html
[38] "Shaping Long Term Care in America Project at Brown University funded in part by the National Institute on Aging (1P01AG027296)." available at: < http://ltcfocus.org/StateTable.aspx>, (Last visited on September 21, 2010).
[39] *Supra* note 30.
[40] Home and community-based service programs for the elderly, funded in whole or part by public funds, include the Alzheimer's Disease Initiative, Alzheimer's Disease Waiver, Community Care for the Elderly, Contracted Services, Home Care for the Elderly, Local Services Program, Channeling, Consumer Directed Care Plus, Frail/Elderly Program, Medicaid

Florida, like most states, is now spending considerably more on home and community based long-term care services than 10 years ago. The Legislature has determined that the continued growth in the Medicaid budget for nursing home care constrained the ability of the state to meet the needs of its elderly residents through the use of less restrictive and less institutional methods of long-term care. Accordingly, the Legislature has limited the increase in Medicaid nursing home expenditures in order to provide funds to invest in long-term care that is community-based and provides supportive services in a manner that is both more cost-effective and more in keeping with the wishes of the elderly residents of this state.[42]

The Nursing Home Diversion Waiver Program is one of the primary alternate nursing home programs in Florida.[43] This program, as well as others, have helped increase the percentage of individuals who are eligible for Medicaid services to be diverted from nursing home placement. On average, Medicaid dollars can support nearly three older people and adults with physical disabilities in home and community-based settings for every person in a nursing facility.[44] All of Florida's home and community based waiver programs are relatively cost-effective alternatives to nursing home care for several thousand poor and frail elderly persons, especially those without caregivers. Even the most expensive program, the Nursing Home Diversion Waiver Program, is about $2,500 less expensive per person per month than Medicaid-funded nursing home care.[45]

The percentage of nursing home bed days in Florida paid for by Medicaid has also been declining on an annual basis. The following chart reflects total state spending and caseload for nursing home care paid for by Medicaid and the caseload and spending in the Nursing Home Diversion Waiver Program for 10 years:

State Fiscal Year	Medicaid Occupancy (Calendar Year)	Medicaid Nursing Home Caseload	Total Medicaid Expenditures	Nursing Home Diversion Caseload	Total Nursing Home Diversion Expenditures
2001-2002	64.43%	46,892	$1,837,866,321	857	$ 24,089,345
2002-2003	64.28%	47,704	$2,091,999,715	899	$ 25,228,532
2003-2004	63.48%	48,203	$2,238,956,267	1,871	$ 49,863,602
2004-2005	62.36%	47,465	$2,216,008,576	5,333	$131,404,123
2005-2006	61.14%	46,558	$2,296,156,032	6,252	$135,380,277
2006-2007	60.62%	45,856	$2,342,856,744	8,831	$188,774,446
2007-2008	60.69%	43,009	$2,350,109,632	11,083	$237,625,279
2008-2009	61.26%	42,535	$2,488,017,780	13,650	$266,191,975
2009-2010 based on February Social Services Estimating Conference	information not available	43,268	$2,760,065,260	18,114	$338,177,729
2010-2011 based on General Appropriations Act	information not available	44,077	$2,785,799,739	18,617	$347,885,072

Aged and Disabled Adult Waiver, Medicaid Assisted Living for the Elderly, Nursing Home Diversion Waiver Program, Program of All Inclusive Care for the Elderly, and Assistive Care Services. A description of each of these programs is available in the Florida Master Plan on Aging 2007-2009, prepared by The Florida Department of Elder Affairs, beginning on page 21, available at: <http://elderaffairs.state.fl.us/english/pubs/pubs/MasterPlan/FullCopy.pdf>, (Last visited on September 21, 2010). See also Profile of Florida's Medicaid Home and Community-Based Services Waivers, Report No. 10-10, issued January 2010 by the Office of Program Policy Analysis and Government Accountability for a description of the scope and availability of services under each of the Medicaid waiver programs, available at: <http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/1010rpt.pdf>, (Last visited on September 21, 2010).

[41] Florida Master Plan on Aging 2007-2009, prepared by The Florida Department of Elder Affairs, available at: <http://elderaffairs.state.fl.us/english/pubs/pubs/MasterPlan/FullCopy.pdf>, (Last visited on September 21, 2010) (page 4).

[42] s. 408.0435(2), F.S.

[43] The Nursing Home Diversion program is a managed care option under a 1915(c) waiver that is designed to provide community-based services to people who would qualify for Medicaid nursing home placement. The objective of the program is to provide elders community-based care to avoid nursing home placement at a cost less than Medicaid nursing home care.

[44] *Supra* note 30.

[45] Florida's State Profile Tool, July 2009, published by the Florida Department of Elder Affairs, available at: <http://elderaffairs.state.fl.us/english/pubs/pubs/Florida'sStateProfile.pdf>, (Last visited on September 21, 2010). (page 31)

The Department of Elder Affairs' (DOEA) Comprehensive Assessment and Review for Long-Term Care Services (CARES) Program is Florida's federally mandated pre-admission screening program for nursing home applicants. The purpose of the applicant assessment is to identify long-term care needs, establish level of care (medical and functional eligibility for nursing facility care and Medicaid waivers), and recommend the least restrictive, most appropriate placement. Emphasis is placed on enabling people to remain safely in their homes or return to the community after a nursing home stay, through provision of home based services or with alternative community placements such as ALFs.[46]

Nursing home transition is another program intended to reduce nursing home days by selecting nursing home residents from institutions who can be returned home with support. The nursing home transition effort formally began in Florida in March, 2009. As of July 10, 2010, 2,350 individuals have been considered for transition, 1,119 individuals have been transitioned from a nursing home, and 794 of them went into a Medicaid Waiver Program.[47]

The DOEA is also focusing efforts on four important issues facing Florida's seniors and retirees who are not enrolled in Medicaid programs: (1) transportation, (2) housing, (3) employment, and (4) volunteerism. This increased focus has resulted in part from many requests for assistance from elders who wish to maintain an independent lifestyle for as long as possible. These efforts also provide opportunities for elders who require long-term care to find appropriate home- and community-based care options that are less restrictive and less costly than skilled nursing care.[48] However, tens of thousands of individuals who do not qualify for Medicaid are on waiting lists or are assisted by programs exclusively funded by the state. As the population ages and service demand increases, Florida will be challenged to adequately meet this demand.[49]

Similarly, at the federal level, The Affordable Care Act[50] (the Act) addresses, among other things, long-term care. The Act expresses the sense of the Senate that Congress should address long-term services and supports in a comprehensive way that guarantees elderly and disabled individuals the care they need; and long term services and supports should be made available in the community in addition to institutions. The Act provides incentives for home-based care rather than the individual residing in a nursing home, including but not limited to: a new Community First Choice Option[51] for individuals who are otherwise eligible for Medicaid-institutional coverage; expansion of the spousal impoverishment provisions;[52] and the expansion and modification of home and community-based services. The Florida Medicaid program has submitted a letter of intent to the Centers for Medicare and Medicaid Services to apply for a Money Follows the Person grant offered under Section 2403 of the Act.[53]

In addition, the Act requires the Secretary of HHS to adopt regulations to, among other things, ensure that all states develop service systems that are designed to:

- Allocate resources for services in a manner that is responsive to the changing needs and choices of beneficiaries receiving non-institutionally-based long-term services and supports (including services and supports that are provided under programs other than Medicaid), and that provides strategies for

[46] *Id,* at 27.
[47] Source: DOEA email communication to Senate Health Regulation professional staff, dated August 5, 2010, a copy of which is available upon request from the Senate Health Regulation Committee.
[48] DOEA 2010 Summary of Programs and Services, published March 2010. Available at: <http://elderaffairs.state.fl.us/english/pubs/pubs/sops2010/First_page_2010SOPS.html>, (Last visited on September 21, 2010) (page 11).
[49] *Supra* note 45, at 5.
[50] The Patient Protection and Affordable Care Act (H.R. 3590, Public Law 111-148) as amended by the Health Care Education Reconciliation Act of 2010 (H.R. 4872, Public Law 111-152).
[51] Sec. 2401 of Subtitle E of The Affordable Care Act.
[52] Under the spousal impoverishment provisions, the spouse of a nursing facility resident may keep a minimum share of the couple's combined income and assets. The Act extends the current spousal impoverishment provisions to spouses of Medicaid beneficiaries receiving home and community based services.[52] This avoids the institutional bias for a spouse to reside in a nursing home. This provision begins on January 1, 2014, and ends December 31, 2019.
[53] Florida Administrative Weekly, Volume 36, Number 36, September 10, 2010, page 4409.

beneficiaries receiving such services to maximize their independence, including through the use of client-employed providers; and

- Provide the support and coordination needed for a beneficiary in need of such services (and their family caregivers or representative, if applicable) to design an individualized, self-directed, community-supported life.

Trends in supply and demand for elder services and care can be explained on the basis of population growth patterns and disability rates. Disability rates[54] are dependent on demographic factors, particularly age, health conditions and available medical and assistive technologies. Survey data indicates that the impairment rate of Florida's elder population is seven percent less than the national rate, contributing to a relatively low nursing home occupancy rate in comparison with other states. Additional evidence comes from the 2000 Census, which reports that, even though Floridians have overall slightly higher physical disability rates, their disabilities are less likely to be of the type concomitant with the need for supportive care. The Census also reports that the prevalence of severe disability (two or more disabilities, including a self-care disability) among elder Floridians is 17 percent lower than the national average.[55] More recently, the State of Aging and Health in America Report for 2007 published by the Centers for Disease Control and Prevention ranked Florida as the second best state in the country, tied with Connecticut, in terms of the lowest population of elders with a disability.[56] Lower disability rates reduce the number of people requiring nursing home care on two accounts. It reduces the number of disabled persons potentially requiring nursing home care and, at the same time, increases the supply of able caregivers who can provide care longer and at a higher intensity. Family caregivers are the main providers of long-term care services in all states.[57]

Migratory patterns also influence Florida's demand for nursing home care. The large majority of elders who relocate to Florida after retirement are "amenity seeking" retirees. They are characterized by good health and economic self-sufficiency, and most are married. These retirees are usually young elders in their sixties and generally do not place a high demand on nursing home beds. Florida has a net outflow of elders relocating due to increasing frailty, severely disabled migrants, who relocate seeking nearness to adult children, and readily available nursing home facilities. According to Census 2000 figures, Florida had a net migratory loss of persons age 85 and older.[58] Although more current data is not available for the oldest old age group in particular, similar migratory trends have been reported for retirees in the 2007 Florida Aging Population Report published by the Pepper Institute.[59] The Brookings Institute reported net migratory losses for Florida's general population when comparing migratory trends between 2006 – 2007 and 2007 – 2008, with almost a 50 percent reduction in Florida's net migration for the age 65 and older between 2004 – 2005 and 2007-2008.[60]

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[54] *Supra* note 41, at 141.
[55] *Supra* note 41, at 123.
[56] The State of Aging and Health in America report assesses the health status and health behaviors of U.S. adults aged 65 years and older and makes recommendations to improve the mental and physical health of all Americans in their later years. The report includes national- and state-based report cards that examine 15 key indicators of older adult health. The disability indicator measures the percentage of older adults who report having a disability based on an affirmative response to either of the following two questions: "Are you limited in any way in any activities because of physical, mental, or emotional problems?" or "Do you now have any health problem that requires you to use special equipment, such as a cane, a wheelchair, a special bed, or a special telephone?" The report is available at: <http://apps.nccd.cdc.gov/SAHA/Default/IndicatorDetails.aspx?IndId=DIS~N>, (Last visited on September 21, 2010).
[57] *Supra* note 30.
[58] The State of Aging in Florida – A Monograph and Needs Assessment, DOEA, available at: <http://elderaffairs.state.fl.us/english/pubs/stats/StateOfAging.pdf>, (Last visited on September 21, 2010).
[59] Florida's Aging Population, Critical Issues for Florida's Future 3rd Edition, 2007, published by the Florida State University Pepper Institute on Aging and Public Policy, available at: <www.pepperinstitute.org/Population/2007FloridaAgingPopulationReport.pdf>, (Last visited on October 4, 2010) (page 33).
[60] The Great American Migration Slowdown: Regional and Metropolitan Dimensions, published by the Metropolitan Policy Program at the Brookings Institute, December 2009, available at: <http://www.brookings.edu/~/media/files/rc/reports/2009/1209_migration_frey/1209_migration_frey.pdf>, (Last visited on October 4, 2010) (pages 7 and 8, and Appendix F).

Provider Survey Responses

In early-August 2010, an online survey was made available to nursing home administrators statewide to generate opinions on the continuation of the moratorium on the CON. The ten-question survey included three sections: Facility identification, Future Construction Plans, and General Questions on the Moratorium and CON. The survey closed on September 14, 2010. During this time, over 100 responses were received from facilities statewide.[61]

Survey respondents were asked to indicate the age of the facility they represent. Based on responses, the majority of facilities, approximately 30 percent, were between 21-30 years old, and have not undergone any major renovations. A respondent stated that "many facilities need to make changes, renovate or expand, but may not have the capital at this time; however, they may be able to acquire the capital within that time frame." Additionally, approximately 70 percent of the respondents indicated that building a new facility or an expansion to their current facility within the next 10 years is "not likely." Survey results indicated that if a facility were to expand or new facilities were to be built, the number of licensed beds would remain unchanged. According to survey results, if any changes were to occur to a facility, changes would more than likely occur as a culture change concept.[62] Another respondent stated, "It is critical that Florida not be building additional nursing homes unless it is capable of adequately funding its existing providers."[63]

Based on survey results, approximately 71 percent of respondents were in favor of extending the moratorium on issuing certificates of need for nursing homes for an additional five years. Many of the respondents expressed that allowing the moratorium to expire would cause occupancy issues for established nursing homes. Some facilities felt that there are an adequate number of beds to suit community needs, with many beds often remaining unfilled. A respondent stated, "Current census levels indicat[e] that the supply of beds available exceeds demand." Unfilled beds have become commonplace since "people are seeking more at-home care. Currently, [nursing homes] are never full and most residents are coming for rehab back to home." A respondent expressed, "With the shift on ALF placements and the NH transfer and Medicaid Diversion program SNF occupancy and competition has increased. Each year the ability to maintain 95 percent occupancy has declined." Some responses cited the economic downturn as a reason to extend the moratorium. One response explained, "With the economic situation in Florida, we are not seeing the snow birds like we used to as well as the decline in population coming into our State. In fact there still exists a dramatic decline due to hurricanes and cost of living." Consequently, "existing nursing homes already have a difficult time keeping census at level[s] that allow for meeting budgeted expectations."

In addition to occupancy, funding was also a major concern to those respondents in favor of extending the moratorium as reflected in the following comments:

- "Census figures show that adding additional beds along with reduced reimbursement would be a devastating combination to existing providers;"
- "Funding at the hospital level encourages discharges to home, reducing SNF admissions, and there is an increased number of ALFs which also reduces SNF admissions;" and
- "The expiration of the moratorium will not only cause problems for providers in figuring out how to continue to care for Medicaid residents in an increasingly competitive market, but will also sky rocket costs for the state as additional supply will encourage the use of this setting for aged Medicaid residents versus the exploration of less costly settings for care."

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[61] Survey conducted by professional Senate staff of the Health Regulation Committee. Responses are available from the Senate Health Regulation Committee.

[62] "Culture change" is the common name given to the national movement for the transformation of older adult services, based on person-directed values and practices where the voices of elders and those working with them are considered and respected. Core person-directed values are choice, dignity, respect, self-determination and purposeful living. Culture change transformation may require changes in organization practices, physical environments, relationships at all levels and workforce models – leading to better outcomes for consumers and direct care workers without inflicting detrimental costs on providers. See Pioneer Network, available at: <http://www.pioneernetwork.net/CultureChange/Whatis/>, (Last visited on September 21, 2010).

[63] *Supra* note 61.

CON Conditions

Section 408.040, F.S., authorizes the Agency to impose conditions on the issuance of a CON or an exemption. These conditions may be predicated upon statements of intent expressed by an applicant in the application for a CON or an exemption. Any conditions imposed on the CON or exemption that are based on the statements of intent must be stated on the face of the CON or exemption. Each nursing home participating in the Medicaid program provided a statement of intent that includes a specified percentage of the annual patient days at the facility that will be utilized by patients eligible for care under the Medicaid program. The Medicaid-patient-days condition is included on the CON or exemption for these nursing homes.

The holder of a CON or an exemption with conditions may be granted a modification of the conditions by the Agency based on a demonstration of good cause. Additionally, if a nursing home is located in a county in which a long-term care community diversion pilot project has been implemented or in a county with a managed care program for Medicaid recipients who are 60 years of age or older, the Agency must grant a nursing home's request to reduce its annual Medicaid-patient-days condition by not more than 15 percent. A nursing home may submit only one request every 2 years for the automatic reduction. The authority for the automatic reduction expires June 30, 2011.[64]

Since 2006 when this provision authorizing the automatic reduction went into effect,[65] the Agency has granted the automatic 15 percent reduction 230 times.[66] Some licensed nursing homes have been granted reductions on three separate occasions.

Conclusions

Demographic changes projected for Florida within the next 5 to 10 years are not expected to create a surge in the need for additional nursing home beds statewide. Contrary to common notions, nursing home residents do not necessarily follow a downhill, or even static, trajectory in their overall condition. Many stabilize, improve, or adapt. Even if their condition declines, their circumstances and desires may change; for example, family members may come forward as caregivers for them, or they may choose to spend their last days at home, or in hospice care. The state is expanding programs and devoting resources to enable the frail elderly to realize their preference to remain in community settings for as long as possible. This effort is critical to avoiding increased demand for nursing home beds. The challenge for policy makers is to maintain funding and flexibility so that nursing homes are not the default option for older adults and people with disabilities.[67]

Options and/or Recommendations

Options

The 2011 Legislature is confronted with the decision whether to extend the moratorium on the CON for community nursing home beds or allow the moratorium to expire on June 30, 2011.

If the moratorium expires on June 30, 2011, the CON application process for the addition of community nursing home beds would be reactivated. This will increase the regulatory responsibility of the Agency as well as potentially increase the caseload at the Division of Administration Hearings and the court system if challenges to the Agency's decisions regarding CON applications ensue. The Agency has indicated that typically applications for CONs work by precedent. If the moratorium expires and approvals for new community nursing home beds begin to occur, it is likely that more and more new beds might be approved. The industry has expressed concern that his would undermine the solvency of nursing homes in Florida.

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[64] s. 408.040(1)(d), F.S.
[65] Ch. 2006-161, L.O.F.
[66] Source: Agency for Health Care Administration email to Senate Health Regulation professional staff dated August 19, 2010, a copy of which is available from the Senate Health Regulation Committee.
[67] Diversion, Transition Programs Target Nursing Homes' Status Quo, by Susan C. Reihnard, Health Affairs 29, no. 1 (2010): 44-48, doi: 10.1377/hlthaff.2009.0877.

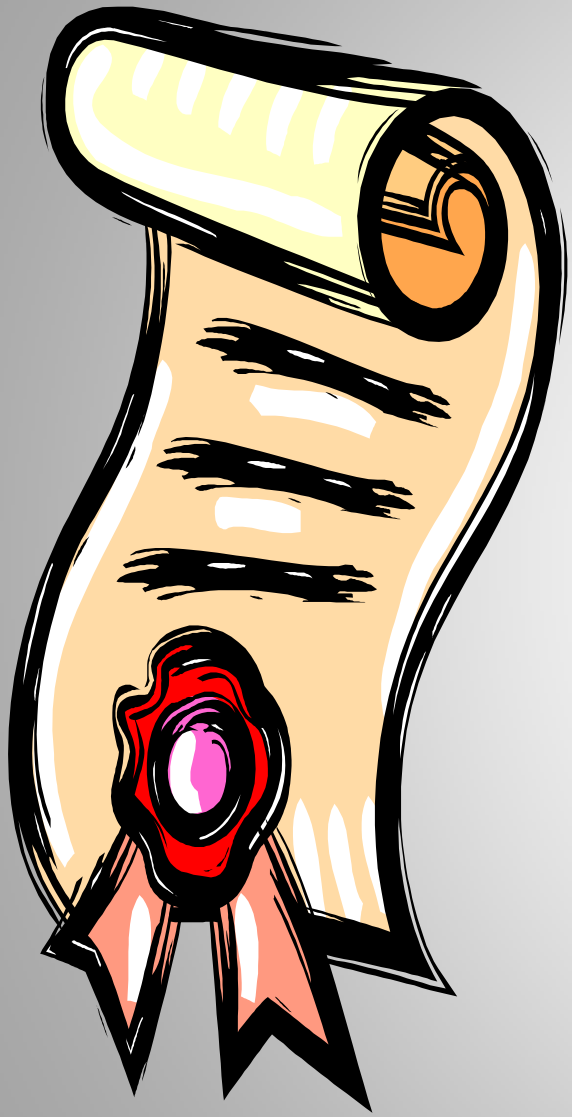
Data suggests that there is currently, and projected to be, an adequate supply of community nursing home beds in the state for the next several years. Authorization exists for the addition of beds if the need arises while the moratorium is in place. In addition, future Legislatures may readdress the moratorium if conditions significantly change that would warrant an earlier expiration of the moratorium should the 2011 Legislature choose to extend the moratorium.

Recommendations

Based on the public's preference for home and community-based residency options, current and projected nursing home occupancy levels through 2016, the economic climate, and the ongoing emphasis that the Legislature has placed on facilitating the ability of Floridians to reside in less restrictive settings than nursing homes, Senate professional staff recommend that the Legislature reenact and continue the moratorium on the CON for community nursing homes beds through the year 2016.

Senate professional staff also recommend that the exceptions and exemptions that the Legislature has enacted to implement the moratorium and address potential surges in occupancy levels be retained. Language regarding the exception to the moratorium in a county having up to 50,000 residents should be clarified to reflect that a facility requesting additional beds must certify that it has not had any class I or class II deficiencies within 30 months or since it was initially licensed if licensed within 25 – 29 months preceding the request for additional beds.

Furthermore, Senate professional staff recommend that the Legislature reenact the automatic 15 percent reduction of the annual Medicaid-patient-days condition for nursing homes located in a county in which a long-term care community diversion pilot project has been implemented or in a county with a managed care program for Medicaid recipients who are age 60 years or older. The recommendation for continuing the automatic reduction is based on the ongoing emphasis to reduce nursing home care in favor or community-based care through diversion and transition programs. Although not directly related to the moratorium on CONs for nursing homes, we recommend that the automatic reduction expire on a date that coincides with the date for continuation of the moratorium. The expiration date will allow a reassessment of the long-term care environment and help ensure that reduction requests do not eliminate the availability of Medicaid nursing home beds below future needs.



REVIEW OF THE MORATORIUM ON NURSING HOME CERTIFICATES OF NEED

Interim Report 2011-125
Senate Health Regulation Committee

BACKGROUND

- A Certificate of Need (CON) is a:

  written statement issued by the Agency for Health Care Administration (AHCA) evidencing a community need for a new, converted, expanded, or otherwise significantly modified health care facility, health service, or hospice. (s. 408.032(3), F.S.)

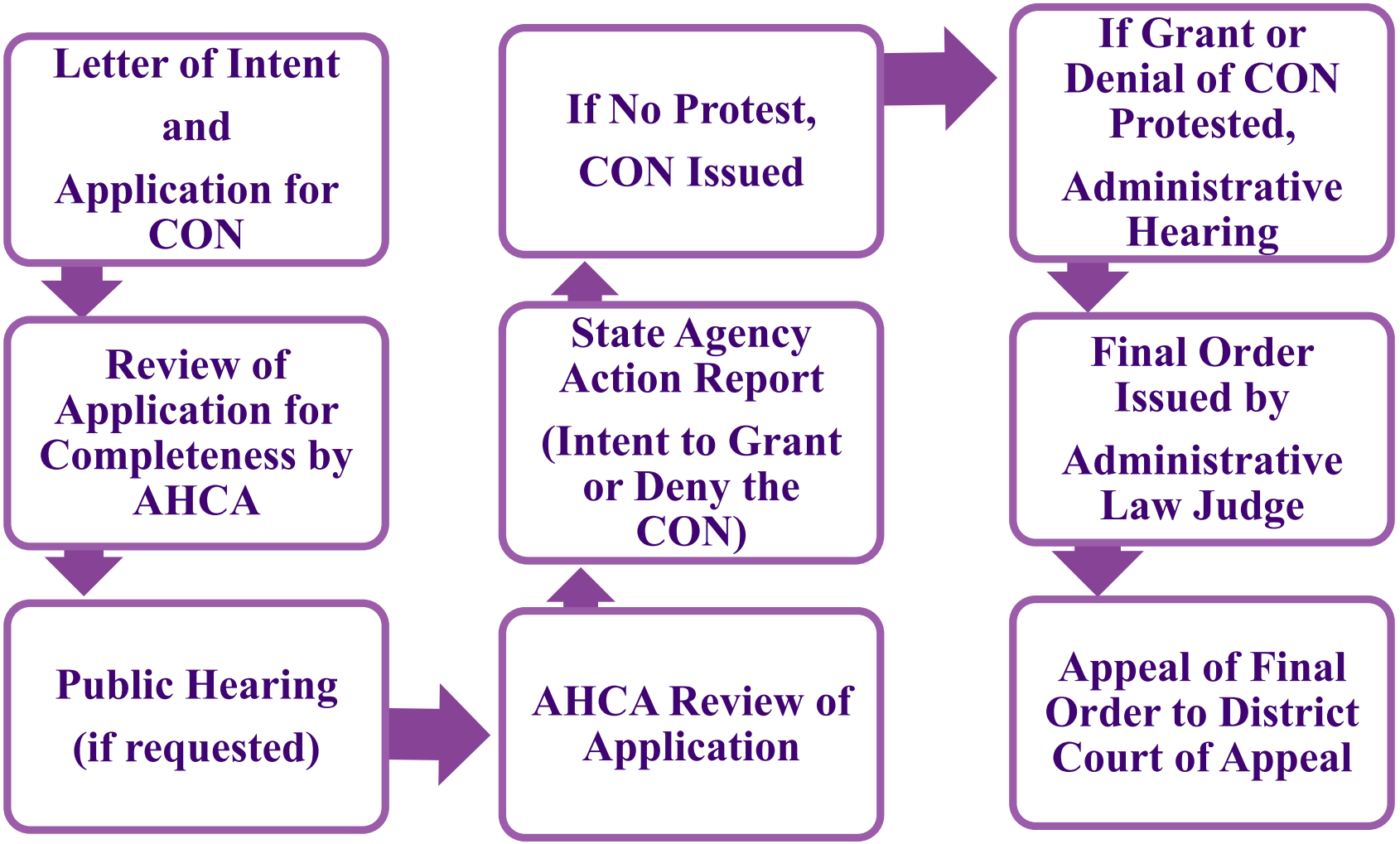
CON REVIEW

THREE LEVELS OF REVIEW BY AHCA

- Full Comparative Review
  - Adding beds in community nursing homes
  - Constructing new health care facilities, including skilled nursing facilities
- Expedited Review
  - Replacing a nursing home within the same district
  - Relocating a portion of a nursing home's licensed beds to a facility within the same district
- Exemptions from CON Review
  - State veteran's nursing homes operated by or on behalf of the Florida Dept. of Veteran's Affairs
  - Replacing a licensed nursing home on the same site, or within 3 miles, if the number of licensed beds does not increase*

*This is not an exhaustive list of exemptions from CON review

CON APPLICATION PROCESS



MORATORIUM ON NURSING HOME CONs

- 2001, Legislature enacted the moratorium on nursing home CONs
- 2006, the moratorium was extended until July 1, 2011
  - exceptions were added to the moratorium to address occupancy needs that might arise

FINDINGS

OCCUPANCY LEVELS

- There are 674 licensed nursing homes and 82,562 licensed nursing home beds in Florida.
- Over the last 10 years, the average nursing home occupancy level in Florida has remained below 90% and has been declining steadily.
- AHCA has projected the January 2016 statewide occupancy level to be 86.55%.
  - Three subdistricts will exceed the desired standard of 94% occupancy.
  - Exceptions to the moratorium in current law will enable nursing homes located in these subdistricts to incrementally expand to meet increased demand

FINDINGS

DEMOGRAPHIC TRENDS

- Older population will burgeon between the years of 2010 and 2030. Nationally, the population of 65 and older will increase from 40 million (2010) to 55 million (2020). By 2030, there will be approximately 72.1 million older persons.
- In Florida, the population of those 65 and older will increase from 3.3 million (2010), to 4.5 million (2020), to 6.2 million in 2030.
- For long-term care purposes, focus on 85 and older. Nationally, they are projected to increase from 5.8 million (2010), to 6.6 million (2020), to 8.7 million in 2030.
- In Florida, the population of 85 and older is projected to increase from 537,926 (2010), to 739,069 (2020), to just over 1 million in 2030.

FINDINGS

LONG-TERM CARE TRENDS

- The majority of Americans age 50 and over (89%) want to stay in their homes for as long as they can.
- Home and community-based services have expanded to meet this preference, which has helped stabilize the nursing home population in Florida.
- Legislature has limited Medicaid nursing home expenditures to invest the funds in community-based long-term care because it is cost-effective and in-keeping with the preference of the elderly.
  - Nursing Home Diversion Waiver Program- On average, Medicaid dollars can support nearly 3 older people in home and community-based settings for every1 person in a nursing facility.
- The federal Affordable Care Act provides incentives for home-based care rather than the individual residing in a nursing home.

FINDINGS

FLORIDA'S ELDERLY

- The impairment rate of Florida's elder population is 7% less than the national rate.
- The Census reports that the prevalence of severe disability among elder Floridians is 17% lower than the national average.
- Retirees that relocate to Florida typically do so in their sixties. However, there is net migratory loss of those 85 and older who relocate out of state to be with adult children or move to readily available nursing homes.

FINDINGS
(SURVEY)

- 100 respondents (nursing home administrators)
- Majority of facilities were between 21-30 years old.
- Approximately 70% indicated that building a new facility or expansion of their facility is “not likely.”
- Approximately 71% were in favor of extending the moratorium for another 5 years.
  - Expiration of moratorium could adversely affect the industry
  - Surplus of beds because of more at-home care, shift in Medicaid funding, and economic downturn means less migration into Florida by the elderly

FINDINGS

CONDITIONS OF A CON

- AHCA may impose conditions on the issuance of a CON or an exemption.
- The Medicaid-patient-days condition:
  - Each nursing home participating in Medicaid must provide in its letter of intent for a CON the percentage of annual patient days that will be utilized by patients eligible for care under Medicaid.
- Nursing homes located in a county with a long-term care community diversion pilot project or managed care program for Medicaid recipients aged 60 or older must be granted a reduction of its Medicaid-patient-days condition by not more than 15% by AHCA.
  - The automatic reduction of this condition expires June 30, 2011.

CONCLUSION

- Surplus of beds
- Trend and preference is elderly receiving more at-home or community-based care
- Established facilities not likely to expand
- Expiration of the moratorium could adversely affect the established nursing home industry
- Florida has a lower population of disabled elderly and the very elderly migrate out of state
- If the moratorium expires, the regulatory responsibility for AHCA and caseload of the Division of Administrative Hearings will increase

And therefore…

CONCLUSION

STAFF RECOMMENDS…

- The Legislature reenact and continue the moratorium on the CON for community nursing home beds through 2016
- The Legislature retain the exceptions and exemptions enacted in 2006 to address potential surges in occupancy levels, with some minor clarifications
- The Legislature reenact the automatic 15 percent reduction of the annual Medicaid-patient-days condition, but with an expiration date concurrent with expiration of the CON moratorium

Questions?

Signed:_____
Title of signer

Signed:_____
Title of signer

Prescription Drug Monitoring Program (PDMP) & Pain Management Clinic (PMC) Implementation Update

Senate Health Regulation Committee
January 11, 2011

Rebecca R. Poston, BPharm
Program Manager, Florida Prescription Drug Monitoring Program

Larry McPherson
Executive Director, Florida Board of Medicine

FLORIDA DEPARTMENT OF HEALTH

Division of Medical Quality Assurance
MQA

PDMP Legislative History

SB 462- 2009

- Created the PDMP within DOH
- Requires DOH to design and establish database
- Outlines reporting requirements and exemptions

SB 2272- 2010

- Defines "program manager" and requires the program manager to work with stakeholders to develop rules
- Authorizes program manager to provide relevant information to law enforcement

PDMP Rulemaking History

- Notice of Proposed Rule Development filed March 31, 2010
- Hearing held November 9, 2010
- Workshop held December 3, 2010
- HB 1565 requiring new SERC
- All rulemaking suspended by Executive Order 11-01

PDMP Procurement Update

- Request for Proposal (RFP) advertised June 30, 2010
  - Rejected all bids following bid protest
- New RFP advertised October 18, 2010
  - Specifications Protest filed
  - Bid Award December 22, 2010
  - Bid Protest January 3, 2011

PDMP Funding Update

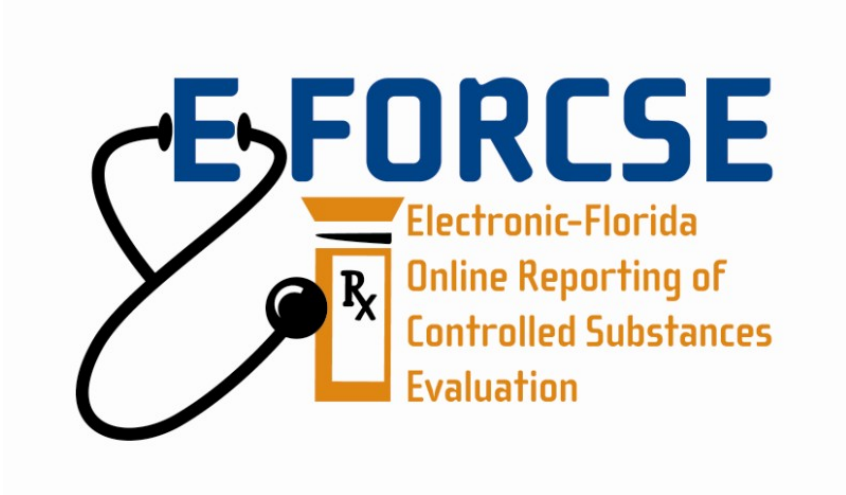
Funding

- Funding received from the following sources:
  - Direct Support Organization $240,660
  - Bureau of Justice Assistance, Hal Rogers Implementation Grant $400,000
  - Bureau of Justice Assistance, Hal Rogers Enhancement Grant $400,000
  - National Association of State Controlled Substances Authorities $26,271
- 2011 National Association of State Controlled Substances Authorities grant application pending.

PDMP Implementation & Next Steps

Other

- Branding: E-FORCSE
- Marketing Plan
- Website launch
- Critical staffing



Next Steps

- Vendor selection
- Approval by Office of Fiscal Accountability & Regulatory Reform to continue rulemaking
- Approval of SERC for PDMP rules
- Potential ratification by Legislature

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Florida's Prescription Drug Monitoring Program

E-FORCSE

ELECTRONIC - FLORIDA ONLINE REPORTING OF CONTROLLED SUBSTANCES EVALUATION PROGRAM

Welcome to E-FORCSE! The State of Florida's Prescription Drug Monitoring Program

The Electronic - Florida Online Reporting of Controlled Substances Evaluation program (E-FORCSE) is Florida's Prescription Drug Monitoring Program (PDMP). The PDMP was created by the

DID YOU KNOW?

- Contact the DSO
- PDMP Statute
- Help for addiction

PMC Legislative History

SB 462- 2009

- Created Registration/Inspection Program with DOH
- Standards of Practice rulemaking with Physician Boards
- Currently 932 PMC registered

SB 2272- 2010

- Expanded PMC Requirements/Limitations:
  - Ownership/operation
  - Prescribing/dispensing
  - Authority to inspect for compliance with statutory provisions as well as compliance with standards of practice rules

PMC Rulemaking History

2009 DOH adopted PMC Registration and Fees for PMC

- Registration data on-line, updated daily

Physician Boards Created Joint Committee to Develop Standards of Practice Rules

- 8 public meetings from August 2009-October 2010
- Testimony from stakeholders including patients, surviving family, law enforcement, medical associations and practitioners
- 4 public rule hearings held by the Physician Boards

Standards of Practice Rules Adopted in November 2010

- Board of Osteopathic Medicine Rule in force November 2010
- Board of Medicine Rule pending approval

Pending PMC Rules

Rules being considered in pending SERC

- BOM Standards of Practice required by SB 462 & SB 2272
- BOM training requirements required by SB 462 & SB 2272
- BOM PMC Registration required by SB 462 & SB 2272
- BOM, BOOM accreditation organization standards in lieu of annual inspection required by SB 462 & SB 2272
- BOM, BOOM rule on maximum number of controlled substance scripts at a pain management clinic during a 24 hour period required by SB 2272
- DOH rule on defining designated physician limitations required by SB 2272
- DOH rule on counterfeit-resistant scripts required by SB 2272

PMC Implementation

- DOH denied registration to 213 PMC applicants
- DOH issued 16 Notices of Intent to Revoke PMC Registrations
- Phase I DOH Inspections of 81 PMC
- BOM disciplined of 15 physicians for violations at PMC in 2010
- Emergency Suspension/Restriction Orders issued to 14 PMC and 19 licensees practicing at a Desist issued in 2010
- Florida licensed MD and DO Florida contacted regarding their interest in helping in Phase II of PMC inspections
- SERC on PMC proposed rules being conducted

PMC Next Steps

- Completion of SERC and rulemaking process for BOM, BOOM and DOH rules
- DOH begins Phase II inspections of PMC
- Continued communication with pain clinic practitioners and the public
- Continued operations with law enforcement partners in criminal investigations

Thank You

Questions?

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