Health Care Appropriations Subcommittee

Meeting Packet

March 24, 2014
3:00 PM—6:00 PM

Webster Hall

Will Weatherford
Speaker

Matt Hudson
Chair

AGENDA

Health Care Appropriations Subcommittee
March 24, 2014
3:00 PM—6:00 PM
Webster Hall

I. Call to Order

II. Roll Call

III. HB 7077—Sterile Compounding by Patronis

IV. HB 531—Public Health Trusts by Richardson

V. CS/HB 751—Telehealth by Cummings

VI. HB 7109—Graduate Medical Education by Hudson

VII. HB 7111—Recovery Care Services by Steube

VIII. HB 7113—Health Care by Brodeur

IX. Adjournment

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 7077 PCB HQS 14-01 PCB HQS 14-01 Sterile Compounding
SPONSOR(S): Health Quality Subcommittee; Patronis
TIED BILLS: **IDEN./SIM. BILLS:** SB 662

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health Quality Subcommittee	13 Y, 0 N	Poche	O'Callaghan
1) Health Care Appropriations Subcommittee		Rodriguez	Pridgeon
2) Health & Human Services Committee			

SUMMARY ANALYSIS

This bill requires any nonresident pharmacy registered with the state and any outsourcing facility, as defined in federal law, to obtain a nonresident sterile compounding permit in order to ship, mail, deliver, or dispense a compounded sterile product in this state.

This bill outlines the requirements for the application and the standards that applicants, and permittees, must meet in order to ship or otherwise introduce compounded sterile products into Florida.

The bill grants authority to the Department of Health and the Board of Pharmacy to enforce the laws and rules governing sterile compounding, including the authority to conduct onsite inspections of out-of-state applicants and permittees and the authority to administratively discipline applicants and permittees for failing to comply with Florida law.

This bill has an indeterminate fiscal impact on state government. However, additional revenues generated from initial permit fees, biennial renewal fees, fines and penalties along with the utilization of existing department resources will offset any fiscal impact related to state government expenditures. The bill also requires costs associated with the inspection of nonresident pharmacies and nonresident sterile compounding permittees to be borne by such pharmacy or permittee.

The bill provides an effective date of October 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Pharmacy Regulation

Chapter 465, F.S., regulates the practice of pharmacy in Florida and contains the minimum requirements for safe practice.[1] The Board of Pharmacy (Board) is tasked with adopting rules to implement the provisions of the chapter and with setting standards of practice within the state.[2] In order to be a licensed pharmacist in the state, a person must meet certain educational and other requirements and pass an examination.[3] A licensed pharmacist must renew her or his license every two years by paying a fee set by statute and meeting continuing professional pharmaceutical education requirements.[4]

Any person who wants to operate a pharmacy in Florida must have a permit. The following permits are issued by the Department of Health (DOH):

- Community pharmacy - A permit is required for each location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.[5]
- Institutional pharmacy - A permit is required for every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.[6]
- Nuclear pharmacy - A permit is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.[7]
- Special pharmacy - A permit is required for every location where medicinal drugs are compounded, dispensed, stored, or sold if the location does not otherwise meet an applicable pharmacy definition in s. 465.003, F.S.[8]
- Internet pharmacy - A permit is required for a location not otherwise licensed or issued a permit under this chapter, within or outside this state, which uses the Internet to communicate with or obtain information from consumers in this state to fill or refill prescriptions or to dispense, distribute, or otherwise practice pharmacy in this state.[9]

A pharmacy located outside of the state and ships, mails, or delivers, in any manner, a dispensed medical drug into the state must be registered as a nonresident pharmacy with the Board.[10] Registration requires application to the Board and payment of an initial registration fee.[11] Renewal of the registration is required every two years with payment of a fee.[12] Further, a registered nonresident

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[1] S. 465.002, F.S.
[2] SS. 465.005, F.S., 465.0155, F.S., and 465.022, F.S.
[3] S. 465.007, F.S.
[4] SS. 465.008, F.S., and 465.009, F.S.
[5] SS. 465.003(11)(a)1. and 465.018, F.S.
[6] SS. 465.003(11)(a)2. and 465.019, F.S.
[7] SS. 465.003(11)(a)3. and 465.0193, F.S.
[8] SS. 465.003(11)(a)4. and 465.0196, F.S.
[9] SS. 465.003(11)(a)5. and 465.0197, F.S.
[10] S. 465.0156, F.S.
[11] S. 465.0156(2) and (3), F.S.
[12] Id.

pharmacy is required to provide services at a high level of competence and patient protection.[13] Lastly, a nonresident pharmacy must submit to the Board the following information:

- That it maintains at all times a valid, unexpired license, permit, or registration to operate the pharmacy in compliance with the laws of the state where it is located;[14]
- The location, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager for dispensing medicinal drugs to residents of this state;[15]
- That it complies with all lawful directions and requests for information from the regulatory or licensing agency of all states in which it is licensed as well as with all requests for information made by the Board;[16]
- That it maintains its records of medicinal drugs dispensed to patients in this state so that the records are readily retrievable;[17] and
- That during its regular hours of operation but not less than 6 days per week, for a minimum of 40 hours per week, a toll-free telephone service is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records.[18]

The Board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy for failure to comply with s. 465.025, F.S., regarding the substitution of drugs, or with any requirement of the section.[19] In addition, the Board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy for conduct which causes serious bodily injury or serious psychological injury to a resident of this state.[20] The Board must refer conduct that caused an injury to the regulatory or licensing agency in the state where the pharmacy is located.[21] If the regulatory or licensing agency fails to investigate within 180 days of the referral, the Board may take appropriate action.[22]

Compounding

In general, compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.[23] Compounding has been an integral part of the practice of pharmacy in the United States since the early 20th century.[24] Commonly compounded products include lotions, ointments, suppositories, and intravenous medications.

There are two types of compounding: sterile and non-sterile. Sterile compounding is the preparation of a custom medication or product in a sterile environment to prevent contamination and protect patient safety. Sterile compounded products are used to treat a variety of diseases and conditions and are categorized as low, medium, or high risk depending upon the preparation and administration of the product. Products intended to be injected, infused, or applied to the eye must be compounded in a

[13] S. 465.0156(1), F.S.
[14] S. 465.0156(2)(a), F.S.
[15] S. 465.0156(2)(b), F.S.
[16] S. 465.0156(2)(c), F.S.
[17] S. 465.0156(2)(d), F.S.
[18] S. 465.0156(2)(e), F.S.
[19] S. 465.0156(4), F.S.
[20] S. 465.0156(5), F.S.
[21] Id.
[22] Id.
[23] U.S. Dept. of Health and Human Services, U.S. Food and Drug Administration, Compounding and the FDA: Questions and Answers, available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm (last viewed on February 9, 2014).
[24] Allen, Loyd V., The Art, Science, and Technology of Pharmaceutical Compounding, 4th Ed., Chapter 1, pages 3-4 (Washington, D.C.: American Pharmacists Association; 2012).

sterile environment to provide special safeguards to prevent injury or death to the people receiving those products.

Non-sterile compounding is similarly categorized depending upon the difficulty of compounding and the danger posed by the individual ingredients combined, mixed, or altered in a non-sterile environment. Simple non-sterile compounding involves mixing medications according to established formulas and creating liquid versions of drugs normally sold in tablet or capsule form. Moderate non-sterile compounding involves making preparations with harmful medications that require special handling. Complex non-sterile compounding requires advanced training and special equipment to make products such as extended-release capsules and transdermal patches.

According to the Board, there are 301 registered nonresident pharmacies engaged in sterile compounding that ship, mail, deliver, or dispense sterile compounded products into the state.[25]

Special Sterile Compounding Permit

Effective September 23, 2013, most pharmacies that engage or intend to engage in the preparation of sterile compounded products in Florida must obtain a Special Sterile Compounding Permit (SSCP).[26] Pharmacies required to obtain this permit must compound sterile products in strict compliance with standards set forth in Rule 64B16-27.797, F.A.C., which contains specific standards for compounding sterile preparations, and Rule 64B16-27.700, F.A.C., which contains standards that must be met for office use compounding.[27] The following entities are not required to obtain the SSCP:

- Stand-alone special parenteral/enteral pharmacies;
- Special parenteral/enteral extended scope pharmacies;
- Pharmacies that only perform non-sterile compounding; and
- Non-resident pharmacies.[28]

A pharmacy that is compounding sterile products under its current pharmacy permit may continue to do so, but must obtain the SSCP on or before March 21, 2014 in order to continue sterile compounding. There is no fee required for existing licensees.[29] New establishments are required to submit $255 with the application for the SSCP, in addition to the $255 fee for the primary pharmacy permit.[30]

Drug Quality and Security Act

On November 27, 2013, President Barack Obama signed the Drug Quality and Security Act (DQSA), which contains provisions relating to the oversight of compounding. Title I of the DQSA, titled the "Compounding Quality Act," describes the conditions[31] under which certain compounded human drug products are entitled to exemptions from three sections of the Food, Drug, and Cosmetic Act (FDCA) requiring:

- Compliance with current good manufacturing practices (cGMP);[32]
- Labeling with adequate directions for use;[33] and

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[25] Florida Dept. of Health, Division of Medical Quality Assurance, Florida Board of Pharmacy Compounding Survey Report, January 23, 2013, page 15 (on file with Health Quality Subcommittee staff).
[26] Rule 64B16-28.100(8), F.A.C.
[27] Rule 64B16-28.802, F.A.C.; "Office use compounding" is the provision and administration of a compounded drug to a patient by a health care practitioner in her or his office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy.
[28] Florida Board of Pharmacy, Special Sterile Compounding Permit, available at www.floridaspharmacy.gov/latest-news/special-sterile-compounding-permit/ (last viewed on February 9, 2014).
[29] Florida Board of Pharmacy, Sterile Compounding Permit, available at www.floridaspharmacy.gov/licensing/sterile-compounding-permit/ (last viewed on February 9, 2014).
[30] Id.
[31] FDCA, s. 503(A)
[32] FDCA, s. 501(a)(2)(B)
[33] FDCA, s. 502(f)(1)

- Food and Drug Administration (FDA) approval prior to marketing of the drug.[34]

In addition, the new law permits a pharmacy or non-pharmacy engaged in compounding to voluntarily register as an "outsourcing facility."[35] An outsourcing facility will be able to qualify for exemptions from the FDA approval requirements and the requirement to label products with adequate directions for use, but not the exemption from cGMP requirements. Outsourcing facilities:

- Must comply with cGMP requirements;
- Will be inspected by FDA according to a risk-based schedule; and
- Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

The FDA anticipates that state boards of pharmacy will continue their oversight and regulation of the practice of pharmacy, including traditional pharmacy compounding. The FDA has indicated its intention to continue to cooperate with state authorities to address pharmacy compounding activities that may violate the FDCA.

According to the FDA, there are currently 24 registered outsourcing facilities in the U.S., one of which is located in Florida.[36]

New England Compounding Center

On September 18, 2012, the Tennessee Department of Health (TDOH) was alerted by a clinician regarding a patient with culture-confirmed fungal meningitis diagnosed 46 days after an epidural steroid injection at a Tennessee ambulatory surgical center.[37] By September 27, 2012, the initial investigation, carried out by the TDOH in collaboration with the Centers for Disease Control and Prevention (CDC) and the North Carolina Department of Health and Human Services, had identified an additional eight patients with clinically diagnosed meningitis: seven in Tennessee and one in North Carolina. All nine patients had received an epidural steroid injection with preservative-free methylprednisolone acetate solution (MPA), compounded at New England Compounding Center (NECC) in Framingham, Massachusetts. Subsequent testing revealed fungal contamination of the MPA vials. After an in-depth investigation of NECC, it was determined that the MPA vials, and other products made by NECC, were compounded in violation of the laws and rules of Massachusetts governing sterile compounding. The investigation found that NECC's sterile compounding processes were not sterile and violated many provisions of the U.S. Pharmacopeia Chapter 797[38].

The infections identified as part of this investigation include fungal meningitis, spinal or paraspinal infections, and infections associated with injections in a knee, shoulder, or ankle. The majority of infections reported to the CDC were in patients with localized spinal or paraspinal infections.

The following map illustrates the number of cases of fungal meningitis and other infections in each state resulting from the contaminated MPA from NECC:[39]

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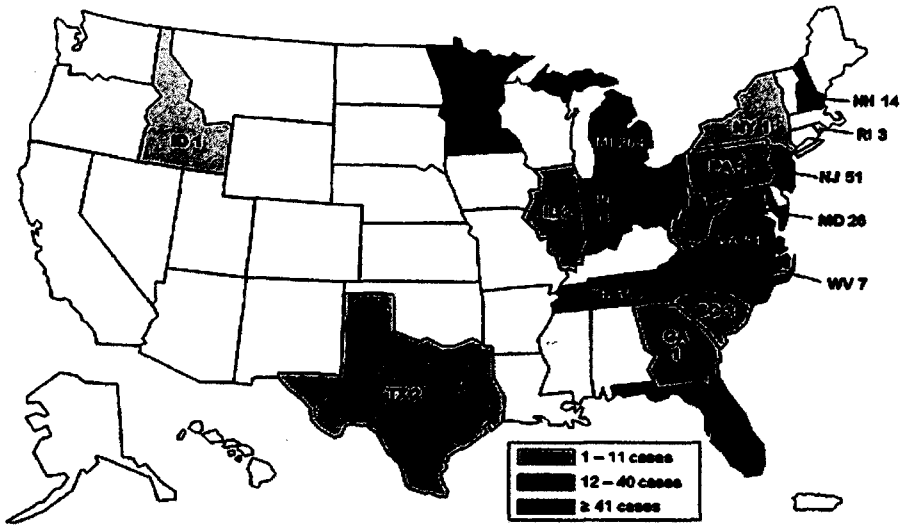
[34] FDCA, s. 505
[35] FDCA, s. 503(B)
[36] U.S. Dept. of Health and Human Services, U.S. Food and Drug Administration, Registered Outsourcing Facilities (updated as of Jan. 31, 2014), available at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm (last viewed on February 9, 2014). The Florida-based registered outsourcing facility is KRS Global Biotechnology, Inc. in Boca Raton.
[37] Kainer, M, and Wiese, A., Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report-Multistate Outbreak of Fungal Infection Associated with Injection of Methylprednisolone Acetate Solution from a Single Compounding Pharmacy -United States, 2012, 61(41);839-842, October 19, 2012, available at www.dcd.gov/mmwr/preview/mmwrhtml/mm614a4.htm?s_cid=mm614a4_w (last viewed on February 9, 2014).
[38] See infra, *U.S. Pharmacopeia and USP 797*, page 6.
[39] Centers for Disease Control and Prevention, Multistate Outbreak of Fungal Meningitis & Other Infections-Case Count, October 23, 2013, available at www.cdc.gov/hai/outbreaks/meningitis-map-large.html (last viewed on February 9, 2014)(according to the CDC, no further case count updates were expected following the Oct. 23, 2013 update).



In total, 751 people in 20 states were sickened by the contaminated MPA injections, including 25 Floridians.[40] Of the 751 people infected, 64 people died and 7 of those deaths were in Florida.

U.S. Pharmacopeia and USP 797

The U.S. Pharmacopeia (USP) is a non-profit agency that develops and publishes standards for drug substances, drug products, excipients, and dietary supplements in the U.S. Pharmacopeia–National Formulary (USP–NF). USP–NF standards play a role in the adulteration and misbranding provisions of the FDCA. USP has no role in enforcement of these or other provisions that recognize USP–NF standards, which is the responsibility of the FDA.

USP 797 refers to chapter 797, "Pharmaceutical Compounding – Sterile Preparations," in the USP-NF. It is the first set of enforceable sterile compounding standards issued by the USP. USP 797 describes the guidelines, procedures and compliance requirements for compounding sterile preparations and sets the standards that apply to all settings in which sterile preparations are compounded. Standards in USP–NF for compounded preparations may be enforced by both the states and the FDA.

The Florida Board of Pharmacy requires compliance with USP 797. At least 24 other states have practice rules which incorporate all, most, or some of the USP 797 standards.[41] Three states consider the USP 797 to be a standard of practice: Hawaii, Oklahoma, and South Carolina.[42]

Effect of Proposed Changes

To ensure the safety and quality of sterile products compounded outside of the state and dispensed to Floridians, the bill requires any nonresident pharmacy registered with the state and any non-pharmacy outsourcing facility to obtain a nonresident sterile compounding permit in order to ship, mail, deliver, or dispense a compounded sterile product in this state. To obtain the permit, a registered nonresident pharmacy or an outsourcing facility must submit an application and fee to DOH. The application must include the following information:

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[40] Centers for Disease Control and Prevention, Cases and Deaths with Fungal Infections Linked to Steroid Injections, available at www.cdc.gov/hai/outbreaks/meningitis-map-large.html#casecount_table (last viewed on February 9, 2014).

[41] These states are Arkansas, Colorado, Delaware, Georgia, Indiana, Iowa, Kentucky, Louisiana, Maryland, Minnesota, Missouri, Nevada, New Jersey, New Mexico, Ohio, Oregon, Rhode Island, South Dakota, Texas, Utah, Virginia, West Virginia, Wisconsin, and Wyoming. Jessen, L., Compounding: What is Manufacturing? What is Compounding?, National Association of Boards of Pharmacy 2012 Triathlon, Interactive Executive Officer Forum, PowerPoint presentation, November 13-14, 2012, slide 9 (on file with Health Quality Subcommittee staff).

[42] Id.

- Proof of registration as an outsourcing facility, if eligible pursuant to the DQSA;
- Proof of registration as a nonresident pharmacy under s. 465.0156, F.S., or, if the applicant is not a pharmacy, proof of a valid, unexpired, and unencumbered license, registration, or permit issued by the state, territory, or district where the applicant is located, which is required to compound sterile products in that jurisdiction;
- Attestation by an owner or officer and the prescription department manager or the pharmacist in charge that:
    - They have read and understand Florida law and rules governing sterile compounding;
    - Any sterile compounded product shipped or otherwise introduced into this state will meet or exceed Florida law and rules governing sterile compounding; and
    - Any sterile compounded product shipped or otherwise introduced has not been, and will not be, compounded in violation of laws and rules governing sterile compounding where the applicant is located.
- Copies of existing policies and procedures governing sterile compounding that meet certain standards; and
- A current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state, territory or district where the applicant is located.

The bill establishes a timeframe within which an inspection report will be considered current. The inspection report must be dated no later than six months from the application for an initial permit and no later than twelve months from the application for renewal of the permit. The bill takes into account unforeseen circumstances that prevent an applicant from submitting a current inspection report, and authorizes the Board to define what is considered unforeseen or acceptable circumstances. If an applicant claims that unforeseen or acceptable circumstances prevent it from including a current inspection report with the application, or if the applicant has never undergone an inspection by a regulatory or licensing agency, the bill authorizes DOH to:

- Conduct an onsite inspection of the applicant, or contract with a third party to conduct the onsite inspection;
- Accept a satisfactory inspection report, as determined by rule, from an entity approved by the Board; or
- Accept an inspection report from the FDA, conducted pursuant to the provisions of the DQSA.

A permittee may not ship or otherwise introduce a compounded sterile product into Florida that was compounded in violation of the laws and rules of the place where it is located and does not meet or exceed the standards governing sterile compounding in this state.

A registered nonresident pharmacy which is shipping or otherwise introducing a compounded sterile product into the state may continue to do so as long as the product is compounded in accordance with all laws and rules in its home state and in Florida and it obtains a permit by February 28, 2015, which is the expiration date of all pharmacy permits in Florida. However, an applicant seeking to register as a nonresident pharmacy on or after the effective date of the bill is required to obtain a permit before it may ship, mail, deliver, or dispense a compounded sterile product into Florida.

The bill grants the Board authority to administratively discipline a nonresident sterile compounding permittee for failing to comply with the requirements of s. 465.0158, F.S., violating statutes that outline acts and omissions which are grounds for discipline, and violating the provisions of s. 465.0156, F.S. The bill specifies that the Board may impose fines on violators.

The bill gives the Board the authority to administratively discipline a registered nonresident pharmacy for failing to comply with s. 465.017, F.S., which allows the Board to inspect a nonresident pharmacy to ensure compliance with applicable laws and rules, or failing to comply with s. 465.0158, F.S. In

addition, the bill subjects a registered nonresident pharmacy to the health care fraud provisions and penalties in s. 456.0635, F.S.[43]

The bill gives DOH the authority to inspect a nonresident pharmacy or a nonresident sterile compounding permittee to ensure compliance with applicable laws and rules. The pharmacy or permittee is required to bear all costs of such an inspection.

Lastly, the bill adds the definitions of "compounding" and "outsourcing facility" to chapter 465, F.S.

B. SECTION DIRECTORY:

Section 1: Amends s. 465.003, F.S., relating to definitions.
Section 2: Amends s. 465.0156, F.S., relating to registration of nonresident pharmacies.
Section 3: Creates s. 465.0158, F.S., relating to nonresident sterile compounding permit.
Section 4: Amends s. 465.017, F.S., relating to authority to inspect; disposal.
Section 5: Provides an effective date of October 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

This bill will have a positive impact on state revenues. DOH will collect new fees associated with applications for initial permits and biennial renewal of permits. DOH estimates that approximately 350 applications for nonresident sterile compounding permits will be received.[44] Initial permit fee and renewal fees are $250 plus $5 for an Unlicensed Activity fee. In total, $255 times the estimated number of nonresident permittees (350) equals $89,250. Less the 8% surcharge to General Revenue, the anticipated additional revenue would be approximately $82,110 annually. Revenues collected from initial permit fees and biennial renewal fees are deposited into the Medical Quality Assurance Trust Fund.

DOH or the Board may impose fines or penalties on either nonresident pharmacies or nonresident sterile compounding permittees found in violation of laws or rules associated with this bill. Revenues collected from fines and penalties are deposited into the Medical Quality Assurance Trust Fund.

2. Expenditures:

DOH has reported that the following nonrecurring costs will be borne by the department as a result of the passage of this bill:[45]

- Rulemaking;
- Mail notifications to non-resident permittees and;
- Updating the existing licensure system to accommodate the new nonresident sterile compounding permit.

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[43] Pursuant to s. 456.0635, F.S., each board shall refuse to admit a candidate to any examination and refuse to issue a license, certificate, or registration to any applicant if the candidate or applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant has, for example, been convicted of a felony in conjunction with participation in the Medicaid program or been terminated for cause from the Medicaid program. The statute lists several other crimes or activities that disqualify an applicant or candidate from consideration for a license, certificate, or registration issued by a board.
[44] Florida Department of Health, 2014 Agency Legislative Bill Analysis for HB 7077. Submitted on the Agency Bill Analysis Request (ABAR) online portal on March 13, 2014 (last viewed – March 20, 2014).
[45] *Id.*

DOH has reported that these nonrecurring costs may be absorbed within the department's current resources.[46]

DOH has reported that the recurring increases in workload associated with the permitting of nonresident permittees and the enforcement of provisions of this bill may be absorbed within the department's current resources.[47]

This bill gives DOH the authority to conduct an onsite inspection of an applicant for an initial nonresident sterile compounding permit or renewal of a permit which is located outside of Florida. DOH has estimated the cost of conducting an onsite inspection of an out-of-state applicant to range, depending on the location of the applicant in the U.S., from $1,786 to $2,371. The average cost of an inspection is estimated to be $2,100.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

In addition to the initial permit fee and renewal fees of $255, a nonresident pharmacy or outsourcing facility is required to pay all costs associated with an inspection conducted in conjunction with an application for a nonresident sterile compounding permit. Also, a nonresident pharmacy and a nonresident sterile compounding permittee are required to pay all costs associated with an inspection pursuant to s. 465.017.

The cost for registration as an outsourcing facility is $15,000, adjusted for inflation and for small businesses as detailed in the federal law.[48] The cost for registration as an outsourcing facility charged to a small business, defined as a business with gross annual sales of $1,000,000 or less, is one-third of the establishment fee. The cost of reinspection of an outsourcing facility required by the FDA is $15,000.[49]

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

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[46] *Id.*
[47] *Id.*
[48] DQSA, Pub. L. No. 113-54, s. 744K
[49] Id.

B. RULEMAKING AUTHORITY:

The bill provides sufficient rulemaking authority to the Department of Health to implement the provisions of the act.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to sterile compounding; amending s. 465.003, F.S.; defining the terms "compounding" and "outsourcing facility" as used in the Florida Pharmacy Act; amending s. 465.0156, F.S.; providing additional grounds for administrative discipline of a nonresident pharmacy, to which penalties apply; authorizing the Board of Pharmacy to administratively discipline a nonresident pharmacy for certain conduct; deleting a requirement that the board first refer such conduct to a certain regulatory or licensing agency; providing that a nonresident pharmacy is subject to certain health care fraud provisions; creating s. 465.0158, F.S.; requiring a nonresident pharmacy and an outsourcing facility to hold a nonresident sterile compounding permit to ship, mail, deliver, or dispense a compounded sterile product into this state; providing permit application requirements; requiring the Department of Health to conduct an onsite inspection of a nonresident pharmacy or contract with a third party to conduct such inspection; requiring the department to accept a satisfactory inspection report from specified entities; providing restrictions on the shipment, mailing, delivery, or dispensation of a compounded sterile product by permittees, nonresident pharmacies, and applicants for

registration as a nonresident pharmacy; authorizing the board to administratively discipline a permittee for failing to comply with or violating certain provisions; providing rulemaking authority; amending s. 465.017, F.S.; authorizing the department to inspect a registered nonresident pharmacy or permittee; requiring such pharmacy or permittee to bear the cost of the inspection; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsections (18) and (19) are added to section 465.003, Florida Statutes, to read:

465.003 Definitions.—As used in this chapter, the term:

(18) "Compounding" means a practice in which a licensed pharmacist or, in the case of an outsourcing facility, a person acting under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug or product to create another drug or product.

(19) "Outsourcing facility" means a single physical location registered as an outsourcing facility under the federal Drug Quality and Security Act, Pub. L. No. 113-54, at which sterile compounding of a product is conducted.

Section 2. Subsections (4) and (5) of section 465.0156, Florida Statutes, are amended, and subsection (6) is added to

that section, to read:

465.0156 Registration of nonresident pharmacies.—

(4) The board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy for failure to comply with s. 465.025, s. 465.017(2), s. 465.0158, or ~~with~~ any requirement of this section in accordance with the provisions of this chapter.

(5) In addition to the prohibitions of subsection (4) the board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy in accordance with ~~the provisions of~~ this chapter for conduct which causes or could cause serious bodily ~~injury~~ or ~~serious~~ psychological injury to a human or serious bodily injury to a nonhuman animal in ~~resident of~~ this state ~~if the board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and the regulatory or licensing agency fails to investigate within 180 days of the referral~~.

(6) A nonresident pharmacy is subject to the provisions of s. 456.0635.

Section 3. Section 465.0158, Florida Statutes, is created to read:

465.0158 Nonresident sterile compounding permit.—

(1) In order to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into this state, a nonresident pharmacy registered under s. 465.0156, or an outsourcing facility as defined in s. 465.003, must hold a

nonresident sterile compounding permit. For purposes of this section, an outsourcing facility is a nonresident facility that is not a pharmacy.

(2) An application for a nonresident sterile compounding permit shall be submitted on a form furnished by the board. The board may require such information as it deems reasonably necessary to carry out the purposes of this section. The fee for an initial permit and biennial renewal of the permit shall be set by the board pursuant to s. 465.022(14).

(3) An applicant must submit to the board to obtain an initial permit, or to the department to renew a permit, the following:

(a) Proof of registration as an outsourcing facility with the Secretary of the United States Department of Health and Human Services if the applicant is eligible for such registration pursuant to the federal Drug Quality and Security Act, Pub. L. No. 113-54.

(b) Proof of registration as a nonresident pharmacy, pursuant to s. 465.0156, unless the applicant is an outsourcing facility, in which case the application must include proof of the active and unencumbered license, permit, or registration issued by the state, territory, or district in which the outsourcing facility is physically located which allows the outsourcing facility to engage in compounding and ship, mail, deliver, or dispense a compounded sterile product into this state.

(c) Written attestation by an owner or officer of the applicant, and by the applicant's prescription department manager or pharmacist in charge, that:

1. The applicant has read and understands the laws and rules governing sterile compounding in this state.

2. A compounded sterile product shipped, mailed, delivered, or dispensed into this state will meet or exceed this state's standards for sterile compounding.

3. A compounded sterile product shipped, mailed, delivered, or dispensed into this state must not have been, and may not be, compounded in violation of the laws and rules of the state in which the applicant is located.

(d) The applicant's existing policies and procedures for sterile compounding, which must comply with pharmacy standards in United States Pharmacopoeia chapter 797, to the extent required by board rule, or current good manufacturing practices for an outsourcing facility.

(e) A current inspection report from an inspection conducted by the regulatory or licensing agency of the state, territory, or district in which the applicant is located. The inspection report must reflect compliance with the requirements of this chapter. An inspection report is current if the inspection was conducted no more than 6 months before the date of submission of the application for the initial permit or no more than 1 year before the date of submission of the application for renewal of the permit. If an applicant is unable

to submit a current inspection report due to unforeseeable or other acceptable circumstances, as established by rule, or if an inspection has not been performed, the department shall:

1. Conduct, or contract with an entity approved by the board to conduct, an onsite inspection, for which all costs shall be borne by the applicant;

2. Accept a satisfactory inspection report in lieu of an onsite inspection, as determined by rule, from an entity approved by the board; or

3. Accept an inspection report from the United States Food and Drug Administration conducted pursuant to the federal Drug Quality and Security Act, Pub. L. No. 113-54, in lieu of an onsite inspection.

(4) A permittee may not ship, mail, deliver, or dispense a compounded sterile product into this state if the product was compounded in violation of the laws or rules of the state in which the permittee is located or does not meet or exceed this state's sterile compounding standards.

(5) In accordance with this chapter, the board may deny, revoke, or suspend the permit of, fine, or reprimand a permittee for:

(a) Failure to comply with the requirements of this section;

(b) A violation listed under s. 456.0635, s. 456.065, or s. 456.072;

(c) A violation under s. 465.0156(5); or

(d) A violation listed under s. 465.016.

(6) A nonresident pharmacy registered under s. 465.0156 which ships, mails, delivers, or dispenses a compounded sterile product into this state may continue to do so if the product meets or exceeds the standards for sterile compounding in this state, the product is not compounded in violation of any law or rule of the state where the pharmacy is located, and the pharmacy applies for and is issued a permit under this section on or before February 28, 2015.

(7) An applicant registering on or after October 1, 2014, as a nonresident pharmacy under s. 465.0156 may not ship, mail, deliver, or dispense a compounded sterile product into this state until the applicant is registered as a nonresident pharmacy and is issued a permit under this section.

(8) The board shall adopt rules as necessary to administer this section, including rules for:

(a) Developing an application for the permit required by this section.

(b) Determining how, when, and under what circumstances an inspection of a nonresident sterile compounding permittee shall be conducted.

(c) Evaluating and approving entities from which a satisfactory inspection report will be accepted in lieu of an onsite inspection by the department or an inspection by the licensing or regulatory agency of the state, territory, or district where the applicant is located.

Section 4. Section 465.017~~,~~ Florida Statutes, is amended to read:

465.017 Authority to inspect; disposal.—

(1) Duly authorized agents and employees of the department shall have the power to inspect in a lawful manner at all reasonable hours any pharmacy, hospital, clinic, wholesale establishment, manufacturer, physician's office, or any other place in the state in which drugs and medical supplies are compounded, manufactured, packed, packaged, made, stored, sold, offered for sale, exposed for sale, or kept for sale for the purpose of:

(a) Determining if any ~~of the~~ provision~~s~~ of this chapter or any rule adopted ~~promulgated~~ under its authority is being violated;

(b) Securing samples or specimens of any drug or medical supply after paying or offering to pay for such sample or specimen; or

(c) Securing such other evidence as may be needed for prosecution under this chapter.

(2) Duly authorized agents and employees of the department may inspect a nonresident pharmacy registered under s. 465.0156 or a nonresident sterile compounding permittee under s. 465.0158 pursuant to this section. The costs of such inspections shall be borne by such pharmacy or permittee.

(3)~~(2)~~(a) Except as permitted by this chapter, and chapters 406, 409, 456, 499, and 893, records maintained in a

pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs shall not be furnished to any person other than to the patient for whom the drugs were dispensed, or her or his legal representative, or to the department pursuant to existing law, or, in the event that the patient is incapacitated or unable to request said records, her or his spouse except upon the written authorization of such patient. Such records may be furnished in any civil or criminal proceeding, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice to the patient or her or his legal representative by the party seeking such records.

(b) The board shall adopt rules establishing ~~to establish~~ practice guidelines for pharmacies to dispose of records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs. Such rules shall be consistent with the duty to preserve the confidentiality of such records in accordance with applicable state and federal law.

Section 5. This act shall take effect October 1, 2014.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 531 Public Health Trusts
SPONSOR(S): Richardson
TIED BILLS: **IDEN./SIM. BILLS:** SB 640

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 0 N	McElroy	O'Callaghan
2) Health Care Appropriations Subcommittee		Rodriguez	Pridgeon
3) Health & Human Services Committee			

SUMMARY ANALYSIS

This bill amends s.154.11, F.S., to authorize the board of trustees for a public health trust to lease, as lessor, office space controlled by the public trust without the approval of the board of county commissioners.

This bill has no fiscal impact on state government. However, this bill may result in additional revenues being generated by a public health trust from the lease of real property under its control.

The bill provides an effective date of July 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Public Health Trusts

Each county is authorized to create a public corporate body known as a public health trust.[1] A public health trust may only be created if the governing body of the county of a public health trust declares that there is a need for the trust to function.[2] The governing body of the county must then designate health care facilities to be operated and governed by the trust and appoint a board of trustees (board).[3]

The purpose of a public health trust is to exercise supervisory control over the operation, maintenance, and governance of the designated health care facilities. A designated facility is any county-owned or county-operated facility used in connection with the delivery of health care.[4] Designated facilities include: [5]

- Sanatoriums;
- Clinics;
- Ambulatory care centers;
- Primary care centers;
- Hospitals;
- Rehabilitation centers;
- Health training facilities;
- Nursing homes;
- Nurses' residence buildings;
- Infirmaries;
- Outpatient clinics;
- Mental health facilities;
- Residences for the aged;
- Rest homes;
- Health care administration buildings; and
- Parking facilities and areas serving health care facilities.

The board of each public health trust is authorized to become the operator of, and governing body for, any designated facility.[6] The board is selected by the governing body of the county where the trust is located and consists of between 7 and 21 members.[7] The members must be residents of the county in which the trust is located and are appointed on staggered terms which may not exceed 4 years.[8] The members serve without compensation, but are entitled to necessary expenses incurred in the discharge of their duties.[9]

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[1] Section 154.07, F.S.
[2] Id.
[3] Section 154.08, F.S., and s. 154.09, F.S.
[4] Section 154.08, F.S.
[5] Id.
[6] Id.
[7] Section 154.09, F.S.
[8] Id.
[9] Id.

The board of each public health trust is deemed to exercise a public and essential governmental function of both the state and the county.[10] The board is granted specific authority and powers to accomplish this function. This authority is subject to the limitation of the governing body of the county where the trust is located and includes the authority to: [11]

- Sue and be sued;
- Make and adopt bylaws and rules and regulations for the board's guidance and for the operation, governance, and maintenance of designated facilities;
- Make and execute contracts;
- Appoint and remove a chief executive officer of the trust;
- Appoint, remove, or suspend employees or agents of the board;
- Cooperate with and contract with any governmental agency or instrumentality, federal, state, municipal, or county;
- Employ legal counsel; and
- Lease, either as lessee or lessor, or rent for any number of years and upon any terms and conditions real property, except that the board shall not lease or rent, as lessor, any real property except in accordance with the requirements of s. 125.35, F.S.

Section 125.35, F.S., authorizes the board of county commissioners sell and convey any real or personal property, and to lease real property, belonging to the county, whenever the board determines that it is in the best interest of the county to do so.

Public Health Trust of Miami-Dade County

Miami-Dade County is the only county to have created a public health trust. In 1973 Miami-Dade County created the Public Health Trust of Miami-Dade County (Trust).[12] The Trust's designated facilities include Jackson Memorial Hospital and all related facilities and real and personal property. The related facilities include: [13]

- Multiple primary care and specialty care centers;
- A variety of school-based clinics serving many elementary, middle and high schools;
- Two long-term care nursing facilities;
- Six corrections health services clinics;
- A network of mental health facilities;
- Holtz Children's Hospital;
- Jackson Rehabilitation Hospital;
- Jackson Behavioral Health Hospital;
- Jackson North Medical Center; and
- Jackson South Community Hospital.

Effect of Proposed Changes

Currently, s. 154.11(f), F.S., authorizes the board of trustees of a public health trust to lease, as lessor, any real property under its control. However, any such lease is subject to the approval by the board of county commissioners of the county where the public health trust is located.[14] The bill authorizes the board of trustees for a public health trust to lease, as lessor, office space controlled by the public health trust without the approval of the board of county commissioners.

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[10] Section 154.11, F.S.
[11] Id.
[12] Chapter 25A of the Miami-Dade County Code.
[13] *About Jackson Health System: Overview*, http://www.jacksonhealth.org/about.asp (last visited on March 1, 2014)
[14] Section 125.35, F.S.

B. SECTION DIRECTORY:

Section 1: Amends s. 154.11, F.S., relating to powers of board of trustees.
Section 2: Provides an effective date of July 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   This bill may result in additional revenues being generated by a public health trust from the lease of real property under its control.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to public health trusts; amending s. 154.11, F.S.; authorizing public health trusts to lease certain real property; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (f) of subsection (1) of section 154.11, Florida Statutes, is amended to read:

154.11 Powers of board of trustees.—

(1) The board of trustees of each public health trust shall be deemed to exercise a public and essential governmental function of both the state and the county and in furtherance thereof it shall, subject to limitation by the governing body of the county in which such board is located, have all of the powers necessary or convenient to carry out the operation and governance of designated health care facilities, including, but without limiting the generality of, the foregoing:

(f) To lease, either as lessee or lessor, or rent for any number of years and upon any terms and conditions real property, except that the board shall not lease or rent, as lessor, any real property <u>other than office space controlled by a public health trust,</u> except in accordance with the requirements of s. 125.35<u>, Florida Statutes</u> ~~(F. S.~~ 1973~~)~~.

Section 2. This act shall take effect July 1, 2014.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 751 Telehealth
SPONSOR(S): Select Committee on Health Care Workforce Innovation; Cummings; Jones, M.
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Select Committee on Health Care Workforce Innovation	15 Y, 0 N, As CS	McElroy	Calamas
2) Health Care Appropriations Subcommittee		Rodriguez	Pridgeon
3) Health & Human Services Committee			

SUMMARY ANALYSIS

This bill creates s. 456.47, F.S., relating to the use of telehealth to provide health care services.

The bill:

- Provides definitions for "Telehealth" and "Telehealth provider";
- Requires a telehealth provider to use the same standard of care for telehealth as for in-person health care services currently provided by licensed health care practitioners in the state;
- Allows both the patient and the treating health care professional to use telehealth from any location;
- Provides that a non-physician telehealth provider using telehealth and acting within the relevant scope of practice may not be interpreted as practicing medicine without a license;
- Requires a telehealth provider to document the services provided via telehealth in the patient's medical records according to the same standard applicable for in-person services;
- Allows out-of-state health care professionals to use telehealth to provide health care services to Florida patients, requires them register with the Department of Health (DOH) or the applicable board, establishes eligibility requirements for registration and requires a registration fee of $75;
- Prohibits out-of-state telehealth providers from opening an office in Florida and from providing in-person health care services to patients located in Florida;
- Requires out-of-state telehealth providers to notify the applicable board or DOH of restrictions placed on the health care professional's license to practice or disciplinary actions taken against the health care practitioner and prohibits a health care professional whose license has been revoked to register as a telehealth provider;
- Provides exceptions to the registration requirement for emergencies, infrequent use, or physician to physician consultations; and
- Authorizes DOH or an applicable board to adopt rules to administer the requirements set forth in the bill.

This bill has an indeterminate fiscal impact on state government. However, additional revenues generated from the $75 registration fee along with the utilization of existing department resources are expected to offset any fiscal impact related to state government expenditures.

The bill provides an effective date of July 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Health Care Professional Shortage

There is currently a physician shortage in the U.S.[1] This shortage is predicted to continue into the foreseeable future and will likely worsen with the aging and growth of the U.S. population[2] and the passage of the Patient Protection and Affordable Care Act.[3] Aging populations create a disproportionately higher health care demand.[4] Additionally, as more individuals qualify for health care benefits, there will necessarily be a greater demand for more health care professionals to provide these services. There are several other factors which will likely increase the demand for a larger health care workforce. These include:[5]

- Shortage of healthcare professionals being educated, trained and licensed;
- Lack of specialists and health facilities in rural areas;
- Adverse events, injuries and illness at hospitals and physician's offices; and
- Need to improve community and population health.

Florida is not immune to the national problem and is experiencing a health care provider shortage itself. This is evidenced by the fact that there are 908 federally designated Health Professional Shortage Areas (HPSA) within the state. For example, Florida is currently experiencing a shortage of over 900 primary care physicians[6] and an unmet demand of over 1,500 physical therapists.[7]

Numerous solutions have been proposed to combat the health care professional shortage. These proposals seek to address both the current and future shortages. Long-term proposals include the creation of new scholarships and residency programs for emerging health care providers.[8] These proposals address the shortage in the future by creating new health care professionals. Short-term proposals include broadening the scope of practice for certain health care professionals[9] and more efficient utilization of our existing workforce through the expanded use of telehealth.[10]

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[1] This information is available at the U.S. Department of Health and Human Services' Health Resources and Services Administration's website, http://www.hrsa.gov/shortage/ (last visited on February 28, 2014).
[2] There will be a significant increase in the U.S. population, estimated to grow 20 percent (to 363 million) between 2008-2030.
[3] *Department of Health and Human Services Strategic Plan: Goal 5: Strengthen the Nation's Health and Human Service Infrastructure and Workforce*, U.S. Department of Health and Human Services, http://www.hhs.gov/secretary/about/goal5.html (last visited on February 28, 2014).
[4] Petterson, Stephen M., et al., "Projecting U.S. Primary Care Physician Workforce Needs: 2010-2025", Annals of Family Medicine, vol. 10, No. 6, Nov./Dec. 2012, available at: http://www.annfammed.org/content/10/6/503.full.pdf+html (last visited on February 24, 2014).
[5] *Telemedicine: An Important Force in the Transformation of Healthcare*, Matthew A. Hein, June 25, 2009.
[6] This information is available at the U.S. Department of Health and Human Services' Health Resources and Services Administration's website, http://www.hrsa.gov/shortage/ (last visited on February 28, 2014).
[7] Florida Department of Economic Opportunity's presentation to the Florida House of Representative's Select Committee on Health Care Workforce Innovation, January 15, 2014.
[8] U.S. Department of Health and Human Services, *supra* note 3.
[9] Id.
[10] *Department of Health and Human Services Strategic Plan: Goal 1: Strengthen the Nation's Health and Human Service Infrastructure and Workforce*, U.S. Department of Health and Human Services, http://www.hhs.gov/secretary/about/goal5.html (last visited on February 28, 2014).

Telehealth

There is no universally accepted definition of telehealth. In broad terms telehealth is:

> The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment[11] and prevention of disease and injuries[12], research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities.[13]

More specific definitions vary greatly from country to country, as well as between the numerous states authorizing the use of telehealth to deliver health care services. In fact, definitions of telehealth occasionally differ between the various professions within a specific state.[14] There are however common elements among the varied definitions of telehealth.

Telehealth generally consists of synchronous and/or asynchronous transmittal of information.[15] Synchronous refers to the live[16] transmission of information between patient and provider during the same time period.[17] Asynchronous telehealth is the transfer of data over a period of time, and typically in separate time frames.[18] This is commonly referred to as "store and forward". Definitions of telehealth also commonly contain restrictions related to the location where telehealth may be used. For example, the use of the "hub and spoke" model is a common location restriction. A hub site is the location from which specialty or consultative services originate, i.e., the provider. A spoke site is a remote site where the patient is presented during the telehealth encounter. Under this model, health services may be provided through telehealth only if the patient is located at a designated spoke site and the provider is located at a designated hub site.

Telehealth is a broad term which includes telemedicine and telemonitoring. Telemedicine is focused on the delivery of traditional clinical services, like diagnosis and treatment. Telemonitoring is the process of using audio, video, and other telecommunications and electronic information processing technologies to monitor the health status of a patient from a distance.[19] Telehealth more broadly includes non-clinical services, such as patient and professional health-related education, public health and health administration.[20]

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[11] The University of Florida's Diabetes Center of Excellence utilizes telehealth to deliver treatment to children with diabetes and other endocrine problems who live in Volusia County. This allows the children to receive specialized treatment without the necessity of traveling from Volusia County to Gainesville. The Florida Department of Health's Children's Medical Services underwrites the program. https://ufhealth.org/diabetes-center-excellence/telemedicine (last visited on February 28, 2014).

[12] The University of South Florida has partnered with American Well to provide health care services to the residents of the Villages via telehealth. The goal is to reduce hospital admissions, readmission rates, and pharmacy costs, while maintaining Medicare beneficiaries in their homes rather than long-term care settings. http://hscweb3.hsc.usf.edu/blog/2012/06/22/usf-health-and-american-well-to-bring-telehealth-to-seniors-living-at-the-villages/ (last visited on February 28, 2014).

[13] *Telemedicine: Opportunities and Developments in Member States, Global Observatory for Ehealth Series- Volume 2,* Section 1.2, page 9.

[14] *State Telehealth Laws and Reimbursement Policies*, Center for Connected Health Policy, The National Telehealth Policy Resource Center, November 2013.

[15] The majority of telehealth definitions allow for both synchronous and asynchronous transmittal of information. Some definitions however omit asynchronous from the definition of telehealth.

[16] This is also referred to as "real time" or "interactive" telehealth.

[17] *Telemedicine Nomenclature*, American Telemedicine Association, located at http://www.americantelemed.org/practice/nomenclature#.Uu1G6qNOncs (last visited on February 28, 2014). The use of live video to evaluate and diagnosis a patient would be considered synchronous telehealth.

[18] Id. A common example of synchronous telehealth is the transfer of x-rays or MRI images from one health care provider to another health care provider for review in the future.

[19] *Glossary and Acronyms*, U.S. Department of Health and Human Services http://www.hrsa.gov/ruralhealth/about/telehealth/glossary.html#t (last visited March 1, 2014).

[20] Id.

Telehealth is not a type of health care service but rather is a mechanism for delivery of health care services. Health care professionals use telehealth as a platform to provide traditional health care services in a non-traditional manner. These services include, among others, primary and specialty care services and health management.

Telehealth, in its modern form,[21] started in the 1960s in large part driven by the military and space technology sectors.[22] Specifically, telehealth was used to remotely monitor physiological measurements of certain military and space program personnel. As this technology became more readily available to the civilian market, telehealth began to be used for linking physicians with patients in remote, rural areas. As advancements were made in telecommunication technology, the use of telehealth became more widespread to include not only rural areas but also urban communities. Due to recent technology advancements and general accessibility, the use of telehealth has spread rapidly and is now becoming integrated into the ongoing operations of hospitals, specialty departments, home health agencies, private physician offices as well as consumer's homes and workplaces.[23] In fact, there are currently about 200 telehealth networks, with 3,500 service sites in the U.S.[24]

Telehealth is used to address several problems in the current health care system. Inadequate access to care is one of the primary obstacles to obtaining quality health care.[25] This occurs in both rural areas and urban communities.[26] Telehealth reduces the impact of this issue by providing a mechanism to deliver quality health care, irrespective of the location of a patient or a health care professional. Cost is another barrier to obtaining quality health care.[27] This includes the cost of travel to and from the health care facility, as well as related loss of wages from work absences. Costs are reduced through telehealth by decreasing the time and distance required to travel to the health care professional. Two more issues addressed through telehealth are the reutilization of health care services and hospital readmission. These often occur due to a lack of proper follow-up care by the patient[28] or a chronic condition.[29] These issues however can potentially be avoided through the use of telehealth and telemonitoring.

Telehealth and Federal Law

Several federal laws and regulations apply to which address the delivery of health care services through telehealth.

Prescribing Via the Internet

Federal law specifically prohibits prescribing controlled substances via the internet without an in-person evaluation. The federal regulation under 21 CFR §829 specifically states:

> No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed or dispensed by means of the Internet without a valid prescription.

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[21] Historically, telehealth can be traced back to the mid to late 19th century with one of the first published accounts occurring in the early 20th century when electrocardiograph data were transmitted over telephone wires. *Telemedicine: Opportunities and Developments in Member States, Global Observatory for Ehealth Series- Volume 2,* Section 1.2, page 9.

[22] *Telemedicine: Opportunities and Developments in Member States, supra* note14.

[23] *What is Telemedicine*, American Telemedicine Association, http://www.americantelemed.org/learn/what-is-telemedicine#.Uu6eGqNOncs (last visited on February 28, 2014).

[24] *Telemedicine Frequently Asked Questions*, American Telemedicine Association, http://www.americantelemed.org/learn/what-is-telemedicine/faqs#.Uu5vyaNOnct (last visited on February 22, 2014).

[25] U.S. Department of Health and Human Services, *supra* note 10.

[26] Id.

[27] Id.

[28] Post-surgical examination subsequent to a patient's release from a hospital is a prime example. Specifically, infection can occur without proper follow-up and ultimately leads to a readmission to the hospital.

[29] For example, diabetes is a chronic condition which can benefit by treatment through telehealth.

A valid prescription is further defined under the same regulation as one issued by a practitioner who has conducted an in-person evaluation. The in-person evaluation requires that the patient be in the physical presence of the provider without regard to the presence or conduct of other professionals.[30] However, the Ryan Haight Online Pharmacy Consumer Protection Act,[31] signed into law in October 2008, created an exception for the in-person medical evaluation for telehealth practitioners. The practitioner is still subject to the requirement that all controlled substance prescriptions be issued for a legitimate purpose by a practitioner acting in the usual course of professional practice.

Medicare Coverage

Specific telehealth[32] services delivered at designated sites are covered under Medicare. The Federal Centers for Medicare and Medicaid Services' regulations require both a distant site and a separate originating site (hub and spoke model) under their definition of telehealth. Asynchronous (store and forward) activities are only reimbursed under Medicare in federal demonstration projects.[33] To qualify for Medicare reimbursement, the originating site must be:

- Located in a federally defined rural county;
- Designated rural;[34] or
- Identified as a participant in a federal telemedicine demonstration project as of December 21, 2000.[35]

In addition, an originating site must be one of the following location types as further defined in federal law and regulation:

- The office of a physician or practitioner;
- A critical access hospital;
- A rural health clinic;
- A federally qualified health center;
- A hospital;
- A hospital-based or critical access hospital-based renal dialysis center (including satellites);
- A skilled nursing facility; or
- A community mental health center.[36]

Protection of Personal Health Information

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects personal health information. Privacy rules were initially issued in 2000 by the U.S. Department of Health and Human Services and later modified in 2002. These rules address the use and disclosure of an individual's personal health information as well as create standards for information security.

Only certain entities are subject to HIPAA's provisions. These "covered entities" include:

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[30] 21 CFR §829(e)(2).
[31] Ryan Haight Online Consumer Protection Act of 2008, Public Law 110-425 (H.R. 6353).
[32] Medicare covers a broader set of services using the term telehealth. Medicare defines telehealth as the use of telecommunications and information technology to provide access to health assessment, diagnosis, intervention, consultation, supervision and information across distance.
[33] Only two states have a federal demonstration project that meets these qualifications, Hawaii and Alaska.
[34] The rural definition was expanded through a final federal regulation released on December 10, 2013 to include health professional shortage areas located in rural census tracts of urban areas as determined by the Office of Rural Health Policy. See 78 FR 74229, 74400-74402, 74812 (December 10, 2013).
[35] See 42 U.S.C. sec. 1395(m)(m)(4)(C)(i).
[36] See 42 U.S.C. sec. 1395(m)(m)(4)(C)(ii).

- Health plans;
- Health care providers;
- Health care clearinghouses; and
- Business associates of any of the above.

Covered entities are obligated to meet HIPAA's requirements to ensure privacy and confidentiality personal health information, regardless of the method in which the medical service is delivered.

In 2009, the Health Information Technology for Economic Clinical Health (HITECH) Act was enacted as part of American Recovery and Reinvestment Act (ARRA).[37] The HITECH Act promoted electronic exchange and use of health information by investing $20 billion in health information technology infrastructure and incentives to encourage doctors and hospitals to use health information technology.[38] HITECH was intended to strengthen existing HIPAA security and privacy rules.[39] It expanded HIPAA to entities not previously covered; specifically, "business associates" now includes Regional Health Information Organizations, and Health Information Exchanges.[40] Similarly, it made changes to the privacy rule to better protect personal health information held, transferred, or used by covered entities.[41]

Under the provisions of HIPAA and the HITECH Act, a health care provider or other covered entity participating in the electronic exchange of personal health information are subject to HIPAA and HITECH. These federal laws apply to covered entities in Florida, regardless of whether there is an express reference to them in Florida law.

Interstate Medical Licensure Compact

The Federation of State Medical Boards, a non-profit organization representing state medical boards that license and discipline allopathic and osteopathic physicians, has drafted eight consensus principles aimed at addressing the process of licensing and regulating physicians who practice across state lines. Under an interstate compact, the participating state medical boards would retain their licensing and disciplining authority but would share essential information to streamline the process for those physicians who practice across state lines, including telemedicine.[42] The draft of the Interstate Medical Licensure Compact, which would be voluntary on the part of both physicians and states, is expected to be released in 2014.[43]

Telehealth Barriers

There are several barriers which impede the use of telehealth. These barriers include:[44]

- Lack of a standard definition for telehealth;
- Lack of standard regulations for the practice of telehealth;
- Licensure requirements which prohibit cross-state practice; and
- Restrictions on the location where telehealth services may be provided.

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[37] "Complying with the Health Information Technology for Economic and Clinical Health (HITECH) Act, HIPAA, Security and Privacy, and Electronic Health Records", Deloitte, December 2009, available at https://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/us_lshc_LeadingPracticesandSolutionsforPrivacyandSecurityGuidelines_031710.pdf, last viewed March 1, 2014.
[38] Id.
[39] Id.
[40] Id.
[41] Id.
[42] Federation of State Medical Boards, *Interstate Compact for Physician Licensure Moves Forward with Consensus Principles* (October 7, 2013), http://www.fsmb.org/pdf/nr_interstate_compact.pdf (last visited February 28, 2014).
[43] Federation of State Medical Boards, *State Medical Board Effort to Streamline Medical Licensing Gains Support in U.S. Senate* (January 14, 2014), http://www.fsmb.org/pdf/interstate_compact_senators_january13C.pdf (last visited February 28, 2014).
[44] *State Telehealth Laws and Reimbursement Policies*, Center for Connected Health Policy, The National Telehealth Policy Resource Center, November 2013.

Standardized Definition

Lack of a standard definition[45] presents a barrier to the use of telehealth. As previously noted, there is no universally accepted definition. A health care professional is left to speculate as to whether the service he or she is providing constitutes telehealth. This can have far-reaching consequences which range from a denial of reimbursement for the services provided to an inquiry as to whether the services provided equate to the unlicensed practice of medicine. Florida law does not define telehealth.

Standardized Regulations

The absence of a uniform regulatory structure governing the use of telehealth presents another barrier to its use. Currently, 13 states[46] do not have a statutory structure for the delivery of health care services through telehealth.[47] This absence places the burden upon individual professionals to determine what is appropriate, and invites health professional licensing boards to fill the regulatory gap. This can lead to an inconsistent regulation of telehealth amongst the varying health care professions and impede the use of telehealth.

For example, a common telehealth regulation is the requirement that a health care professional conduct an in-person examination of the patient prior to providing services via telehealth.[48] Many times an exception is expressly contained within the regulation which allows the in-person requirement to be met through telehealth.[49] This exception however can vary between the differing health care professions in the absence of a uniform regulation. For example, an audiologist may be authorized to conduct the initial evaluation through telehealth while a physical therapist is required to perform an in-person physical examination prior to providing services through telehealth. There may not be any reasonable justification for this disparate treatment.

Licensure

Licensure requirements present one of the greatest barriers to the use of telehealth. States, not the federal government, license and regulate health care professionals.

Currently, 35 states prohibit health care professionals from providing health care services unless he or she is licensed in the state where the patient is located.[50] Most states have exceptions to this requirement, applicable only in certain limited circumstances, which include:[51]

- Physician-to-physician consultations (not between practitioner and patient);
- Educational purposes;
- Residency training;
- U.S. Military;
- Public health services; and
- Medical emergencies (Good Samaritan) or natural disasters.

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[45] No two states define telehealth exactly alike, although some similarities exist between certain states. *State Telehealth Laws and Reimbursement Policies*, Center for Connected Health Policy, The National Telehealth Policy Resource Center, November 2013.
[46] This includes Florida.
[47] *State Telehealth Laws and Reimbursement Policies*, Center for Connected Health Policy, The National Telehealth Policy Resource Center, November 2013. Even amongst states with telehealth statutory regulations, no two states regulate telehealth in exactly the same manner.
[48] *State Telehealth Laws and Reimbursement Policies*, Center for Connected Health Policy, The National Telehealth Policy Resource Center, November 2013.
[49] Id.
[50] Id. This includes Florida.
[51] *Licensure and Scope of Practice FAQs,* Telehealth Resource Centers, http://www.telehealthresourcecenter.org/toolbox-module/licensure-and-scope-practice#what-are-the-exceptions-to-state-licensure-require (last visited on February 28, 2014).

Additionally, special telehealth license or certificate which allows an out-of-state licensed health care professional to provide health care services through telehealth to patients located within that particular state are currently offered in 9 states.[52] Four of these states (Montana, Nevada, Tennessee and Texas) however, only offer the telehealth license to board eligible or board certified specialists.

In the absence of an exception or a state regulation authorizing otherwise, it appears that a health care professional will have to be licensed in the state where the patient is located to provide health care services through telehealth. Requiring health care professionals to obtain multiple state licenses to provide health care services through telehealth may be burdensome and may inhibit the use of telehealth across state borders.

Location Restrictions

Generally, there are essentially two types of location restrictions. The first restricts the use of telehealth to certain designated areas within a state. For example, only individuals in areas designated as a rural area or a medically underserved area may be authorized to receive health care services through telehealth.

The second restriction relates to limitations on the specific location where telehealth services may be provided. The most common example of this type of limitation is the hub and spoke model.[53] Under this model, "hub" refers to the location to where the health care professional must be located while "spoke" refers to the location where the patient must be located.

The two types of restrictions are not mutually exclusive and are commonly used in conjunction. This presents a significant obstacle to access to care by placing arbitrary restrictions on the use of telehealth which inhibits the effectiveness, as well as the use of telehealth to deliver health care services.

Telehealth in Florida

Florida does not have a statutory structure for the delivery of health care services through telehealth. The only reference to telehealth in the Florida Statutes is contained within s. 364.0135, F.S. This statute is related to the promotion of broadband internet services by telecommunication companies and does not define or regulate telehealth in any manner. Further, the only references to telehealth in the Florida Administrative Code relate to the Board of Medicine, Board of Osteopathic Medicine, and the Child Protection Team Program. The Florida Medicaid program also outlines certain requirements relating to telehealth coverage in its rules.[54]

Florida Board of Medicine

In 2003, the Florida Board of Medicine (Board) adopted Rule 64B8-9.014, F.A.C., "Standards for Telemedicine Prescribing Practice" (Rule).[55] The Rule sets forth requirements and restrictions for physicians and physician assistants prescribing medications.[56] The Rule also states that telemedicine "shall include, but is not limited to, prescribing legend drugs to patients through the following modes of

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[52] *State Telehealth Laws and Reimbursement Policies*, Center for Connected Health Policy, The National Telehealth Policy Resource Center, November 2013. These states are AL, LA, MN, MT, NM, NV, OH, TN and TX. Additionally, six states (HI, MD, MS, OR, PA and WA) provide exceptions to their state licensure requirements under limited circumstances, i.e. only for radiology or only for border states, or were not telehealth specific exceptions.

[53] Florida's Department of Health's Children's Medical Services Program (CMS) currently uses the hub and spoke model to provide services via telehealth to children enrolled in the program.

[54] *See* Agency for Health Care Administration, Florida Medicaid, "Practitioner Services Coverage and Limitations Handbook," December 2012, pg. 2-119, available at: http://portal.flmmis.com/FLPublic/Tab/125/content/public/handbooks/cl_12_12-12-01_practitioner_services_handbook.pdf.spage (last visited on February 28, 2014).

[55] The current telemedicine rules and regulations for the Board of Medicine and the Board of Osteopathic Medicine are virtually identical. Rules 64B8-9.014 and 64B15-14.008, F.A.C.

[56] Rule 64B8-9.014, F.A.C.

communication: (a) Internet; (b) Telephone; and (c) Facsimile."[57] The Rule however fails to fully define telemedicine or regulate its use in any other way. The Board only regulates allopathic physicians, so this rule does not apply to any other profession.[58]

The Board recently adopted a new rule[59] setting forth standards for telemedicine.[60] The new rule defines telemedicine as the practice of medicine by a licensed Florida physician or physician assistant where patient care, treatment, or services are provided through the use of medical information exchanged from one site to another via electronic communications.[61] The definition could be interpreted to limit the use of telemedicine to physicians and physician assistants; however, the Board does not have the authority to regulate other professions.[62] The new rule provides that:

- The standard of care is the same as that required for services provided in person;
- A physician-patient relationship may be established through telemedicine;
- A physician or physician assistant is responsible for the quality and safety of the equipment and used to provide services through telemedicine; and
- The same patient confidentiality and record-keeping requirements applicable to in-person services are applicable to services provided through telemedicine.[63]

The new rule however prohibits prescribing controlled substances through telemedicine.[64]

Child Protection Teams

The Child Protection Team (CPT) program under Children's Medical Services utilizes a telehealth network to perform child assessments. Rule 64C-8.001(9), F. A.C., relating to the Child Protection Team, defines telemedicine as "the use of telecommunication and information technology to provide clinical care to individuals at a distance and to transmit the information needed to provide that care." The CPT is a medically directed multi-disciplinary program that works with local Sheriff's offices and the Department of Children and Families in cases of child abuse and neglect to supplement investigative activities.[65] The CPT patient is seen at a "remote site" and a registered nurse assists with the medical exam. A physician or an advanced registered nurse practitioner is located at the "hub site" and has responsibility for directing the exam.

Hub sites are comprehensive medical facilities that offer a wide range of medical and interdisciplinary staff whereas the remote sites tend to be smaller facilities that may lack medical diversity. In 2013, CPT telehealth services were available at 14 sites and 437 children were provided medical or other assessments via telehealth technology.[66]

Florida Medicaid Program

Florida's Medicaid program reimburses for a limited number of services provided by designated practitioners using telehealth.[67] Medicaid limits the use of telehealth to behavioral health, dental, and

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[57] Id.
[58] The Board of Osteopathic Medicine rule only applies to osteopathic physicians.
[59] The Board of Medicine and the Board of Osteopathic Medicine rules for telemedicine are identical.
[60] Rule 64B8-9.0141, F.A.C., which has an effective date of March 12, 2014.
[61] Rule 64B8-9.0141, F.A.C.
[62] The Board of Osteopathic Medicine definition only applies to osteopathic physicians.
[63] Id.
[64] Id.
[65] Florida Department of Health, *Child Protection Teams*, http://www.floridahealth.gov/AlternateSites/CMS-Kids/families/child_protection_safety/child_protection_teams.html (last visited February 28, 2014).
[66] Florida Department of Health, *Maternal and Child Health Block Grant Narrative for 2013, http://www.floridahealth.gov/healthy-people-and-families/womens-health/pregnancy/mch-fl-2013-1narrative.pdf* p.21, (last visited: February 28, 2014).
[67] Section 409.919, F.S.; Agency for Health Care Administration, *Highlights of Practitioner Services Coverage and Limitations Handbook Presentation*, Bureau of Medicaid Services, Summer 2013, p.30.

physician services. Audio only, email messages, facsimile transmissions, or communications with an enrollee through another mechanism other than the spoke site, known as the site where the patient is located, are not covered under Florida Medicaid.

The distant or hub site, where the provider is located, is eligible for reimbursement; the spoke site, where the patient is located, is not eligible for reimbursement unless a separate service is performed on the same day. Medicaid also requires that the referring physician and the patient be present during the consultation.[68]

Medicaid services are reimbursable only in the hospital outpatient, inpatient and physician office settings. During the 2013 Legislative Session, Medicaid provider enrollment requirements were revised to allow the enrollment of physicians actively licensed in Florida to interpret diagnostic testing results through telecommunications and information technology provided from a distance.[69]

Under the Medicaid Medical Assistance Program enacted in 2011, the vast majority of Medicaid recipients will be covered through managed care. Newly procured Medicaid contracts contain broader allowance for telehealth. Not only may plans use telehealth for behavioral health, dental, and physician services as before but, upon approval by the Agency for Health Care Administration, may also use telehealth to provide other covered services.[70] The new contract additionally eliminates numerous prior restrictions related to types of services and the type of providers who may utilize telehealth.[71]

Florida Emergency Trauma Telemedicine Network

Various designated trauma centers participate in the Florida Emergency Trauma Telemedicine Network (FETTN). Coordinated by DOH, FETTN facilitates the treatment of trauma patients between trauma centers and community or rural hospitals.[72] FETTN allows for multiple interface options and currently 7 out of 25 trauma centers are part of the network.[73] In 2011-12, the seven Level 1 or Level 2 trauma centers that participated as a hub site, known as the location where the consulting physician is delivering the services, were Holmes Regional Medical Center, Tallahassee Memorial Hospital, Sacred Heart Hospital, University of Miami, Shands-Gainesville, Shands-Jacksvonille, and Orlando Health.[74]

Other Department of Health Initiatives

DOH utilizes tele-radiology through the Tuberculosis (TB) Physician's Network.[75] The ability to read electronic chest X-Rays remotely can lead to a faster diagnosis, treatment and a reduction in the spread of the disease, according to the department. This service is not currently reimbursed by Medicaid.

Jurisdiction and Venue

A Florida court has jurisdiction over a resident health care professional due to his or her presence in the state. For a nonresident health care professional, a Florida patient must establish in court that:

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[68] Id.
[69] *See* Chapter 2013-150, L.O.F., sec. 1.
[70] Model Agreement, Attachment II, Exhibit II A, Medicaid Managed Medical Assistance Program, Agency for Health Care Administration, February, 2014, available at http://ahca.myflorida.com/Medicaid/statewide_mc/index.shtml#mmaplans (last viewed March 1, 2014).
[71] Id.
[72] Florida Department of Health, 2014 Agency Legislative Bill Analysis of HB 167, on file with the Florida House of Representative's Select Committee on Health Care Workforce Innovation (October 21, 2013).
[73] Id.
[74] Florida Department of Health, *Long Range Program Plan* (September 28, 2012).
[75] Florida Department of Health, *supra* note 72.

1) The health care professional subjected himself or herself to jurisdiction through Florida's long-arm statute; and
2) The health care professional had sufficient minimum contacts with the state so that he or she should reasonably anticipate being haled into court in Florida.[76]

Under the long-arm statute any health care professional (irrespective of whether he or she is a resident of the state) who commits certain enumerated acts is subject to the jurisdiction of Florida.[77] These acts include:[78]

- Operating, conducting, engaging in, or carrying on a business or business venture in this state;
- Committing a tortious act within this state;
- Causing injury to persons within this state arising out of an act or omission by a health care professional outside this state, if, at or about the time of the injury, the health care professional was engaged in solicitation or service activities within this state; and
- Breaching a contract in this state by failing to perform acts required by the contract to be performed in this state.

"Venue" refers to the geographical area, that is the county or district, where a cause may be heard or tried.[79] For Florida residents, actions may be brought in the county where the defendant resides, where the cause of action accrued, or where the property in litigation is located.[80] An action against a non-resident may be brought in any county of the state.[81]

Effect of Proposed Changes

The bill amends ch. 456, F.S., to create s. 456.47, F.S., relating to the use of telehealth to provide health care services.

"Telehealth" is defined in the bill to mean the use of synchronous or asynchronous telecommunications technology by a telehealth provider to provide health care services including, but not limited to, patient assessment, diagnosis, consultation, treatment, monitoring and transfer of medical data, patient and professional health-related education, public health and health administration. Thus, health care professionals can use telehealth to provide services to patients through both "live" and "store and forward" methods. It also authorizes the use of telemonitoring. Audio-only telephone calls, e-mail messages, and facsimile transmissions are expressly excluded from the definition of telehealth. The definition does not place any additional limitations on the type of technology that can be used in telehealth.

The bill defines "telehealth provider" as any person who provides health care related services using telehealth and who is licensed as one of the following professions:[82]

- Acupuncturist;
- Allopathic physician;
- Osteopathic physician;
- Chiropractor;
- Podiatrist;

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[76] Venetian Salami Company v. Parthenais, 554 So.2d 499 (Fla. 1989).
[77] Section 48.193, F.S.
[78] Id.
[79] Metnick & Levy v. Seuling, 123 So.3d 639 (Fla. 4th DCA 2013).
[80] Section 47.011, F.S.
[81] Metnick & Levy v. Seuling *supra* note 79. This is subject to the doctrine of forum non conveniens.
[82] These are professionals licensed under ch. 457; ch. 458; ch. 459; ch. 460; ch. 461; ch. 463; ch. 464; ch. 465; ch. 466; ch. 467; part I, part III, part IV, part V, part X, part XIII, and part XIV, ch. 468; ch. 478; ch. 480; part III, ch. 483; ch. 484; ch. 486; ch. 490; or ch. 491.

- Optometrist;
- Nurse;
- Pharmacist;
- Dentist;
- Midwife;
- Speech therapist;
- Occupational therapist;
- Radiology technician;
- Electrologist;
- Orthotist;
- Pedorthist;
- Prosthetist;
- Massage therapist;
- Optician;
- Hearing aid specialist;
- Clinical laboratory personnel;
- Respiratory therapist;
- Physical therapist;
- Psychologist;
- Psychotherapist;
- Dietician/Nutritionist; or
- Athletic trainer.

The bill establishes that the standard of care for telehealth providers is the same as the standard of care for health care practitioners or health care providers providing in-person health care services to patients. This ensures that a patient receives the same standard of care irrespective of the modality used by the health care professional to deliver the services. The bill provides that a patient receiving telehealth services may be in any location at the time that the telehealth services are rendered and that a telehealth provider may be in any location when providing telehealth services to a patient. The bill specifies a non-physician telehealth provider using telehealth and acting within the relevant scope of practice may not be interpreted as practicing medicine without a license.

The bill requires that a telehealth provider document the telehealth services rendered in the patient's medical records according to the same standard as that required for in-person services. The bill requires that such medical records be kept confidential in accordance with ss. 395.3025(4) and 456.057, F.S. Section 456.057, F.S., relates to all licensed health care professionals while s. 395.3025(4), F.S., relates to all health care facilities licensed under ch. 395, F.S. (hospitals, ambulatory surgical centers, and mobile surgical centers). Thus, the same confidentiality requirements placed upon health care facilities and health care practitioners for medical records generated as part of in-person treatment apply to any medical records generated as part of treatment rendered through telehealth.

The bill allows out-of-state professionals who meet certain criteria and register annually with DOH or applicable board to provide telehealth services in the state. To register as an out-of-state telehealth provider, the health care professional must:

- Submit an application to DOH;
- Pay a $75 registration fee;
- Hold an active unencumbered license, consistent with the definition of "telehealth provider" listed above, in a U.S. state or jurisdiction and against whom no disciplinary action has been taken during the five years before submission of the application; and
- Never had his or her license revoked in any U.S. state or jurisdiction.

The bill prohibits an out-of-state telehealth provider from opening an office in Florida and from providing in-person health care services to patients located in Florida.

The bill requires out-of-state telehealth providers to notify the applicable board or DOH of restrictions placed on the health care professional's license to practice or disciplinary actions taken against the health care practitioner.

The bill provides exceptions to the registration requirement for emergencies, infrequent use, or physician to physician consultations.

The bill authorizes DOH or an applicable board to adopt rules to administer the requirements set forth in the bill.

The bill provides an effective date of July 1, 2014.

B. SECTION DIRECTORY:

Section 1: Creates s. 456.47, F.S., relating to telehealth services.
Section 2: Provides an effective date of July 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The bill requires out-of-state telehealth providers to pay a $75 registration fee to DOH. Similar to fees collected by DOH for other health care practitioner licensure, these funds would be deposited into the Medical Quality Assurance Trust Fund. It is unknown how many out-of-state health care practitioners will apply for registration. Therefore, the positive fiscal impact to the Medical Quality Assurance Trust Fund cannot be determined at this time.

2. Expenditures:

   DOH will incur a recurring increase in workload and costs associated with the new registration of out-of-state health care practitioners to practice telehealth. However, the revenues generated from the registration fee would offset the cost of regulating telehealth providers. Other costs associated with regulating telemedicine providers may be absorbed within existing department resources.

   DOH will incur nonrecurring costs associated with rulemaking, development of a registration application and updating the health practitioner licensure database to accommodate the registration requirements. DOH has reported that the Division of Medical Quality Assurance's existing budget authority is sufficient to absorb these costs.[83]

   DOH may incur costs associated with enforcing the provisions of this bill. This bill provides that an applicable board or the department may adopt rules to administer the requirements of this section. DOH may promulgate rules to address the enforcement of this bill including but not limited to recuperating costs of investigations through the assessment of fines or penalties. Additionally, other costs associated with enforcement may be absorbed within existing department resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

[83] Florida Department of Health, 2014 Agency Legislative Bill Analysis for CS/HB 751. Submitted on the Agency Bill Analysis Request (ABAR) online portal. (last viewed – March 19, 2014).

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULEMAKING AUTHORITY:

The bill provides sufficient rulemaking authority to DOH to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to telehealth; creating s. 456.47, F.S.; defining terms; providing for certain practice standards for telehealth providers; providing for the maintenance and confidentiality of medical records; requiring the registration of health care professionals not licensed in this state in order to use telehealth to deliver health care services; providing registration requirements; prohibiting registrants from opening an office or providing in-person health care services in this state; requiring a registrant to notify the appropriate board or the Department of Health of certain actions against the registrant's professional license; prohibiting a health care professional with a revoked license from being registered as a telehealth provider; providing exemptions to the registration requirement; providing rulemaking authority; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 456.47, Florida Statutes, is created to read:

456.47 Use of telehealth to provide services.—

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

(a) "Telehealth" means the use of synchronous or asynchronous telecommunications technology by a telehealth provider to provide health care services, including, but not limited to, patient assessment, diagnosis, consultation, treatment, monitoring and transfer of medical data, patient and professional health-related education, public health, and health administration. The term does not include audio-only telephone calls, e-mail messages, or facsimile transmissions.

(b) "Telehealth provider" means any person who provides health care and related services using telehealth and who is licensed under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part III, part IV, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part III of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491; or who is registered under this section and is in compliance with paragraph (4)(a).

(2) PRACTICE STANDARD.—

(a) The standard of care for telehealth providers providing medical care is the same as the standard of care for health care professionals providing in-person health care services to patients. A telehealth provider is not required to research a patient's medical history or conduct a physical examination of the patient before using telehealth to provide services to the patient if the telehealth provider conducts a

patient evaluation sufficient to diagnose and treat the patient. The evaluation may be performed using telehealth.

(b) A telehealth provider and a patient may each be in any location when telehealth is used to provide health care services to a patient.

(c) A nonphysician telehealth provider using telehealth and acting within the relevant scope of practice may not be interpreted as practicing medicine without a license.

(3) RECORDS.—A telehealth provider shall document in the patient's medical record the health care services rendered using telehealth according to the same standard as used for in-person services. Medical records, including video, audio, electronic, or other records generated as a result of providing such services, are confidential pursuant to ss. 395.3025(4) and 456.057.

(4) REGISTRATION OF OUT-OF-STATE TELEHEALTH PROVIDERS.—

(a) A health care professional not licensed in this state may provide health care services to a patient located in this state using telehealth if the telehealth provider annually registers with the applicable board, or the department if there is no board.

(b) The board, or the department if there is no board, shall register a health care professional as a telehealth provider if the health care professional:

1. Completes an application form developed by the department;

2. Pays a $75 registration fee; and

3. Holds an active, unencumbered license for a profession included in paragraph (1)(b) issued by another state, the District of Columbia, or a possession or territory of the United States and against whom no disciplinary action has been taken during the 5 years before submission of the application. The department shall use the National Practitioner Data Bank to verify information submitted by an applicant.

(c) A health care professional registered under this section is prohibited from opening an office in this state and from providing in-person health care services to patients located in this state.

(d) A health care professional registered under this section must immediately notify the appropriate board, or the department if there is no board, of restrictions placed on the health care professional's license to practice, or disciplinary action taken against the health care professional, in any state or jurisdiction.

(e) A health care professional whose license to provide health care services has been revoked in any state or jurisdiction may not register under this section.

(5) EXEMPTIONS.—A health care professional who is not licensed to provide health care services in this state but who holds an active license to provide health care services in another state or jurisdiction, and who provides health care services using telehealth to a patient located in this state, is

not subject to the registration requirement under this section if the services are provided:

(a) In response to an emergency medical condition as defined in s. 395.002;

(b) No more than 10 times per calendar year; or

(c) In consultation with a health care professional licensed in this state and that health care professional retains ultimate authority over the diagnosis and care of the patient.

(6) RULEMAKING.—The applicable board, or the department if there is no board, may adopt rules to administer the requirements of this section.

Section 2. This act shall take effect July 1, 2014.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 7109 PCB SCHCWI 14-02 Graduate Medical Education
SPONSOR(S): Select Committee on Health Care Workforce Innovation, Hudson
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Select Committee on Health Care Workforce Innovation	15 Y, 0 N	Poche	Calamas
1) Health Care Appropriations Subcommittee		Clark	Pridgeon

SUMMARY ANALYSIS

Graduate medical education (GME) is the period of training following graduation from medical school when a physician refines the clinical skills necessary to practice in a specific medical field. GME or "residency" programs for allopathic and osteopathic physicians include internships, residency training and fellowships, and can range from three to six years or more in length of time. GME positions are funded primarily through the Medicare and Medicaid programs, but also through other government programs, such as the Department of Defense, U.S Department of Veterans Affairs, and state programs, and private funding.

In order to track and analyze Florida's GME programs, and identify potential areas of investment of state funds to expand or create GME programs to train future physicians in specialties for which there is, or will be, a shortage of physicians, House Bill 7109 requires the Physician Workforce Advisory Council (Council), within the Department of Health, to annually survey the state's medical schools and accredited GME institutions. The survey will include requests for data regarding medical school graduates, number of GME positions, funding sources, and any other data necessary to evaluate the physician workforce and develop strategies and policies to create and expand GME programs in the state.

The bill requires the Council to compile all responses to the survey and create the Statewide Graduate Medical Education Report, which will be made available to the public.

The bill has an indeterminate, but likely insignificant fiscal impact that can be absorbed within existing Department of Health resources.

The bill provides an effective date of July 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

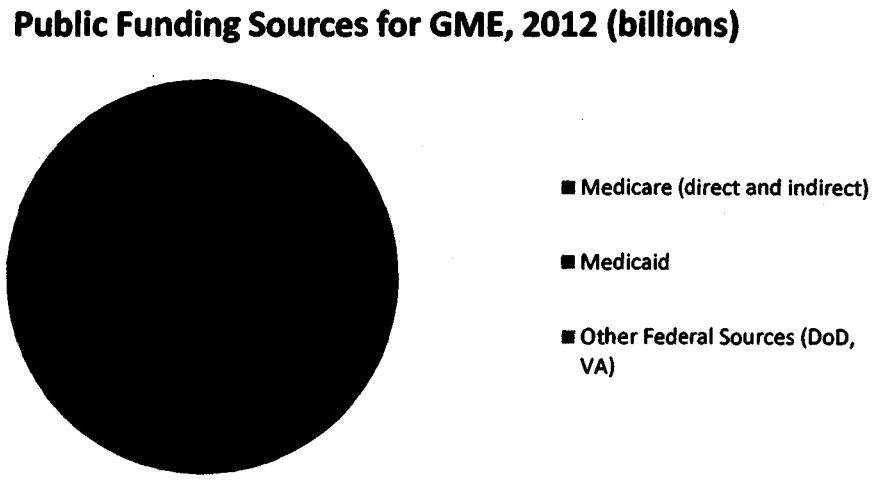
Background

Graduate Medical Education

Graduate medical education (GME) is the period of training following graduation from medical school when a physician refines the clinical skills necessary to practice in a specific medical field. GME or "residency" programs for allopathic and osteopathic physicians include internships, residency training and fellowships, and can range from three to six years or more in length of time.[1] Allopathic GME programs are accredited by the Accreditation Council for Graduate Medical Education (ACGME) and osteopathic GME programs are accredited by the American Osteopathic Association (AOA). During academic year 2012-2013, there were 117,717 residents in GME programs across the country.[2]

Funding

The chart below illustrates the sources of public funding for GME in the United States.[3]



Medicare is the single largest funding source for GME nationwide. There are two types of Medicare GME funding- direct GME and indirect GME. Direct GME payments support "overhead" aspects of residency programs, such as resident salaries and benefits, faculty salaries, and other administrative expenses. The payment amount is determined by a methodology that includes a hospital's "per resident amount," Medicare utilization rate, and number of full-time equivalent residents at the hospital.

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[1] Florida Department of Health, *Annual Report on Graduate Medical Education in Florida*, January 2010, page 6, available at: www.floridahealth.gov/provider-and-partner-resources/community-health-workers/physician-workforce-development-and-recruitment/gmereport2010.pdf (last viewed on March 7, 2014).

[2] Accreditation Council for Graduate Medical Education, *GME Data Resource Book-Academic Year 2012-2013*, page 24, available at http://acgme.org/acgmeweb/Portals/0/PFAssets/PublicationsBooks/2012-2013_ACGME_DATABook_DOCUMENT_Final.pdf (last viewed March 7, 2014).

[3] The Florida Legislature, Office of Program Policy Analysis & Government Accountability, *Florida's Graduate Medical Education System*, Report No. 14-08, February 2014, page 4, available at www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/1408rpt.pdf (last viewed on March 7, 2014).

Indirect GME, or IME, payments defray the higher costs of patient care associated with teaching hospitals, such as greater resources devoted to sicker and more medically-complex patients, the development and use of emerging technologies, and the decreased efficiencies realized by allowing residents to "learn by doing." The payment amount is determined by a methodology that includes the hospital's teaching intensity, diagnosis related group payments, and IME adjustment factor for the current year.

The estimated annual funding for GME in Florida is approximately $540 million, primarily from Medicare and Medicaid.[4] Other sources of funding for GME in Florida include the Community Health Education Program,[5] U.S. Department of Veterans Affairs, the Department of Defense, and private funding sources.[6]

The number of GME positions funded by Medicare has been stable since 1997, when it was capped by the federal Balanced Budget Act (BBA).[7] The cap was implemented due to the prediction of an oversupply of physicians. The cap limited federal spending on health care and aligned the number of GME positions with the number of U.S. medical graduates at the time. Hospitals that had GME positions existing at the time the BBA was enacted are essentially "frozen," for Medicare reimbursement purposes, at the number of positions that existed in 1997. Several Florida accredited GME institutions have self-funded additional GME positions since 1997.

Teaching hospitals that started residency programs after 1997 are also eligible for Medicare reimbursement for GME positions. These hospitals have a five-year window to establish the largest number of FTE residents in any residency program measured during the fifth program year.[8] The window opens when the hospital begins training residents in its first residency program.[9] The number of FTE residents determined by the methodology will be the hospital's permanent cap on residents.[10]

Medicaid GME Funding in Florida

In 2013, Senate Bill 1520 created the Statewide Medicaid Residency Program (Program) in the AHCA.[11] Through the Program, Medicaid GME dollars are removed from regular hospital reimbursement payments and are subject to a formula-based redistribution. Each hospital participating in the Program receives an annual allocation determined by a calculation of its percentage of total residents statewide and its percentage of total Medicaid inpatient reimbursement among participating hospitals. The law defines the primary factors that are used in each hospital's annual allocation as follows:

- A "resident" is defined as a medical intern, fellow, or resident enrolled in a program accredited by the ACGME, the American Association of Colleges of Osteopathic Medicine, or the AOA.[12]
- "Full-time equivalent" (FTE) is defined as a resident who is in his or her initial residency period (IRP), not to exceed five years. A resident training beyond the IRP is counted as one-half of one FTE, unless his or her chosen specialty is in general surgery or primary care, in which case the resident is counted as one FTE. For purposes of the Program, primary care specialties include:

[4] Id. at page 12.
[5] The Community Health Education Program (CHEP) was established in s. 381.0403, F.S., and was repealed in 2013 in s.1, ch. 2013-48, Laws of Fla. Some funding issued by the CHEP continues.
[6] See supra, FN 3.
[7] Pub. L. 105-33.
[8] Association of American Medical Colleges, *Becoming a New Teaching Hospital-A Guide to the Medicare Requirements*, January 2013, page 10 (on file with Select Committee for Health Care Workforce Innovation staff).
[9] Id.
[10] Id.
[11] S. 5, ch. 2013-48, Laws of Fla.; *see also* s. 409.909, F.S.
[12] S. 409.909(2)(c), F.S.

- Family medicine;
- General internal medicine;
- General pediatrics;
- Preventive medicine;
- Geriatric medicine;
- Osteopathic general practice;
- Obstetrics and gynecology; and
- Emergency medicine.[13]

- "Medicaid payments" are defined as payments made to reimburse a hospital for direct inpatient services, as determined by the AHCA, during the fiscal year preceding the date on which calculations for the Program's allocations take place for any fiscal year.[14]

The AHCA, on or before September 15, calculates an allocation fraction for each hospital participating in the Program, using the following formula:[15]

HAF = [0.9 x (HFTE/TFTE)] + [0.1 x (HMP/TMP)][16]

Where:

HAF = A hospital's total allocation fraction.
HFTE = A hospital's total number of full-time equivalent residents.
TFTE = The total full-time equivalent residents for all participating hospitals.
HMP = A hospital's Medicaid payments.
TMP = The total Medicaid payments for all participating hospitals.[17]

A hospital's annual allocation equals the funds appropriated for the Program in the General Appropriations Act multiplied by its allocation fraction.[18] If the annual allocation calculation exceeds $50,000 per FTE resident, the allocation will be reduced to equal $50,000 per FTE resident.[19] The excess funds will be redistributed to participating hospitals whose annual allocation does not exceed $50,000 per FTE resident.[20]

The AHCA is required to distribute to each participating hospital one-fourth of that hospital's annual allocation on the final business day of each quarter of a state fiscal year.[21] Total quarterly distribution under the methodology for FY 2013-2014 is $19,995,161, which has been distributed in two payments, on September 17, 2013, and December 11, 2013.[22]

OPPAGA Study on Florida's GME System

The Office of Program Policy Analysis and Government Accountability (OPPAGA) examined Florida's GME system and produced a report on their findings to the Legislature, which was provided in February 2014. The following are pertinent findings of GME programs during the 2013-2014 academic year, except where otherwise indicated:

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[13] S. 409.909(2)(a), F.S.
[14] S. 409.909(2)(b), F.S.
[15] S. 409.909(2), F.S.
[16] S. 409.909(3), F.S.
[17] Id.
[18] S. 409.909(4), F.S.
[19] Id.
[20] Id.
[21] See supra, FN 15.
[22] Agency for Health Care Administration, *Graduate Medical Education/Statewide Residency Program Overview, Reimbursement under Statewide Residency Program* (on file with Select Committee on Health Care Workforce Innovation staff).

- There are 53 accredited GME institutions in Florida, of which 44 are administering 407 residency programs with a total of 5,157 positions.[23]
- 21 GME programs are accredited by ACGME, 16 by AOA, and 7 programs are accredited by both.[24]
- Approximately 89 percent of the residency positions were filled.[25]
- Of the 407 residency programs, 24 percent are in primary care specialties, such as family medicine, internal medicine, and general surgery, 25 percent are non-primary care specialties, such as dermatology and neurology, and 51 percent are subspecialties, such as cardiology and nephrology.[26]
- Over 73 percent of GME positions were filled by graduates of out-of-state medical schools.[27]
- Overall, 94 percent of residents who started a GME position in 2006-07 completed the program by 2012-13.[28]
- GME institutions reported a 100 percent completion rate for the following GME programs:
    - Dermatology;
    - Geriatric medicine;
    - Neurology;
    - Obstetrics and gynecology; and
    - Psychiatry.
- Four other specialties had completion rates greater than 90 percent:
    - Pediatrics (99 percent)
    - Emergency medicine (98 percent)
    - Family medicine (93 percent)
    - Internal medicine (91 percent)
- From 2000 through 2013, 9,294 students graduated from Florida medical schools. 3,073 students, or 38 percent, matched to a Florida residency program and 5,094, or 62 percent, matched to an out-of-state residency program.[29]
- From 2000 through 2013, 72 percent of Florida medical school graduates who matched with a Florida-based residency program went to a primary care specialty.[30]

In order to maximize the state's return on its investment in educating and training the next generation of physicians and to stem any shortage of competent physicians in the areas of critical need, such as primary care specialties, it is essential to keep the residents who trained in Florida in the state when their residency is complete. A study cited in the OPPAGA report estimated that 47 percent of physicians stayed or returned to the state where they completed their most recent GME and 66 percent of physicians who completed undergraduate education and GME in the same state remained in that state.[31]

No systemic annual reporting or tracking of the data compiled by OPPAGA is currently in place. In its report, OPPAGA recommended collecting institution- and physician-level data, such as residency program type, size, and rotation sites; approved and filled residency positions; use of Medicare FTEs; and GME institution residency completion lengths and rates, to track and analyze GME programs and positions statewide.[32]

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[23] See supra, FN 3 at page 5.
[24] Id.
[25] Id. at page 7.
[26] Id. at page 6.
[27] See supra, FN 25.
[28] Id. at page 8.
[29] Id. at page 9.
[30] Id. at page 10.
[31] Association of American Medical Colleges, *2013 State Physician Workforce Data Book*, pages 46-47, available at https://members.aamc.org/eweb/upload/State%20Physician%20Workforce%20Data%20Book%202013%20(PDF).pdf (last viewed on March 8, 2014).
[32] Id. at page 15.

OPPAGA also suggested that the information be reported on an annual basis.[33] The data, according to OPPAGA, could help assess GME priorities and challenges and inform decisions about programs and positions and funding opportunities.[34]

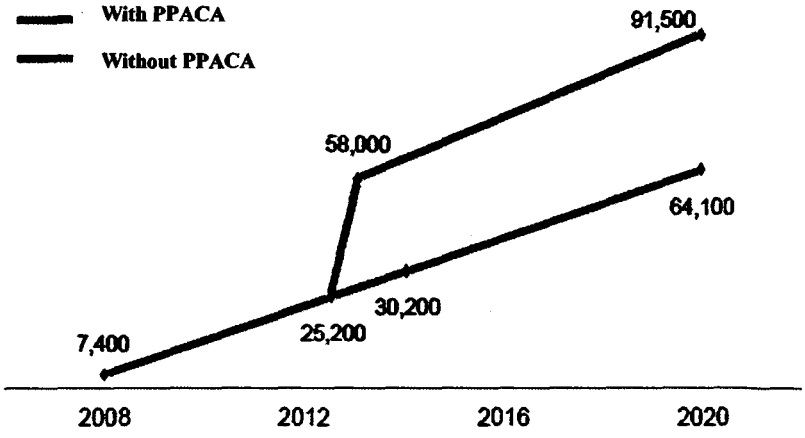
Physician Workforce Data

The Association of American Medical Colleges Center for Workforce Studies estimates that, in 2015, the U.S. will face a physician shortage of 62,900 that will increase to 130,000 across all specialties by 2025.[35]

In 2012, there were 260.5 physicians[36] actively practicing per 100,000 population in the U.S., ranging from a high of 421.5 in Massachusetts to a low of 180.8 in Mississippi. The states with the highest number of physicians per 100,000 population are concentrated in the northeastern states.[37] Regarding primary care physicians, there were 90.1 per 100,000 population.[38]

The following chart illustrates the projected physician shortage, nationally, with and without full implementation of the Patient Protection and Affordable Care Act.

National projected physician shortages



Source: Kirch DG, Henderson MK, Dill MJ (2011). "Physician Workforce Projections in an Era of Health Care Reform." *Annual Review of Medicine.*

Florida had 252.9 actively practicing physicians per 100,000 population in 2012. Although Florida is the fourth most populous state in the nation,[39] it ranks as having the 23rd highest physician to population ratio.[40] In 2012, Florida had a ratio of 84.8 primary care physicians per 100,000 population, ranking

[33] Id.
[34] Id.
[35] American Medical Association, "Reducing medical student debt strengthens the physician workforce," available at: http://www.ama-assn.org/resources/doc/mss/student-debt-mss-advocacy.pdf (last visited on February 14, 2014).
[36] These totals include allopathic and osteopathic doctors.
[37] AAMC, "2013 State Physician Workforce Data Book," November 2013, pg. 4, available at: https://www.aamc.org/download/362168/data/2013statephysicianworkforcedatabook.pdf (last visited on February 11, 2014).
[38] Id. at pg. 5.
[39] The U.S. Census Bureau estimated Florida to have 19,552,860 residents in 2013, behind California (38,332,521), Texas (26,448,193), and New York (19,651,127). U.S. Census Bureau, "Annual Estimates of the Resident Population: 2013 Population Estimates," available at: http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk (last visited on February 11, 2014).
[40] See supra, FN 37, at pg. 9.

Florida 30th compared to other states.[41] In 2013, 13.2 percent of Florida's physicians reported that they were planning to retire within the next five years, which will exacerbate Florida's shortage of physicians.[42]

As of November 2013, the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services designated approximately 5,800 locations in the U.S. as primary care Health Professional Shortage Areas (HPSAs).[43] Primary care HPSAs are based on a physician to population ratio of 1:3,500. In other words, when there are 3,500 or more people per primary care physician, an area is eligible to be designated as a primary care HPSA. Applying this formula, it would take approximately 7,500 additional primary care physicians to eliminate the current primary care HPSA designations, nationally.[44]

As of November 2014, there were 327 primary care HPSAs in Florida. Those HPSAs would need at least 890 primary care physicians to remove the HPSA designation. In addition to Florida's primary care HPSAs, the state has 275 dental HPSAs and 306 mental health care HPSAs, which would require 870 dentists and 155 psychiatrists, respectively, to remove the HPSA designation.[45]

A different analysis measured current primary care utilization (office visits) and projected the impact of population increases, aging, and insured status changes. The study found that the total number of office visits to primary care physicians will increase from 462 million in 2008 to 565 million in 2025, and (because of aging) the average number of visits will increase from 1.60 to 1.66. The study concluded that the U.S. will require 51,880 *additional* primary care physicians by 2025.[46] The table below illustrates the study's findings.

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[41] See supra, FN 37, at pg. 13.

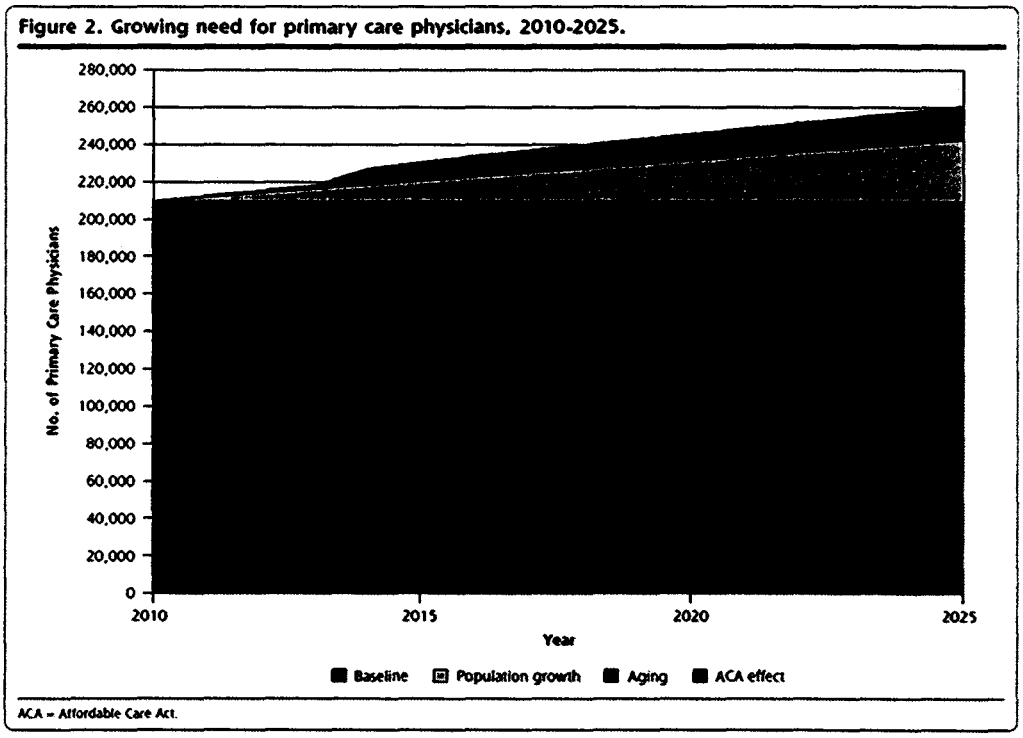
[42] Florida Department of Health, "2013 Physician Workforce Annual Report," available at: http://www.floridahealth.gov/provider-and-partner-resources/community-health-workers/physician-workforce-development-and-recruitment/physicianworkforce13final.pdf (last visited on February 11, 2014).

[43] U.S. Department of Health and Human Services, Health Resources and Services Administration, "Shortage Designation: Health Professional Shortage Areas & Medically Underserved Areas/Populations," available at: http://www.hrsa.gov/shortage/ (last visited on February 11, 2014).

[44] While the 1:3,500 ratio has been a long-standing ratio used to identify high need areas, it is important to note that there is no generally accepted ratio of physician to population ratio. Furthermore, primary care needs of an individual community will vary by a number of factors such as the age of the community's population. Additionally, the formula used to designate primary care HPSAs does not take into account the availability of additional primary care services provided by Nurse Practitioners and Physician Assistants in an area. U.S. Department of Health and Human Services, Health Resources and Services Administration, "Shortage Designation: Health Professional Shortage Areas & Medically Underserved Areas/Populations," available at: http://www.hrsa.gov/shortage/ (last visited on February 11, 2014).

[45] Florida Department of Health, Presentation on Health Care Workforce: Physician Workforce and Florida CHARTS Data, November 6, 2013, available at: http://myfloridahouse.gov/Sections/Documents/loaddoc.aspx?PublicationType=Committees&CommitteeId=2786&Session=2014&DocumentType=Meeting Packets&FileName=schcwi 11-6-13.pdf (last visited on February 11, 2014).

[46] Petterson, Stephen M., et al., "Projecting U.S. Primary Care Physician Workforce Needs: 2010-2025", Annals of Family Medicine, vol. 10, No. 6, Nov./Dec. 2012, available at: http://www.annfammed.org/content/10/6/503.full.pdf+html (last visited on February 24, 2014).



One factor contributing to the shortage of primary care physicians is that medical students are choosing to go into specialty practice to pay off large student loans that they have accumulated.[47] Physicians in 12 specialties, such as radiology, psychiatry and anesthesiology, may earn up to twice the income (from $191,000 to >$400,000 per year) of primary care physicians (from $183,000 to $201,000 per year).[48] It is estimated that 86% of the medical school graduating class of 2013 will have education-related debt.[49] With an average medical student debt of $169,901, debt plays a major role in medical students' career decisions.[50]

The type of residencies that are available to medical school graduates also has a role in those career decisions. Data on residencies funded by Medicare (1998-2008) indicates program growth is predominantly in subspecialty training and non-primary-care core specialties.[51] For example, 133 internal medicine subspecialty programs opened in that time. Conversely, there was a net loss of 390 first-year family medicine resident positions. Similarly, 865 general internal medicine positions were lost, converted to preliminary year positions, or offset by opportunities to subspecialize. Primary care also lost 40 family medicine and 25 internal medicine programs during this time. The chart below indicates the change in the number of first-year residency programs by specialty in that time.[52]

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[47] A study conducted by the Robert Graham Center found that the income gap between primary care and subspecialists has an impressively negative impact on choice of primary care specialties and of practicing in rural or underserved settings. Robert Graham Center, "What Influences Medical Student & Resident Choices?", March 2, 2009, available at: http://www.graham-center.org/online/etc/medialib/graham/documents/publications/mongraphs-books/2009/rgcmo-specialty-geographic.Par.0001.File.tmp/Specialty-geography-compressed.pdf (last visited on February 14, 2014).

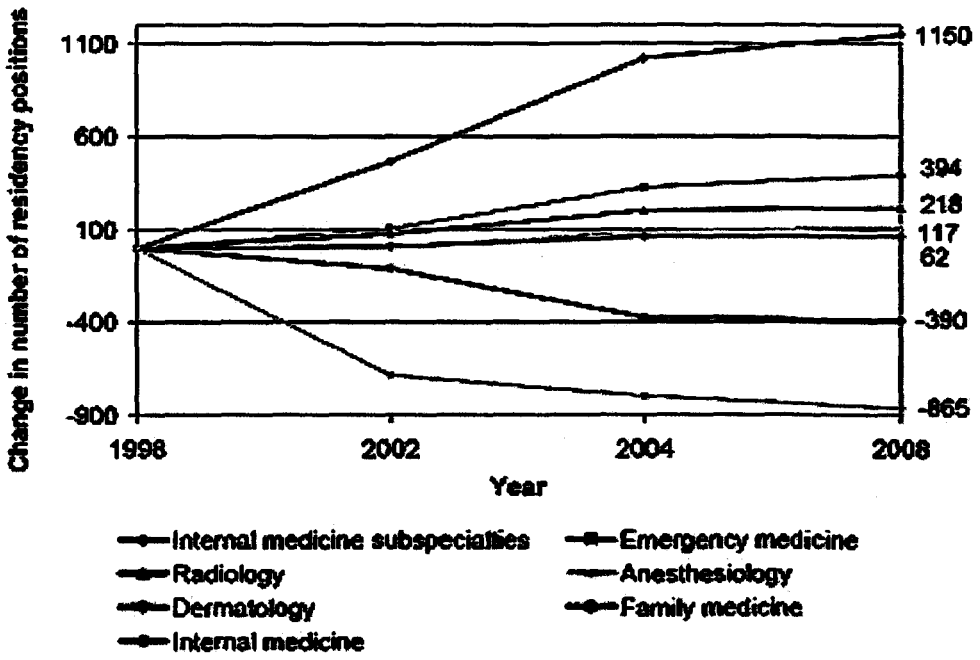
[48] Grayson, M., Newton, D., Thompson, L., "Payback time: the associations of debt and income with medical student career choice," *Medical Education*, Vol. 46, Issue 10, pg. 984, October 2012, on file with committee staff.

[49] Association of American Medical Colleges, "Medical Student Education: Debt, Costs, and Loan Repayment Fact Card," October 2013, available at: https://www.aamc.org/download/152968/data/debtfactcard.pdf (last visited on February 14, 2014).

[50] Id.

[51] Weida NA, Phillips RL Jr, Bazemore AW, Dodoo MS, Petterson SM, Xierali I, Teevan B., "Loss of Primary Care Residency Positions Amidst Growth in other Specialties. *Am Fam Physician*, 2010 Jul 15;82(2):121, available at: http://www.graham-center.org/online/graham/home/publications/onepagers/2010/op66-loss-primary.html (last visited on February 25, 2014).

[52] Id.



Several researchers have advocated the position that GME is a public good that should be supported by and held accountable to the public for the purpose of developing the number and specialty mix of physicians to meet public need.[53]

Physician Workforce Advisory Council

The Physician Workforce Advisory Council (Council) was created within the Department of Health (DOH) in 2010.[54] The Council consists of 19 members, including the State Surgeon General, who serves as its chair.[55] The remaining members are appointed by the State Surgeon General and include individuals from the medical community and the academic community.[56] The Council is required to meet at least twice a year[57], and must:

- Advise the State Surgeon General and the DOH on matters concerning current and future physician workforce needs;
- Review survey materials and the compilation of survey information;
- Annually review the number, location, cost, and reimbursement of graduate medical education programs and positions;
- Provide recommendations to the DOH regarding the survey completed by physicians licensed under chapter 458 or chapter 459;
- Assist the DOH in preparing the annual report to the Legislature pursuant to ss. 458.3192[58] and 459.0082, F.S.;[59]

[53] Josiah Macy Jr. Foundation, *Creating an Accountable Graduate Medical Education System-2011 Annual Report*, page 8, available at http://macyfoundation.org/docs/annual_reports/JMF_11_AnnualReport_WEBPDF.pdf (last viewed on March 8, 2014); see also Carnegie Foundation for the Advancement of Teaching, *News Release-Educating Physicians: A Call for Reform of Medical School and Residency*, June 2010, available at www.carnegiefoundation.org/newsroom/press-releases/educating-physicians-call-reform-medical-school-and-residency (last viewed on March 8, 2014).

[54] S. 29, ch. 2010-161, Laws of Fla.

[55] S. 381.4018(4)(c), F.S.

[56] S. 381.4018(4)(a), F.S.

[57] S. 381.4018(4)(e), F.S.

[58] The report referenced in this subparagraph contains information gathered from the Physician Surveys concerning the number of physicians who are delivering children in the state, reading mammograms, and performing on-call emergency care for a hospital ER department, and other physician-specific data.

[59] See supra, FN 58.

- Assist the DOH in preparing an initial strategic plan, conduct ongoing strategic planning in accordance with this section, and provide ongoing advice on implementing the recommendations;
- Monitor and provide recommendations regarding the need for an increased number of primary care or other physician specialties to provide the necessary current and projected health and medical services; and
- Monitor and make recommendations regarding the status of the needs relating to graduate medical education.[60]

Neither the Council nor the DOH collects or studies data on GME in Florida.

Effect of Proposed Changes

The bill requires the Council to conduct an annual survey of all state public and private allopathic and osteopathic medical schools, hospitals and other entities regarding GME programs in Florida. The collection of this information will allow GME programs, resident retention, and chosen practice areas to be tracked and analyzed statewide. Such analysis may include the performance of existing GME programs and identify the need for additional GME programs in certain specialties and subspecialties.

In developing the content and design of the survey, the bill requires the Council to consult with the Department of Economic Opportunity, the Board of Governors, and the Council of Florida Medical School Deans. The Council is also required to compile all of the survey responses to create the Statewide Graduate Medical Education Report and make it publicly available by July 1st each year.

The bill requires each medical school to report annually through the survey the following information for the preceding year:

- The number of students enrolled in the school who graduated from Florida-based programs;
- The number of students enrolled in the school who graduated from out-of-state programs;
- The number of students matched to a Florida residency program;
- The location and setting of each Florida residency program with a graduate from the school and number of graduates in each of those programs;
- The number of students matched to an out-of-state residency program;
- The location and setting of each out-of-state residency program with a graduate from the school and the number of graduates in each of those programs; and
- Any other data necessary to evaluate the physician workforce and develop strategies to increase the existing GME programs and create new GME programs in the state.

The bill requires each accredited GME institution to report annually through the survey the following information for the preceding year for each hospital or entity that serves as a rotating site for the institution:

- The number of approved GME program positions and the number of filled positions by primary care specialty, non-primary care specialty, and subspecialty;
- The number of Medicare FTE positions in the GME program;
- The location and setting of each GME program position;
- The cost of each GME program position;
- The amounts received and the sources of funding for the GME program, including, but not limited to, Medicare payments, Medicaid payments, Community Hospital Education Program funding, federal Health Resources and Services Administration funding, Department of Defense funding, and U.S. Department of Veterans Affairs funding;
- The GME program budget;

[60] S. 381.4018(4)(f)1, through 8., F.S.

- Completion rates by program for primary care specialties, non-primary care specialties, and subspecialties;
- The licensing test and board certification examination results by specialty and subspecialty, if applicable, for each resident completing her or his residency;
- The location and setting of each medical practice of each new physician who completed her or his residency;
- Any other data necessary to evaluate the physician workforce and develop strategies to increase the existing GME programs and create new GME programs in the state.

Each school and accredited GME institution must report its survey responses to the Council each year by January 1st.

The bill provides an effective date of July 1, 2014.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.4018, F.S., relating to physician workforce assessment and development.
Section 2: Provides an effective date of July 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The DOH is required to create survey forms for all state public and private allopathic and osteopathic medical school and all accredited GME institutions, which will have an indeterminate, but likely insignificant fiscal impact on the DOH. Expenditures required to carry out the provisions of the bill can be absorbed by DOH by utilizing current department resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Medical schools and accredited GME institutions may see an increase in administrative costs associated with gathering the necessary information to complete the survey, recording the information on the survey form, and submitting the survey to the DOH.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rule-making authority to the DOH to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to graduate medical education; amending s. 381.4018, F.S.; requiring the Physician Workforce Advisory Council within the Department of Health to conduct an annual survey of certain medical schools, hospitals, and other entities regarding graduate medical education programs; providing reporting criteria; requiring the department to consult with the Department of Economic Opportunity, the Board of Governors, and the Council of Florida Medical School Deans to develop survey content and design; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (f) of subsection (4) of section 381.4018, Florida Statutes, is amended, and subsection (5) is added to that section, to read:

381.4018 Physician workforce assessment and development.—

(4) PHYSICIAN WORKFORCE ADVISORY COUNCIL.—There is created in the department the Physician Workforce Advisory Council, an advisory council as defined in s. 20.03. The council shall comply with the requirements of s. 20.052, except as otherwise provided in this section.

(f) The council shall:

1. Advise the State Surgeon General and the department on

matters concerning current and future physician workforce needs in this state.~~,~~

2. Conduct an annual survey of all state public and private allopathic and osteopathic medical schools, hospitals, and other entities regarding graduate medical education programs in the state pursuant to subsection (5).

3.~~2.~~ Review survey materials and the compilation of survey information.~~,~~

~~3. Annually review the number, location, cost, and reimbursement of graduate medical education programs and positions,~~

4. Provide recommendations to the department regarding the survey completed by physicians licensed under chapter 458 or chapter 459.~~,~~

5. Assist the department in preparing the annual report to the Legislature pursuant to ss. 458.3192 and 459.0082.~~,~~

6. Assist the department in preparing an initial strategic plan, conduct ongoing strategic planning in accordance with this section, and provide ongoing advice on implementing the recommendations.~~,~~

7. Monitor and provide recommendations regarding the need for an increased number of primary care or other physician specialties to provide the necessary current and projected health and medical services for the state.~~, and~~

8. Monitor and make recommendations regarding the status of the needs relating to graduate medical education in this

state.

(5) GRADUATE MEDICAL EDUCATION PROGRAM REPORTING.—

(a) Each state public or private allopathic or osteopathic medical school shall report each year to the council by January 1, on a survey form furnished by the department, the following information for the preceding year:

1. The number of students enrolled in the school who matriculated from programs located in this state.

2. The number of students enrolled in the school who matriculated from an out-of-state program.

3. The number of students matched to a residency program in this state, the location and setting of each residency program in this state that has a graduate from the school currently in that residency program, and the number of graduates from the school in each residency program.

4. The number of students matched to an out-of-state residency program, the location and setting of each out-of-state residency program that has a graduate from the school currently in that residency program, and the number of graduates from the school in each residency program.

5. Any other data deemed necessary by the department to evaluate the physician workforce and develop strategies and policies to create and expand graduate medical education programs in this state.

(b) Each accredited graduate medical education institution shall report each year to the council by January 1, on a form

furnished by the department, the following information for the preceding year for each hospital or entity that serves as a rotating site for the institution:

1. The number of approved graduate medical education program positions in the hospital or entity by primary care specialty, nonprimary care specialty, and subspecialty and the number of filled positions.

2. The number of Medicare full-time equivalent positions in the graduate medical education program at the hospital or entity.

3. The location and setting of each graduate medical education program position.

4. The cost to the hospital or entity of each graduate medical education program position.

5. The amounts received and sources of funding for the hospital or entity's graduate medical education program, including, but not limited to, Medicare payments, Medicaid disproportionate share hospital payments, Statewide Medicaid Residency Program funding, community hospital education program funding, Health Resources and Services Administration funds, United States Department of Defense funds, and United States Department of Veterans Affairs funds.

6. The graduate medical education program budget for the hospital or entity.

7. Completion rates by program for primary care specialty, nonprimary care specialty, and subspecialty.

8. The licensing test and board certification examination results by specialty and subspecialty, if applicable, for each resident completing her or his residency.

9. The location and setting of each medical practice of each new physician who completed her or his residency.

10. Any other data deemed necessary by the department to evaluate the physician workforce and develop strategies and policies to create and expand graduate medical education programs in this state.

(c) The council shall compile all information received pursuant to paragraphs (a) and (b) to create the Statewide Graduate Medical Education Report, which shall be made available to the public by July 1 of each year.

(d) The department shall by rule adopt a survey form for purposes of this section. The department shall consult with the Department of Economic Opportunity, the Board of Governors, and the Council of Florida Medical School Deans to develop survey content and design.

Section 2. This act shall take effect July 1, 2014.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 7111 PCB HIS 14-02 Recovery Care Services
SPONSOR(S): Health Innovation Subcommittee, Steube
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health Innovation Subcommittee	7 Y, 5 N	Guzzo	Shaw
1) Health Care Appropriations Subcommittee		Clark	Pridgeon
2) Health & Human Services Committee			

SUMMARY ANALYSIS

Pursuant to s. 395.002, F.S., an ambulatory surgical center (ASC) is a facility, that is not a part of a hospital, the primary purpose of which is to provide elective surgical care, in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight. Federal law prohibits a patient from staying longer than 24 hours after admission.

The bill changes the allowable length of stay in an ASC from less than one working day to no more than 24 hours, which is the Federal length of stay standard.

The bill creates a new license for a Recovery Care Center (RCC). The new RCC license is modeled after the current licensing procedures for hospitals and ASCs subjecting RCCs to similar regulatory standards, inspections, and rules.

The bill defines RCC as a facility the primary purpose of which is to provide recovery care services. The bill defines recovery care services as:

- Postsurgical and post-diagnostic medical and general nursing care to patients for whom acute-hospitalization is not required and an uncomplicated recovery is reasonably expected; and
- Postsurgical rehabilitation services.

Recovery care services do not include intensive care services, coronary care services, or critical care services.

The bill requires all patients to be certified as medically stable and not in need of acute-hospitalization by their attending or referring physician prior to admission in an RCC. A patient may receive recovery care services in an RCC upon:

- Discharge from an ASC after surgery;
- Discharge from a hospital after surgery or other treatment; or
- Receiving an out-patient medical treatment such as chemotherapy.

RCCs must have emergency care and transfer protocols, including transportation arrangements, and referral or admission agreements with at least one hospital.

The bill has an indeterminate, but likely insignificant fiscal impact that can be managed within existing Agency for Health Care Administration resources.

The bill provides an effective date of July 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Ambulatory Surgical Centers (ASCs) - General

An ASC is a facility, that is not a part of a hospital, the primary purpose of which is to provide elective surgical care, in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight.[1]

Outpatient procedures account for a growing proportion of surgeries in the United States due to advances in surgical technology and anesthesia. Nationally, 63 percent of all surgeries in 2005 did not require an overnight hospital stay, compared to 51 percent in 1990 and 16 percent in 1980.[2]

In Florida, ambulatory procedures are performed in two settings, hospital-based outpatient facilities and freestanding ASCs. Currently, there are 633 ASCs in Florida, including 429 freestanding ASCs and 204 hospital-based facilities.[3]

In 2008, there were 3,121,428 visits to ASCs in Florida. The visits were equally split, with hospital outpatient facilities accounting for 50.8 percent and free standing ASCs accounting for 49.2 percent of the total number of visits. However, the breakdown of the $21 billion in total charges shows that hospital-based facilities accounted for 74 percent of the charges, while ASCs accounted for 26 percent. The average charge at the hospital-based facilities ($9,781) was larger than the average charge at the freestanding ASCs ($3,554).[4] These visits and charges were paid mainly by commercial Insurance and Medicare. Commercial insurance paid for 46.6 percent of all charges (a total of $9.8 billion), while Medicare paid for 39.1 percent ($8.2 billion). The other three payer groups (Medicaid, Other Government and Self-Pay/Charity) accounted for a total of 14.3% ($3.1 billion) of the charge total. The data and results have been similar since 2006.[5]

In 2012, there were 4,396,508 surgical procedures performed in ASCs in Florida. The top three procedures accounting for the highest percentage of visits to ASCs were upper gastrointestinal endoscopy, colonoscopy, and cataract removal.[6]

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[1] Section 395.002(3), F.S. "Ambulatory surgical center" or "mobile surgical facility" means a facility the primary purpose of which is to provide elective surgical care, in which the patient is admitted to and discharged from such facility within the same working day and is not permitted to stay overnight, and which is not part of a hospital. However, a facility existing for the primary purpose of performing terminations of pregnancy, an office maintained by a physician for the practice of medicine, or an office maintained for the practice of dentistry shall not be construed to be an ambulatory surgical center, provided that any facility or office which is certified or seeks certification as a Medicare ambulatory surgical center shall be licensed as an ambulatory surgical center pursuant to s. 395.003. Any structure or vehicle in which a physician maintains an office and practices surgery, and which can appear to the public to be a mobile office because the structure or vehicle operates at more than one address, shall be construed to be a mobile surgical facility.

[2] U.S. Department of Health and Human Services; Agency for Healthcare Research and Quality; *Healthcare Cost and Utilization Project; Statistical Brief #86* (February 2010).

[3] Agency for Health Care Administration, Facilities: All Florida Outpatient Ambulatory Surgical Centers, available at http://www.floridahealthfinder.gov/CompareCare/ListFacilities.aspx (report generated February 23, 2014).

[4] Agency for Health Care Administration, *Statistical Brief, Ambulatory Surgery Procedures in Florida, by Payer and Gender, 2008,* July 2010.

[5] Agency for Health Care Administration, *Data Summaries and Reports, Total Outpatient Visits by Facility Type 1992-2012,* available at http://www.floridahealthfinder.gov/researchers/QuickStat/quickstat.aspx (last visited February 23, 2014).

[6] Agency for Health Care Administration, *Ambulatory Surgery and Outpatient Procedures, 2012, Total Visits by Category.*

ASC - Licensure

ASCs are licensed and regulated by the Agency for Health Care Administration (AHCA) under the same regulatory framework as hospitals.[7]

Applicants for ASC licensure must submit certain information to AHCA prior to accepting patients for care or treatment, including the:[8]

- Affidavit of compliance with fictitious name;
- Registration of articles of incorporation; and
- ASC's zoning certificate or proof of compliance with zoning requirements.

Upon receipt of an initial application, AHCA is required to conduct a survey to determine compliance with all laws and rules. ASCs are required to provide certain information during the initial inspection, including the:[9]

- Governing body bylaws, rules and regulations;
- Roster of registered nurses and licensed practical nurses with current license numbers;
- Fire plan; and
- Comprehensive Emergency Management Plan.

Rules for ASCs

Pursuant to s. 395.1055, F.S., AHCA is authorized to adopt rules for hospitals and ASCs. Separate standards may be provided for general and specialty hospitals, ASCs, mobile surgical facilities, and statutory rural hospitals, but the rules for all hospitals and ASCs must include minimum standards for ensuring that:

- A sufficient number of qualified types of personnel and occupational disciplines are on duty and available at all times to provide necessary and adequate patient care;
- Infection control, housekeeping, sanitary conditions, and medical record procedures are established and implemented to adequately protect patients;
- A comprehensive emergency management plan is prepared and updated annually;
- Licensed facilities are established, organized, and operated consistent with established standards and rules; and
- Licensed facility beds conform to minimum space, equipment, and furnishing standards

AHCA adopted rule 59A-5, F.A.C., to implement the minimum standards for ASCs.

Staff and Personnel Rules

ASCs are required to have written policies and procedures for surgical services, anesthesia services, nursing services, pharmaceutical services, and laboratory and radiologic services. In providing these services, ACSs are required have certain professional staff available, including:[10]

- A Registered nurse to serve as operating room circulating nurse;
- An Anesthesiologist or other physician, or a certified registered nurse anesthetist under the on-site medical direction of a licensed physician in the ASC during the anesthesia and post-anesthesia recovery period until all patients are alert or discharged; and
- A Registered professional nurse in the recovery area during the patient's recovery period.

[7] Sections 395.001-395.1065, F.S., and Part II, Chapter 408, F.S.
[8] Rule 59A-5.003(4), F.A.C.
[9] Rule 59A-5.003(5), F.A.C.
[10] Rule 59A-5.0085, F.A.C.

Infection Control Rules

ASCs are required to establish an infection control program, which must include written policies and procedures reflecting the scope of the infection control program. The written policies and procedures must be reviewed at least every two years by the infection control program members. The infection control program must include:[11]

- Surveillance, prevention, and control of infection among patients and personnel;
- A system for identifying, reporting, evaluating and maintaining records of infections;
- Ongoing review and evaluation of aseptic, isolation and sanitation techniques employed by the ASC; and
- Development and coordination of training programs in infection control for all personnel.

Emergency Management Plan Rules

ASCs are required to develop and adopt a written comprehensive emergency management plan for emergency care during an internal or external disaster or emergency. The ASC must review the plan and update it annually.

Accreditation

ASCs may seek voluntary accreditation by the Joint Commission for Health Care Organizations or the Accreditation Association for Ambulatory Health Care. AHCA is required to conduct an annual licensure inspection survey for non-accredited ASCs. AHCA is authorized to accept survey reports of accredited ASCs from accrediting organizations if the standards included in the survey report are determined to document that the ASC is in substantial compliance with state licensure requirements. AHCA is required to conduct annual validation inspections on a minimum of 5 percent of the ASCs which were inspected by an accreditation organization.[12]

AHCA is required to conduct annual life safety inspections of all ASCs to ensure compliance with life safety codes and disaster preparedness requirements. However, the life-safety inspection may be waived if an accreditation inspection was conducted on an ASC by a certified life safety inspector and the ASC was found to be in compliance with the life safety requirements.[13]

Currently, 373 of the 429 total licensed ASCs in Florida are accredited by a national accrediting organization.[14]

Federal Requirements

Medicare

ASCs are required to have an agreement with the Centers for Medicare and Medicaid Services (CMS) to participate in Medicare. ASCs are also required to comply with specific conditions for coverage. CMS defines "ASC" as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours[15] following an admission.[16]

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[11] Rule 59A-5.011, F.A.C.
[12] Rule 59A-5.004, F.A.C.
[13] *Id.*
[14] Agency for Health Care Administration, *Ambulatory Surgical Center Regulatory Overview,* March 2014. (on file with subcommittee staff).
[15] State Operations Manual Appendix L, *Guidance for Surveyors: Ambulatory Surgical Centers* (Rev. 99, 01-31-14) exceeding the 24-hour time frame is expected to be a rare occurrence, and each rare occurrence is expected to be demonstrated to have been something which ordinarily could not have been foreseen. Not meeting this requirement constitutes condition-level noncompliance with §416.25. In addition, review of the cases that exceed the time frame may also reveal noncompliance with CfCs related to surgical services, patient admission and assessment, and quality assurance/performance improvement.
[16] Section 416.2, Title 42, C.F.R.

CMS may deem an ASC to be in compliance with all of the conditions for coverage if the ASC is accredited by a national accrediting body, or licensed by a state agency, that CMS determines provides reasonable assurance that the conditions are met.[17] All of the CMS conditions for coverage requirements are specifically required in AHCA rule 59A-5, F.A.C., and apply to all ASCs in Florida. The conditions for coverage require ASCs to have a:

- Governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation;
- Quality assessment and performance improvement program;
- Transfer agreement with one or more acute care general hospitals, which will admit any patient referred who requires continuing care;
- Disaster preparedness plan;
- Organized medical staff;
- Fire control plan;
- Sanitary environment;
- Infection control program;
- Procedure for patient admission, assessment and discharge;

Recovery Care Centers

Recovery care centers (RCCs) are entities that provide short-term nursing care, support, and pain control for patients that do not require acute hospitalization.[18] RCC patients are typically healthy persons that have had elective surgery. RCCs can be either freestanding or attached to an ASC or hospital. In practice, RCCs typically provide care to patients transferred from ASCs following surgery, which allows ASCs to perform more complex procedures.[19]

RCCs are not eligible for Medicare reimbursement.[20] One 1999 survey noted that RCCs received payment in the following breakdown: 41% from managed care plans, 29% from self-pay, 16% from indemnity plans, and 9% from workers' compensation.[21]

Three states, Arizona, Connecticut, and Illinois, have specific licenses for "recovery care centers."[22] Other states license RCCs as nursing facilities or hospitals.[23] One study found that eighteen states allow RCCs to have stays over 24 hours, usually with a max stay of 72 hours.[24]

[17] Section 416.26(1), Title 42, C.F.R.
[18] MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: MEDICARE PAYMENT FOR POST-SURGICAL RECOVERY CARE CENTERS 3 (2000).
[19] *Id.* at 4.
[20] *See* MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 7.
[21] MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 7, at 6 (citing Federated Ambulatory Surgery Association, Post-Surgical Recovery Care, (2000)).
[22] ARIZ. REV. STAT. ANN. §§ 36-448.51-36-448.55; CONN. AGENCIES REGS. § 19A-495-571; 210 ILL. COMP. STAT. ANN. 3/35.
[23] Sandra Lee Breisch, *Profits in Short Stays*, AM. ACAD. OF ORTHOPAEDIC SURGEONS BULLETIN (June, 1999), *available at* http://www2.aaos.org/bulletin/jun99/asc.htm.
[24] MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 7, at 4 (citing Federated Ambulatory Surgery Association, Post-Surgical Recovery Care, (2000)).

Comparison of RCC Regulations in Arizona, Connecticut, and Illinois

	Arizona[25]	Connecticut[26]	Illinois[27]
Licensure Required	X	X	X
Written Policies	X	X	X
Maintain Medical Records	X	X	X
Patient's Bill of Rights	X	X	X
Allows Freestanding Facility or Attached	Not Available.	X	X
Length of Stay	Not Available.	Expected 3 days Max 21 days	Expected 48 hours Max 72 hours
Emergency Care Transfer Agreement	Not Available.	With a hospital and an ambulance service.	With a hospital within fifteen minutes travel time.
Prohibited Patients	Patients needing: • Intensive care • Coronary care • Critical care	Patients needing: • Intensive care • Coronary care • Critical care	• Patients with chronic infectious conditions • Children under 3 years of age
Prohibited Services	• Surgical • Radiological • Pediatric • Obstetrical	• Surgical • Radiological • Pre-adolescent pediatric • Hospice • Obstetrical services over 24 week gestation • Intravenous therapy for non-hospital based RCC	• Blood administration (only blood products allowed)
Required Services	• Laboratory • Pharmaceutical • Food	• Pharmaceutical • Dietary • Personal care • Rehabilitation • Therapeutic • Social work	• Laboratory • Pharmaceutical • Food • Radiological
Bed Limitation	Not Available.	Not Available.	20
Required Staff	• Governing authority • Administrator	• Governing body • Administrator	• Consulting committee
Required Medical Personnel	• At least two physicians • Director of nursing	• Medical advisory board • Medical director • Director of nursing	• Medical director • Nursing supervisor
Required Personnel When Patients Are Present	• Director of nursing forty hours per week • One registered nurse • One other nurse	• Two persons for patient care	• One registered nurse • One other nurse

[25] ARIZ. REV. STAT. ANN. §§ 36-448.51-36-448.55; ARIZ. ADMIN. CODE §§ R9-10-501-R9-10-518 (updated in 2013, formerly R9-10-1401-R9-10-1412).
[26] CONN. AGENCIES REGS. § 19A-495-571.
[27] 210 ILL. COMP. STAT. ANN. 3/35; ILL. ADMIN. CODE tit. 77, §§ 210.2500 & 210.2800.

Effect of Proposed Changes

Pursuant to s. 395.002(3), F.S., patients receiving services in an ASC must be discharged on the same working day that they were admitted and they are not permitted to stay overnight. Federal regulations limit the length of stay in an ASC to 24 hours following admission. The bill amends s. 395.002(3), F.S., to allow a patient to stay at an ASC for no longer than 24 hours to conform to the federal length of stay requirements.

The bill creates a new license for a Recovery Care Center (RCC). The new RCC license is modeled after the current licensing procedures for hospitals and ASCs in Chapters 395 and 408, F.S. The bill adds RCCs to the list of facilities subject to the provisions of Chapter 395, Part I. An applicant for RCC licensure will have to follow the general licensing procedures of Chapter 408, Part II. Additionally, the applicant will be subject to the license, inspection, safety, facility and other requirements of Chapter 395, Part I.

The bill defines RCC as a facility the primary purpose of which is to provide recovery care services. The bill defines recovery care services are defined as:

- Postsurgical and post-diagnostic medical and general nursing care to patients for whom acute-hospitalization is not required and an uncomplicated recovery is reasonably expected; and
- Postsurgical rehabilitation services.

Recovery care services do not include intensive care services, coronary care services, or critical care services.

The bill requires all patients to be certified as medically stable and not in need of acute-hospitalization by their attending or referring physician prior to admission in an RCC. A patient may receive recovery care services in an RCC upon:

- Discharge from an ASC after surgery;
- Discharge from a hospital after surgery or other treatment; or
- Receiving an out-patient medical treatment such as chemotherapy.

RCCs must have emergency care and transfer protocols, including transportation arrangements, and referral or admission agreements with at least one hospital.

Further, AHCA is authorized to adopt rules to implement admission and discharge procedures.

Section 395.1055, F.S., directs AHCA to adopt rules for hospitals and ASCs that set standards to ensure patient safety, including requirements for:

- Staffing;
- Infection control;
- Housekeeping;
- Medical records;
- Emergency management;
- Inspections;
- Accreditation;
- Organization, including a governing body and organized medical staff;
- Departments and services;
- Quality assessment and improvement;
- Minimum space; and
- Equipment and furnishings.

The bill authorizes AHCA to adopt by rule appropriate standards for RCCs.

In addition, the bill requires AHCA to adopt rules to set standards for dietetic departments, proper use of medications, and pharmacies in RCCs.

The license fee for the RCC license will be set by rule by AHCA and must be at least $1,500.[28]

B. SECTION DIRECTORY:

Section 1: Amends s. 395.001, F.S., relating to legislative intent.
Section 2: Amends s. 395.002, F.S., relating to definitions.
Section 3: Amends s. 395.003, F.S., relating to licensure; denial, suspension, and revocation.
Section 4: Creates s. 395.0171, F.S., relating to recovery care center admissions; emergency and transfer protocols; discharge planning and protocols.
Section 5: Amends s. 395.1055, F.S., relating to rules and enforcement.
Section 6: Amends s. 395.10973, F.S., relating to powers and duties of the agency.
Section 7: Amends s. 395.301, F.S., relating to itemized patient bill; form and content prescribed by the agency.
Section 8: Amends s. 408.802, F.S., relating to applicability.
Section 9: Amends s. 408.820, F.S., relating to exemptions.
Section 10: Provides an effective date of July 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Section 408.805, F.S., requires AHCA to set license fees that are reasonably calculated to cover the cost of regulation. The AHCA estimates that five entities may apply for licensure. These applicants will be subject to a Plans and Construction project review fee of $2,000 plus $300 per hour for building plan reviews, an application fee of at least $1,500, and a licensure inspection fee of $400.[29]

2. Expenditures:

   The creation of the RCC license will require AHCA to regulate these facilities in accordance with chapters 395 and 408, F.S., and any rules adopted by AHCA. This will result in a minimal negative fiscal impact; however, the fees associated with the new license are anticipated to cover the expenses incurred by AHCA in enforcement and regulation of the new license.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Individuals needing surgery may save money by being able to stay longer in an ASC or stay in an RCC rather than having to be transferred to a hospital.

Being able to keep patients longer in an ASC may have a positive fiscal impact on the ASC by being able to perform more complex procedures.

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[28] Section 395.004, F.S.
[29] AHCA Agency Bill Analysis, dated March 20, 2014 (on file with Health Care Appropriations Subcommittee Staff).

Hospitals may experience a negative fiscal impact if patients receive care in an ASC or RCC.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rule-making authority to AHCA to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to recovery care services; amending s. 395.001, F.S.; providing legislative intent regarding recovery care centers; amending s. 395.002, F.S.; revising and providing definitions; amending s. 395.003, F.S.; including recovery care centers as facilities licensed under chapter 395, F.S.; creating s. 395.0171, F.S.; providing admission criteria for a recovery care center; requiring emergency care, transfer, and discharge protocols; authorizing the Agency for Health Care Administration to adopt rules; amending s. 395.1055, F.S.; authorizing the agency to establish separate standards for the care and treatment of patients in recovery care centers; amending s. 395.10973, F.S.; directing the agency to enforce special-occupancy provisions of the Florida Building Code applicable to recovery care centers; amending s. 395.301, F.S.; providing for format and content of a patient bill from a recovery care center; amending s. 408.802, F.S.; providing applicability of the Health Care Licensing Procedures Act to recovery care centers; amending s. 408.820, F.S.; exempting recovery care centers from specified minimum licensure requirements; amending ss. 394.4787, 409.97, and 409.975, F.S.; conforming cross-references; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 395.001, Florida Statutes, is amended to read:

395.001 Legislative intent.—It is the intent of the Legislature to provide for the protection of public health and safety in the establishment, construction, maintenance, and operation of hospitals, ambulatory surgical centers, recovery care centers, and mobile surgical facilities by providing for licensure of same and for the development, establishment, and enforcement of minimum standards with respect thereto.

Section 2. Subsections (25) through (33) of section 395.002, Florida Statutes, are renumbered as subsections (27) through (35), respectively, subsections (3), (16), and (23) are amended, and new subsections (25) and (26) are added to that section, to read:

395.002 Definitions.—As used in this chapter:

(3) "Ambulatory surgical center" or "mobile surgical facility" means a facility the primary purpose of which is to provide elective surgical care, in which the patient is admitted to and discharged from such facility within 24 hours ~~the same working day and is not permitted to stay overnight,~~ and which is not part of a hospital. However, a facility existing for the primary purpose of performing terminations of pregnancy, an office maintained by a physician for the practice of medicine,

or an office maintained for the practice of dentistry shall not be construed to be an ambulatory surgical center, provided that any facility or office which is certified or seeks certification as a Medicare ambulatory surgical center shall be licensed as an ambulatory surgical center pursuant to s. 395.003. Any structure or vehicle in which a physician maintains an office and practices surgery, and which can appear to the public to be a mobile office because the structure or vehicle operates at more than one address, shall be construed to be a mobile surgical facility.

(16) "Licensed facility" means a hospital, ambulatory surgical center, recovery care center, or mobile surgical facility licensed in accordance with this chapter.

(23) "Premises" means those buildings, beds, and equipment located at the address of the licensed facility and all other buildings, beds, and equipment for the provision of hospital, ambulatory surgical, recovery, or mobile surgical care located in such reasonable proximity to the address of the licensed facility as to appear to the public to be under the dominion and control of the licensee. For any licensee that is a teaching hospital as defined in s. 408.07(45), reasonable proximity includes any buildings, beds, services, programs, and equipment under the dominion and control of the licensee that are located at a site with a main address that is within 1 mile of the main address of the licensed facility; and all such buildings, beds, and equipment may, at the request of a licensee or applicant, be

included on the facility license as a single premises.

(25) "Recovery care center" means a facility the primary purpose of which is to provide recovery care services.

(26) "Recovery care services" means postsurgical and postdiagnostic medical and general nursing care provided to patients for whom acute care hospitalization is not required and an uncomplicated recovery is reasonably expected. The term includes postsurgical rehabilitation services. The term does not include intensive care services, coronary care services, or critical care services.

Section 3. Subsection (1) of section 395.003, Florida Statutes, is amended to read:

395.003 Licensure; denial, suspension, and revocation.—

(1)(a) The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to ss. 395.001-395.1065 and part II of chapter 408 and to entities licensed by or applying for such licensure from the Agency for Health Care Administration pursuant to ss. 395.001-395.1065. A license issued by the agency is required in order to operate a hospital, ambulatory surgical center, recovery care center, or mobile surgical facility in this state.

(b)1. It is unlawful for a person to use or advertise to the public, in any way or by any medium whatsoever, any facility as a "hospital," "ambulatory surgical center," "recovery care center," or "mobile surgical facility" unless such facility has first secured a license under the provisions of this part.

2. This part does not apply to veterinary hospitals or to commercial business establishments using the word "hospital," "ambulatory surgical center," "recovery care center," or "mobile surgical facility" as a part of a trade name if no treatment of human beings is performed on the premises of such establishments.

(c) Until July 1, 2006, additional emergency departments located off the premises of licensed hospitals may not be authorized by the agency.

Section 4. Section 395.0171, Florida Statutes, is created to read:

395.0171 Recovery care center admissions; emergency and transfer protocols; discharge planning and protocols.—

(1) Admissions to a recovery care center shall be restricted to patients who need recovery care services.

(2) All patients must be certified by their attending or referring physician or by a physician on staff at the facility as medically stable and not in need of acute care hospitalization before admission.

(3) A patient may be admitted for recovery care services upon discharge from a hospital or an ambulatory surgery center. A patient may also be admitted postdiagnosis and posttreatment for recovery care services.

(4) A recovery care center must have emergency care and transfer protocols, including transportation arrangements, and referral or admission agreements with at least one hospital.

(5) A recovery care center must have procedures for discharge planning and discharge protocols.

(6) The agency may adopt rules to implement this subsection.

Section 5. Subsections (2) and (8) of section 395.1055, Florida Statutes, are amended, and subsection (10) is added to that section, to read:

395.1055 Rules and enforcement.—

(2) Separate standards may be provided for general and specialty hospitals, ambulatory surgical centers, recovery care centers, mobile surgical facilities, and statutory rural hospitals as defined in s. 395.602.

(8) The agency may not adopt any rule governing the design, construction, erection, alteration, modification, repair, or demolition of any public or private hospital, intermediate residential treatment facility, recovery care center, or ambulatory surgical center. It is the intent of the Legislature to preempt that function to the Florida Building Commission and the State Fire Marshal through adoption and maintenance of the Florida Building Code and the Florida Fire Prevention Code. However, the agency shall provide technical assistance to the commission and the State Fire Marshal in updating the construction standards of the Florida Building Code and the Florida Fire Prevention Code which govern hospitals, intermediate residential treatment facilities, recovery care centers, and ambulatory surgical centers.

(10) The agency shall adopt rules for recovery care centers which include fair and reasonable minimum standards for ensuring that recovery care centers have:

(a) A dietetic department, service, or other similarly titled unit, either on the premises or under contract, which shall be organized, directed, and staffed to ensure the provision of appropriate nutritional care and quality food service.

(b) Procedures to ensure the proper administration of medications. Such procedures shall address the prescribing, ordering, preparing, and dispensing of medications and appropriate monitoring of the effects of such medications on the patient.

(c) A pharmacy, pharmaceutical department, or pharmaceutical service, or similarly titled unit, on the premises or under contract.

Section 6. Subsection (8) of section 395.10973, Florida Statutes, is amended to read:

395.10973 Powers and duties of the agency.—It is the function of the agency to:

(8) Enforce the special-occupancy provisions of the Florida Building Code which apply to hospitals, intermediate residential treatment facilities, recovery care centers, and ambulatory surgical centers in conducting any inspection authorized by this chapter and part II of chapter 408.

Section 7. Subsection (3) of section 395.301, Florida

Statutes, is amended to read:

395.301 Itemized patient bill; form and content prescribed by the agency.—

(3) On each itemized statement submitted pursuant to subsection (1) there shall appear the words "A FOR-PROFIT (or NOT-FOR-PROFIT or PUBLIC) HOSPITAL (or AMBULATORY SURGICAL CENTER or RECOVERY CARE CENTER) LICENSED BY THE STATE OF FLORIDA" or substantially similar words sufficient to identify clearly and plainly the ownership status of the licensed facility. Each itemized statement must prominently display the phone number of the medical facility's patient liaison who is responsible for expediting the resolution of any billing dispute between the patient, or his or her representative, and the billing department.

Section 8. Subsection (30) is added to section 408.802, Florida Statutes, to read:

408.802 Applicability.—The provisions of this part apply to the provision of services that require licensure as defined in this part and to the following entities licensed, registered, or certified by the agency, as described in chapters 112, 383, 390, 394, 395, 400, 429, 440, 483, and 765:

(30) Recovery care centers, as provided under part I of chapter 395.

Section 9. Subsection (29) is added to section 408.820, Florida Statutes, to read:

408.820 Exemptions.—Except as prescribed in authorizing

statutes, the following exemptions shall apply to specified requirements of this part:

(29) Recovery care centers, as provided under part I of chapter 395, are exempt from s. 408.810(7)-(10).

Section 10. Subsection (7) of section 394.4787, Florida Statutes, is amended to read:

394.4787 Definitions; ss. 394.4786, 394.4787, 394.4788, and 394.4789.—As used in this section and ss. 394.4786, 394.4788, and 394.4789:

(7) "Specialty psychiatric hospital" means a hospital licensed by the agency pursuant to s. 395.002(30) ~~395.002(28)~~ and part II of chapter 408 as a specialty psychiatric hospital.

Section 11. Paragraph (a) of subsection (4) of section 409.97, Florida Statutes, is amended to read:

409.97 State and local Medicaid partnerships.—

(4) HOSPITAL RATE DISTRIBUTION.—

(a) The agency is authorized to implement a tiered hospital rate system to enhance Medicaid payments to all hospitals when resources for the tiered rates are available from general revenue and such contributions pursuant to subsection (1) as are authorized under the General Appropriations Act.

1. Tier 1 hospitals are statutory rural hospitals as defined in s. 395.602, statutory teaching hospitals as defined in s. 408.07(45), and specialty children's hospitals as defined in s. 395.002(30) ~~395.002(28)~~.

2. Tier 2 hospitals are community hospitals not included

in Tier 1 that provided more than 9 percent of the hospital's total inpatient days to Medicaid patients and charity patients, as defined in s. 409.911, and are located in the jurisdiction of a local funding source pursuant to subsection (1).

3. Tier 3 hospitals include all community hospitals.

Section 12. Paragraph (b) of subsection (1) of section 409.975, Florida Statutes, is amended to read:

409.975 Managed care plan accountability.—In addition to the requirements of s. 409.967, plans and providers participating in the managed medical assistance program shall comply with the requirements of this section.

(1) PROVIDER NETWORKS.—Managed care plans must develop and maintain provider networks that meet the medical needs of their enrollees in accordance with standards established pursuant to s. 409.967(2)(c). Except as provided in this section, managed care plans may limit the providers in their networks based on credentials, quality indicators, and price.

(b) Certain providers are statewide resources and essential providers for all managed care plans in all regions. All managed care plans must include these essential providers in their networks. Statewide essential providers include:

1. Faculty plans of Florida medical schools.

2. Regional perinatal intensive care centers as defined in s. 383.16(2).

3. Hospitals licensed as specialty children's hospitals as defined in s. 395.002(30) ~~395.002(28)~~.

4. Accredited and integrated systems serving medically complex children that are comprised of separately licensed, but commonly owned, health care providers delivering at least the following services: medical group home, in-home and outpatient nursing care and therapies, pharmacy services, durable medical equipment, and Prescribed Pediatric Extended Care.

Managed care plans that have not contracted with all statewide essential providers in all regions as of the first date of recipient enrollment must continue to negotiate in good faith. Payments to physicians on the faculty of nonparticipating Florida medical schools shall be made at the applicable Medicaid rate. Payments for services rendered by regional perinatal intensive care centers shall be made at the applicable Medicaid rate as of the first day of the contract between the agency and the plan. Payments to nonparticipating specialty children's hospitals shall equal the highest rate established by contract between that provider and any other Medicaid managed care plan.

Section 13. This act shall take effect July 1, 2014.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 7111 (2014)

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Care Appropriations Subcommittee

Representative Steube offered the following:

Amendment

Remove lines 80-81 and insert:

(25) "Recovery care center" means a facility the primary purpose of which is to provide recovery care services in which the patient is admitted to and discharged from such facility within 72 hours and which is not part of a hospital.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 7113 PCB HIS 14-01 Health Care
SPONSOR(S): Health Innovation Subcommittee, Brodeur
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health Innovation Subcommittee	8 Y, 4 N	Poche	Shaw
1) Health Care Appropriations Subcommittee		Pridgeon	Pridgeon
2) Health & Human Services Committee			

SUMMARY ANALYSIS

The regulation of trauma centers in Florida is governed by Part II of Chapter 395, F.S., and administered by the Department of Health (DOH) by rule in chapter 64J-2, F.A.C. A trauma center is a type of hospital that provides trauma surgeons, neurosurgeons, and other surgical and non-surgical specialists and medical personnel, equipment, and facilities for immediate or follow-up treatment of severely injured patients. Florida's trauma system is comprised of seven trauma regions and nineteen trauma service areas (TSAs). The DOH is required to apportion, by rule, the number of trauma centers needed for each TSA. In Florida, there are Level I, Level II, and pediatric trauma centers, each of which must meet certain standards of care, quality of care requirements, and patient outcomes standards.

House Bill 7113 includes legislative findings that an integrated, comprehensive, and superior quality trauma system is necessary to protect the health, safety and welfare of Floridians and visitors to the state; that each trauma center currently operating as a trauma center is an integral part of the trauma system and fulfills a critical need for trauma care services in the area where it is located; that a disruption in the operation of a trauma center may disrupt the availability of needed trauma services; and that all currently operating trauma centers are contributing to the trauma system and delivering needed trauma services so that optimal trauma care is available and accessible throughout the state.

Legal challenges to the rule established by the DOH to apportion trauma centers in the TSAs and approve provisional and verified trauma centers, and other litigation, threaten the ongoing inclusive trauma system in the state.

The bill permits a hospital that has operated continuously as a Level I, Level II, or pediatric trauma center for a consecutive 12-month period after enactment of certain laws and submits an application to the American College of Surgeons Committee on Trauma (ACS COT) for a site visit to obtain a consultation report to continue to operate as a trauma center, if it continues to meet the trauma center and patient outcome requirements in s. 395.4025(6), F.S. The new requirement allows all trauma centers currently operating as trauma centers to remain an approved trauma center and ensure the continued operation of a stable, inclusive trauma system.

Any trauma center that obtains a consultation report from the ACS COT must provide a copy to the DOH. The DOH will use the reports in any assessment of the trauma system.

The bill does not appear to have a fiscal impact on state or local government.

The bill provides an effective date July 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

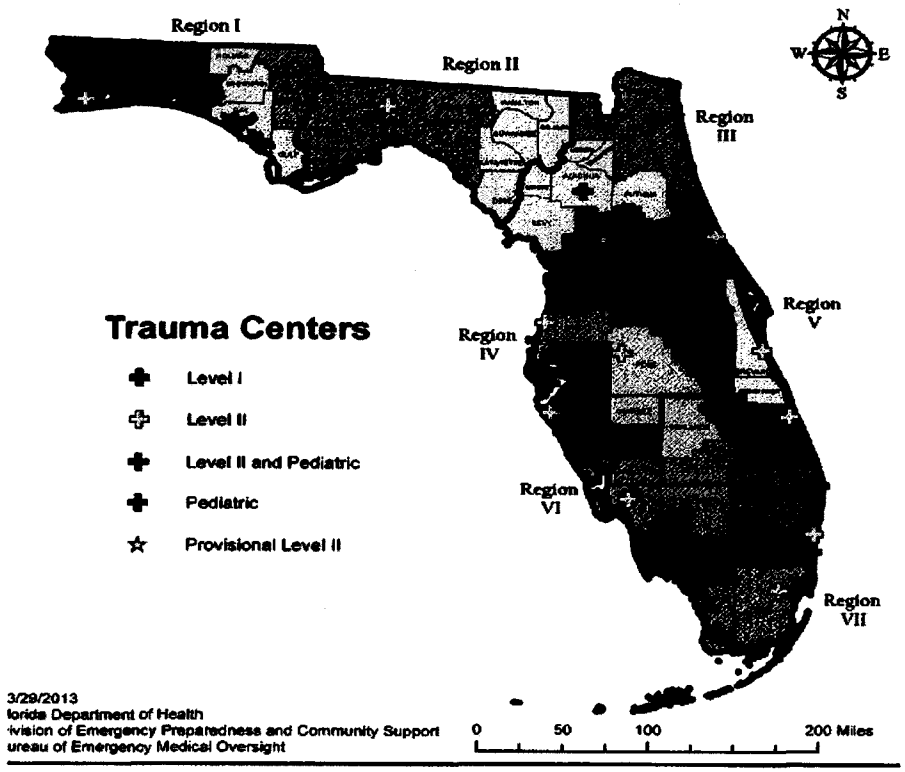
Background

Florida Trauma System

The regulation of trauma centers in Florida is governed by Part II of Chapter 395, F.S., and administered by the Department of Health (DOH) by rule in chapter 64J-2, F.A.C. A trauma center is a type of hospital that provides trauma surgeons, neurosurgeons, and other surgical and non-surgical specialists and medical personnel, equipment, and facilities for immediate or follow-up treatment of severely injured patients who have sustained a single or multisystem injury due to blunt or penetrating means or burns. As part of the state trauma system plan, the DOH is required to establish trauma regions which cover all geographical areas of the state and have boundaries that align with the state's seven Regional Domestic Security Task Force regions.[1] These regions may serve as the basis for the development of department-approved local or regional trauma plans.

Florida Trauma Service Areas, Agencies and Regions

Florida's trauma system is comprised of seven trauma regions and nineteen trauma service areas (TSAs). The trauma system also includes local and regional trauma agencies, but at any one time there have been four agencies in existence- the North Central Florida Trauma Agency, Hillsborough County Trauma Agency, Palm Beach Trauma Agency and Broward County Trauma Agency. The impact of trauma agencies in the current trauma system is unknown. The seven trauma regions, which match the Regional Domestic Security Task Force regions established by the Department of Law Enforcement (FDLE) pursuant to s. 943.0312(1), F.S., are illustrated below.[2]



[1] S. 395.4015, F.S.,

[2] Florida Department of Health, Division of Emergency Preparedness and Community Support, Bureau of Emergency Medical Oversight, *Trauma Centers*, March 29, 2013 (on file with Health Innovation Subcommittee staff).

Florida is divided into nineteen TSAs, detailed below:[3]

TRAUMA SERVICE AREAS (TSAs) IN FLORIDA	
TSA	COUNTIES IN TSA
1	Escambia, Santa Rosa, Okaloosa, Walton
2	Holmes, Washington, Bay, Gulf
3	Jackson, Calhoun, Gadsden, Liberty, Franklin, Leo, Wakulla, Jefferson, Madison, Taylor
4	Hamilton, Suwannee, Lafayette, Dixie, Columbia, Gilchrist, Levy, Union, Bradford, Alachua, Putnam
5	Baker, Nassau, Duval, Clay, St. Johns
6	Marion, Citrus, Hernando
7	Flagler, Volusia
8	Sumter, Lake, Seminole, Orange, Osceola
9	Pasco, Pinellas
10	Hillsborough
11	Polk, Hardee, Highlands
12	Brevard, Indian River
13	Manatee, Sarasota, Desoto
14	Okeechobee, St. Lucie, Martin
15	Charlotte, Lee, Glades, Hendry
16	Palm Beach
17	Collier
18	Broward
19	Dade, Monroe

For purposes of medical response times, the TSAs are designed to provide the best and fastest services to the state's population. Each TSA should have at least one Level I or Level II trauma center and there may be no more than 44 trauma centers in the state.[4] Each Level I and Level II trauma center must be capable of annually treating a minimum of 1,000 and 500 patients, respectively, with an injury severity score of 9 or greater.[5] A Level II trauma center in a county with a population of more than 500,000 must have the capacity to care for 1,000 patients per year.[6] Currently, TSA 17 (Collier) is not directly covered by a trauma center.[7]

The DOH is required to apportion, by rule, the number of trauma centers needed for each TSA.[8] Additionally, the DOH is required to adopt rules based on standards for verification of trauma centers based on national guidelines, to include those established by the American College of Surgeons (ACS) entitled "Hospital and Pre-hospital Resources for Optimal Care of the Injured Patient" and standards specific to pediatric trauma centers are to be developed in conjunction with the DOH Division of Children's Medical Services.[9]

Trauma Centers

A hospital may receive a designation as a Level I, Level II, pediatric, or provisional trauma center if the DOH verifies that the hospital is in substantial compliance with s. 395.4025, F.S., and the relevant

[3] S. 395.402(4)(a), F.S.
[4] S. 395.402(4)(b) and (c), F.S.
[5] S. 395.402(1), F.S.
[6] Id.
[7] Florida Department of Health, Bureau of Emergency Medical Oversight, Health Information and Policy Analysis Program, *Trauma Service Area Assessment*, January 31, 2014, page 23, available at www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/trauma-area-service-assessment.pdf (last viewed on March 9, 2014).
[8] S. 395.402(4)(b), F.S., and Rule 64J-2.010, F.A.C.
[9] S. 395.401(2), F.S., and Rule 64J-2.011, F.A.C.

trauma center standards.[10] A trauma center may have more than one designation; for example, Sacred Heart Hospital in Pensacola carries both a Level II and a pediatric trauma center designation. As of March 6, 2014, the following hospitals are designated trauma centers:[11]

TRAUMA CENTER	LEVEL	COUNTY
All Children's Hospital	Pediatric	Pinellas
Baptist Hospital	Level II	Escambia
Bay Medical Center	Level II	Bay
Bayfront Medical Center	Level II	Pinellas
Blake Medical Center	Level II	Manatee
Broward Health Medical Center	Level I	Broward
Broward Health North	Level II	Broward
Delray Medical Center	Level I	Palm Beach
Halifax Medical Center	Level II	Volusia
Holmes Regional Medical Center	Level II	Brevard
Kendall Regional Medical Center	Level II	Miami-Dade
Jackson Memorial Hospital/ Ryder Trauma Center	Level I	Miami-Dade
Lakeland Regional Medical Center	Level II	Polk
Lawnwood Regional Medical Center	Level II	St. Lucie
Lee Memorial Hospital	Level II	Lee
Memorial Regional Hospital	Level I	Broward
Miami Children's Hospital	Pediatric	Miami-Dade
Ocala Regional Medical Center/ Marion Community Hospital	Provisional Level II	Marion
Orlando Regional Medical Center	Level I	Orange
Regional Medical Center Bayonet Point	Level II	Pasco
Sacred Heart Hospital	Level II / Pediatric	Escambia
St. Joseph's Hospital	Level II / Pediatric	Hillsborough
St. Mary's Hospital	Provisional Level I	Palm Beach
Shands Jacksonville	Level I	Duval
Shands at the University of Florida	Level I	Alachua
Tallahassee Memorial Hospital	Level II	Leon
Tampa General	Level I	Hillsborough

A provisional trauma center is a hospital that has been verified to be in substantial compliance with the requirements in s. 395.4025, is approved by the DOH to operate as a provisional Level I, Level II or pediatric trauma center, and has applied to be a verified trauma center.[12] A hospital that is granted provisional status operates as a provisional trauma center for up to one year while the DOH conducts an in-depth review and a provisional onsite survey prior to the deciding to approve or deny verification.[13] Currently, there is one provisional Level I trauma center, St. Mary's Medical Center in West Palm Beach, and one provisional Level II trauma center, Ocala Regional Medical Center in Ocala.

A Level I trauma center serves as a resource facility to Level II trauma centers, pediatric trauma referral-centers, and general hospitals through shared outreach, education, and quality-improvement activities.[14] A Level I trauma center:[15]

- Must have a minimum of five qualified trauma surgeons, assigned to the trauma service, with at least two trauma surgeons available to provide in-hospital trauma services and backup trauma coverage 24 hours a day when summoned.

[10] The trauma center standards are provided in DH Pamphlet 150-9 and codified in Rule 64J-2.011, F.A.C. The standards were last updated in January 2010.
[11] Florida Department of Health, *Florida Trauma Centers*, available at www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/%20traumacenterlisting2014.pdf (last viewed on March 9, 2014).
[12] S. 395.4001(10), F.S.
[13] S. 395.4025(3), (5), and (6), F.S.
[14] S. 395.4001(6)(b), F.S.
[15] Florida Department of Health, *Trauma Center Standards*, Pamphlet 150-9, January 2010, pages 2.1-2.38, available at www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/%20traumacntrstandpamphlet150-9-2009rev1-14-10.pdf (last viewed on March 9, 2014).

- Must have twelve surgical specialties and eleven non-surgical specialties. These specialties must be available to provide in-hospital trauma services and backup trauma coverage 24 hours when summoned.
- Must have formal research and education programs for the enhancement of both adult and pediatric trauma care.

A Level II trauma center serves as a resource facility to general hospitals through shared outreach, education, and quality improvement activities.[16] A Level II trauma center:[17]

- Must have a minimum of five qualified trauma surgeons, assigned to the trauma service, with at least two trauma surgeons available to arrive promptly to the trauma center to provide trauma services within 30 minutes from inside or outside of the hospital, and backup trauma coverage 24 hours a day when summoned.
- Must have nine surgical specialties and nine non-surgical specialties available to provide trauma services and arrive promptly to provide trauma coverage 24 hours a day when summoned.

In contrast to the requirements of a Level I or Level II trauma center, a pediatric trauma center:[18]

- Must have a minimum of five qualified trauma surgeons[19], assigned to the trauma service, with at least two trauma surgeons available to provide trauma services and backup trauma coverage 24-hours a day when summoned. If the trauma medical director is not a pediatric surgeon, then at least one of the five must be a pediatric surgeon.
- Must have ten surgical specialties and eight non-surgical specialties available 24 hours a day to arrive promptly when summoned.
- Must have formal research and education programs for the enhancement of pediatric trauma care.

All trauma centers are required to submit quality indicator data to the Florida Trauma Registry.[20]

Florida Trauma System Reforms

During the 2003-2004 legislative interim, the Florida Senate's Committee on Home Defense, Public Security, and Ports conducted a study to review Florida's hospital response capacity and examine the disparity of available trauma centers across the state.[21] The study recommended adopting the borders of the seven Regional Domestic Security Task Force regions as the state trauma regions and maintaining the nineteen TSAs.[22]

Following the interim study, numerous bills were filed during the 2004 Legislative Session to amend the trauma system. Senate Bill 1762 (2004) was the only law enacted following that Session.[23] The law required the boundaries of the trauma regions to be coterminous with the boundaries of the Regional Domestic Security Task Force regions established within the FDLE. The law included a grandfather clause to allow the delivery of trauma services coordinated with a trauma agency pursuant to a public or private agreement established before July 1, 2004. The DOH was also directed to complete an

[16] S. 395.4001(7)(b), F.S.
[17] See supra, FN 15 at pages 3.2-3.33
[18] Id. at pages 4.2-4.36
[19] A trauma surgeon is required to be board certified or a trauma surgeon actively participating in the certification process within a specified timeframe may fill the requirement for pediatric surgery if the following conditions are met:
- The trauma medical director attests in writing that the substitute trauma surgeon has competency in the care of pediatric trauma; and
- A hospital grants privileges to the trauma surgeon to provide care to the injured child.

[20] S. 395.404(1)(a), F.S.
[21] The Florida Senate, Committee on Home Defense, Public Security, and Ports, *Hospital Response Capacity*, Report Number 2004-148, available at http://archive.flsenate.gov/data/Publications/2004/Senate/reports/interim_reports/pdf/2004-148hp.pdf (on file with the Health Innovation subcommittee staff).
[22] Id. at page 11.
[23] Ch. 2004-259, Laws of Fla.

assessment of the effectiveness of the trauma system and report its findings to the Governor and Legislature by February 1, 2005. The assessment included:[24]

- Consideration of aligning trauma service areas within the trauma region boundaries as established July 2004.
- Review of the number and level of trauma centers needed for each TSA to provide a statewide, integrated trauma system.
- Establishment of criteria for determining the number and level of trauma centers needed to serve the population in a defined TSA or region.
- Consideration of a criterion within trauma center verification standards based on the number of trauma victims served within a service area.
- Review of the Regional Domestic Security Task Force structure to determine whether integrating the trauma system planning with interagency regional emergency and disaster planning efforts is feasible and to identify any duplication of effort between the two entities.

In conducting this assessment and subsequent annual reviews, the law required the DOH to consider the following:[25]

- The recommendations made as a part of the regional trauma system in plans submitted by regional trauma agencies.
- Stakeholder recommendations.
- Geographical composition of an area to ensure rapid access to trauma care.
- Historical patterns of patient referral and transfer in an area.
- Inventories of available trauma care resources, including professional medical staff.
- Population growth characteristics.
- Transportation capabilities, including ground and air transport.
- Medically appropriate ground and air travel times.
- Recommendations of the Regional Domestic Security Task Force.
- The actual number of trauma victims currently being served by each trauma center.
- Other appropriate criteria.

In February 2005, the DOH submitted the report to the Legislature which included the findings of an assessment conducted by a group of researchers from the University of South Florida and the University of Florida. The report made numerous recommendations, including a recommendation to amend the TSAs to align them with the Regional Domestic Security Task Force regions. To date, the Legislature has not amended the structure of the trauma system to incorporate the recommendations of the report.

In 2013, the Legislature passed, and the Governor signed into law, House Bill 1159 which, among other provisions, amended s. 395.4025(14), F.S., to require the DOH to designate a hospital in an area with limited access to trauma center services as a Level II trauma center if the hospital provided a valid certificate of trauma center verification from the ACS.[26] An area with limited access to trauma center services is defined by the following criteria:

- The hospital is located in a TSA with a population greater than 600,000 persons but a population density of less than 225 persons per square mile;
- The hospital is located in a county with no verified trauma center; and
- The hospital is located at least 15 miles or 20 minutes travel time by ground transport from the nearest verified trauma center.

[24] S. 395.402(2), F.S.
[25] S. 395.402(3), F.S.
[26] S. 3, ch. 2013-153, Laws of Fla.

Based on the DOH Trauma Service Area Assessment from January 2014,[27] and applying the criteria in statute, a hospital in the following counties could be designated as a Level II trauma center, if it holds a certificate of trauma center verification from the ACS:

- TSA 1-
  - Santa Rosa
  - Okaloosa
  - Walton
- TSA 11-
  - Hardee
  - Highlands

As of March 9, 2014, no hospital has been designated as a Level II trauma center under this statute.

Florida Trauma System Administrative Rule Challenge and Associated Litigation

In 2011, four not-for-profit hospitals[28] challenged the DOH approval of new trauma centers in Pasco,[29] Manatee,[30] and Clay[31] counties by initiating a formal challenge to Rule 64J-2.010, F.A.C. ("the Rule"). The Rule sets the number of trauma centers in the state at 42 and apportions to each TSA the number of trauma centers permitted therein.[32] The hospitals argued that, since the Rule was promulgated in 1992, substantial amendments to part II of chapter 395, F.S., effectively repealed and invalidated the Rule. In addition, the hospital argued that 2004 amendments to s. 395.4015, F.S., required the DOH to establish trauma regions coterminous with the boundaries of the seven Regional Domestic Security Task Force regions established in s. 943.0312, F.S. However, the Rule establishes 19 TSAs that are not coterminous with the seven regions. Lastly, the hospitals argued that the 2005 assessment found that it would be feasible to reduce the TSAs to match the seven regions, yet the Rule was never amended to adopt this recommendation. In July 2011, due to the rule challenge, the DOH initiated a special study using national trauma experts and state and local stakeholders to develop evidenced-based guidelines to be used by the DOH in the determination of new trauma center locations.

In September 2011, the Division of Administrative Hearings (DOAH) issued an administrative order finding that the Rule was invalid on both grounds, as alleged. The DOH appealed the ruling and the State Surgeon General suspended the special study and the planning efforts of the trauma program until the rule challenge and resulting litigation were resolved. The DOH continued the trauma program's application, verification and quality assurance activities pending the outcome of the appeal.

On November 30, 2012, the First District Court of Appeal held that the Rule was an invalid exercise of delegated legislative authority, finding:[33]

- The trauma statutes were substantially amended in 2004, yet the rule remains unchanged since 1992. As such, the rule continues to implement outdated provisions of the statutes, without implementing any of the enumerated statutes.
- The Department has not updated the rule to conform to the 2004 amendments or the 2005 Assessment.
- The rule does not implement the 2004 amendment to section 395.4015, which governs state regional trauma planning and trauma regions.

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[27] See supra, FN 7.
[28] Bayfront Medical Center in St. Petersburg, Tampa General Hospital, St. Joseph's Hospital in Tampa, and Shands Jacksonville.
[29] Blake Medical Center in Bradenton.
[30] Regional Medical Center Bayonet Point in Hudson.
[31] Orange Park Medical Center in Orange Park. The trauma center at this facility closed in February 2013 when its provisional license was rescinded after DOH inspectors found standards for approval as a Level II trauma center had not been met. The Medical Center filed for a formal administrative proceeding in May 2013 to challenge the loss of its provisional license. The case was placed in abeyance in November 2013, pending the completion of the rulemaking process described later in this analysis. A status update on the process and whether or not the parties are ready to proceed is due to the court no later than May 15, 2014.
[32] For example, in Rule 64J-2.010(3), F.A.C., limits the number of trauma centers in TSA 9 (Pasco, Pinellas) to 3 and in TSA 16 (Palm Beach) to 2.
[33] See *Department of Health v. Bayfront Medical Center*, 2012 WL 5971201 (Fla.App. 1 Dist.).

- Both the pre-and post-2004 versions of the statute require the Department to establish trauma regions that "cover all geographic areas of the state." However, the 2004 amendment requires that the trauma regions both "cover all geographical areas of the state and have boundaries that are coterminous with the boundaries of the regional domestic security task forces established under s. 943.0312." §395.4015(1), Fla. Stat. (2004).
- Because the rule continues to set forth nineteen trauma service areas that are not coterminous with the boundaries of the seven regional domestic security taskforces, it does not implement the changes in the 2004 version of section 395.4015.

Instead of appealing the decision, the DOH initiated the rulemaking process to develop an inclusive, sustainable trauma system that distributes trauma centers throughout the state. The rulemaking process is discussed in detail below.

There are several cases that are in active litigation as a result of the invalidity of the Rule and the DOH approval of Ocala Regional Medical Center as a provisional Level II trauma center and approval of Regional Medical Center Bayonet Point and Blake Medical Center as provisional, then verified Level II trauma centers. The following is a partial list of those cases:

- Shands at the University of Florida is challenging the designation of Ocala Regional Medical Center as a provisional Level II trauma center. The case is set for administrative hearing on April 14, 2014, to April 16, 2014, and April 21, 2014 to April 23, 2014.
- In a case that was consolidated in February 2014 from two separate cases before the DOAH, Tampa General Hospital and Bayfront Medical Center are challenging the designation of Blake Medical Center as a provisional Level II trauma center. The case is set for administrative hearing from June 16, 2014, to June 19, 2014, and from June 23, 2014, to June 27, 2014.
- In a case that was consolidated in February 2014 from three separate cases before the DOAH, Tampa General Hospital, Bayfront Medical Center, and St. Joseph's Hospital are challenging the designation of Regional Medical Center Bayonet Point as a provisional Level II trauma center. The case is set for administrative hearing from July 7, 2014 to July 11, 2014, and from July 28, 2014 to August 1, 2014.
- Several cases have been filed by the same parties to challenge the designations of Ocala Regional Medical Center, Regional Medical Center Bayonet Point, and Blake Medical Center as verified Level II trauma centers. Those cases are in abeyance and status updates are due to the court at various times in April 2014.

Rulemaking Process to Amend the Rule on Apportionment of Trauma Centers

In December 2012, the DOH held its first rule development workshop to gather input from the trauma system providers and partners on how the Rule could be amended to ensure an inclusive trauma system in Florida. At least 10 rulemaking workshops were held through 2013 in an effort to reach agreement, but no consensus on rule language was reached.

A negotiated rulemaking proceeding was held on January 23, 2014, to draft a mutually acceptable proposed rule addressing the appropriate distribution of trauma centers in Florida. No consensus on draft rule language was reached at the meeting. Subsequently, the DOH published a Notice of Proposed Rule on February 3, 2014, which detailed substantive changes to the Rule governing the apportionment (now called "allocation" in the proposed rule) of trauma centers in the TSAs. A hearing was scheduled to take place of February 25, 2014, to solicit public input on the proposed rule. The DOH is expected to continue finalizing rule language and approve the rule. It is expected that the final allocation rule will be challenged.

American College of Surgeons (ACS)

The ACS is a scientific and educational association of surgeons established in 1913. ACS works to improve the quality of care for the surgical patient by setting high standards for surgical education and

practice. ACS does not designate trauma centers; instead, it verifies the presence of the resources listed in a book, "Resources for Optimal Care of the Injured Patient,"[34] which is recognized as a guide to develop trauma centers in the United States. ACS site surveyors use the book to review trauma centers.

According to ACS, the consultation/verification process helps hospitals to evaluate and improve trauma care by providing an objective, external review of a trauma center's resources and performance. A team of ACS trauma experts complete an on-site review of a hospital to assess relevant features of a trauma program, including commitment, readiness, resources, policies, patient care, and performance improvement. The certification process is voluntary and only those trauma centers that have successfully completed a verification visit are awarded a certificate.[35] ACS awards Level I-IV verifications:[36]

- A Level I facility is a regional resource trauma center that is a tertiary care facility central to the trauma system. The facility must have the capability of providing leadership and total care for every aspect of injury, from prevention through rehabilitation, and must have the depth of resources and personnel. A Level I center is usually university-based teaching hospitals due to the large number of personnel and resources required for patient care, education, and research.
- A Level II facility may not be able to provide the same comprehensive care as a Level I trauma center and more complex injuries may need to be transferred to a Level I center. The Level II trauma center is required to provide initial definitive trauma care regardless of the severity of the injury. A Level II trauma center may be an academic institution or a public or private community facility located in an urban, suburban, or rural area.
- A Level III facility is required to provide prompt assessment, resuscitation, emergency operations, and stabilization for a patient, arrange for possible transfer to another facility that can provide definitive care, and maintain transfer agreements and standardized treatment protocols. General surgeons are required in a Level III trauma center. A Level III trauma center is generally not appropriate in urban or suburban areas with adequate Level I or Level II resources.
- A Level IV facility provides advanced trauma life support before a patient is transferred to another facility for additional care. A Level IV trauma center is located in a remote area where no higher level of care is available and the trauma center services as the de facto primary care provider. Such a facility may be a clinic rather than a hospital and a physician may not be available.

In February 2013, the ACS Committee on Trauma (COT), at the request of the State Surgeon General, conducted a system consultation and review of Florida's trauma system. The final report from ACS was released to the DOH in May 2013. The following are some of the priority recommendations contained in the report:[37]

- Appoint a new Florida Trauma System Advisory Council to provide input to policy development for the trauma system.
- Revise immediately the Florida trauma system plan to address key issues necessary for the further development of the regional and statewide trauma system.[38]

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[34] A copy of this publication is on file with Health Innovation Subcommittee staff.

[35] As of February 19, 2014, ACS verifies trauma centers in 46 states. The hospitals with ACS verification in Florida are Tampa General Hospital (Level I trauma center), and Tampa General Hospital Children's Medical Center (Level I and pediatric trauma center). Verification for both facilities expires on January 29, 2016. See American College of Surgeons, *Verified Trauma Centers*, available at: http://www.facs.org/trauma/verified.html (last viewed on March 8, 2014).

[36] American College of Surgeons, *Description of Hospital Levels*, available at: http://www.facs.org/trauma/hospitallevels.pdf (last viewed on March 8, 2014).

[37] American College of Surgeons Committee on Trauma, Trauma Systems Evaluation and Planning Committee, *Trauma System Consultation Report-State of Florida*, Tallahassee, FL, February 2-5, 2013, available at http://newsroom.doh.state.fl.us/wp-content/uploads/newsroom/2013/05/Report-Final.pdf (last viewed on March 8, 2014).

[38] On March 3, 2014, the DOH released the State Trauma System Plan, a three page document that lays out strategic priorities for the next 36 months for the Florida trauma system based, in part, on the priority recommendations from the ACS. The Plan appears to focus on tasks associated with developing Regional Trauma Agencies statewide and establishing benchmarking and ensuring data

- Use the Regional Domestic Security Task Force regions as the TSA regions, which will enable the integration of trauma centers with emergency medical services, disaster preparedness, and other regional activities.
- Revise the distribution method of the trauma center fund to ensure designated trauma centers receive level-appropriate support for the "cost of readiness."
- Conduct an assessment of the current trauma system to inform decisions regarding the location and level of new trauma center designations.
- Establish a transparent, broadly accepted process for future provisional trauma center designation based upon both capacity and trauma system need.
- Impose a moratorium on any new provisional or verified trauma center designation until new processes are in place.
- Evaluate the content, implementation, and method of enforcement of trauma transport protocols to assure uniformity and efficiency of patient flow both within trauma regions as well as statewide.[39]

Effect of Proposed Changes

The bill includes legislative findings that an integrated, comprehensive, and superior quality trauma system is necessary to protect the health, safety and welfare of Floridians and visitors to the state; that each trauma center currently operating as a trauma center is an integral part of the trauma system and fulfills a critical need for trauma care services in the area where it is located; that a disruption in the operation of a trauma center may disrupt the availability of needed trauma services; and that all currently operating trauma centers are contributing to the trauma system and are delivering needed trauma services so that optimal trauma care is available and accessible throughout the state.

The bill permits a hospital that has operated continuously as a Level I, Level II, or pediatric trauma center for a consecutive 12-month period after enactment of ch. 2004-259 and submits an application to the ACS COT for a site visit to obtain a consultation report to continue to operate as a trauma center, if it continues to meet the trauma center and patient outcome requirements in s. 395.4025(6), F.S., until the approval period in statute expires. A hospital that meets the requirements of the bill is eligible for renewal of its 7-year approval period under s. 395.4025(6).

The bill allows all trauma centers currently operating in the state as a trauma center to be approved by the DOH as a trauma center, to operate for the initial 7-year approval period, and apply for renewal of the 7-year approval period when the initial period expires.

The bill requires each hospital that obtains a trauma center consultation report from the ACS COT following a site visit to submit the report to the DOH, which is then required to use those reports in any assessment of the state trauma system.

B. SECTION DIRECTORY:

Section 1: Provides legislative findings.
Section 2: Creates an unnumbered section of law relating to a hospital operating as a Level I, Level II, or pediatric trauma center.
Section 3: Creates an unnumbered section of law relating to the provision and use of trauma consultation reports to and by the Department of Health.
Section 4: Provides an effective date of July 1, 2014.

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quality for performance improvement. The Plan is available at www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/state-trauma-system-plan-final.pdf.

[39] See supra, FN 37 at pages 12-14.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

A consultation site visit to a trauma center by the ACS COT costs $15,000 for a three person review team and $18,000 for a four person review team.[40] Review teams consist of two trauma surgeons and one nurse supervisor.[41] A four person review team adds a specialist with additional trauma experience.[42] Any additional member of the review team costs $3,000.[43] A consultation site visit to a facility that is a combination trauma center and pediatric trauma center, such as Sacred Heart Hospital in Pensacola, costs $19,500.[44]

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The PCB does not appear to affect county or municipal governments.

2. Other:

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[40] American College of Surgeons, Trauma Consultation/Verification Packet-Site Visit Application, page 2, available at www.facs.org/trauma/site-visit-app.pdf (last viewed on March 10, 2014).
[41] Telephone conference between Molly Lozada, Verification/Consultation Programs Program Administrator, and Health Innovation Subcommittee staff on January 30, 2014.
[42] Id.
[43] Id.
[44] See supra, FN 40.

The Florida Constitution provides that the Legislature shall not enact any special law unless notice is first published.[45] A special law does not apply with geographic uniformity across the state. It operates only upon certain persons or regions, and bears no reasonable relationship to a difference in population or other legitimate criteria.[46] Laws which arbitrarily affect one subdivision of the state, but which fail to encompass other similarly situated subdivisions may be classified as special laws.[47] Even if a bill is enacted as a general law, courts will treat the bill as a special law if the effect is more like a special law.[48] Still other special laws are specifically prohibited by the Florida Constitution, such as laws pertaining to rules of evidence in any court or hunting or fresh water fishing.[49]

However, Florida case law has established that a local law need not apply universally in order to be a general law, and therefore constitutional, as long as "it is one of general import affecting directly or indirectly all the citizens of the state."[50] A general law may apply to a specific area if the classification of the area is permissible and reasonably related to the purpose of the statute, such as the valid exercise of the state's police power.[51] Police power is the sovereign right of the state to enact laws for the protection of lives, health, morals, comfort and general welfare.[52] Legislative action exercised under the state's police power is valid if confined to acts which may reasonably be construed as expedient for the protection of public safety, public welfare, public morals or public health. A great deal of discretion is vested in the Legislature to determine public interest and measures for its protection.[53]

B. RULE-MAKING AUTHORITY:

No rule-making authority is needed to implement the provisions of the PCB.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 11, 2014, the Health Innovation Subcommittee adopted one amendment to PCB HIS 14-01. The amendment clarified that a Level I, Level II, or pediatric trauma center which meets the criteria in the bill may continue to operate as a Level I, Level II, or pediatric trauma. The amendment clarifies that a trauma center that meets the provisions of the bill continues to operate at its current designated level. The PCB does not allow a trauma center to change its designation level.

The PCB was reported favorably as amended. The analysis reflects the PCB as amended.

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[45] Florida Const. Art. III, s. 10; notice may be avoided if a referendum is conducted among those citizens affected by the law.
[46] See *State ex rel. City of Pompano Beach v. Lewis*, 368 So.2d 1298 (Fla. 1979)(statute relating to particular persons or things or other particular subjects of a class is a special law); see also *Housing Auth. v. City of St. Petersburg*, 287 So.2d 307 (Fla. 1973)(defining a special law).
[47] See *Dept. of Bus. Regulation v. Classic Mile, Inc.*, 541 So.2d 1155 (Fla. 1989).
[48] See id.; see also *Anderson v. Board of Pub. Instruction for Hillsborough Cnty.*, 136 So. 334 (Fla. 1931).
[49] Florida Const. Art. III, s. 11.
[50] See *State v. Leavins*, 599 So.2d 1326, 1336 (Fla. 1st DCA 1992)(citing *Cantwell v. St. Petersburg Port Authority*, 21 So.2d 139 (Fla. 1945)).
[51] Id. at 1336-37.
[52] See *Newman v. Carson*, 280 So.2d 426, 428 (Fla. 1973)(citing *State ex rel. Municipal Bond and Inv. Co., Inc. v. Knott*, 154 So. 143 (1934); *Holley v. Adams*, 238 So.2d 401 (Fla.1970)).
[53] Id. (citing *Scarborough v. Newsome*, 7 So.2d 321 (1942); *Holley v. Adams*, supra, 238 So.2d at 407).

A bill to be entitled

An act relating to health care; providing legislative findings; permitting a Level I, Level II, or pediatric trauma center to operate if it has been in continuous operation after the enactment of chapter 2004-259, Laws of Florida, for at least a consecutive 12-month period, submits an application by June 31, 2015, for a site visit by the American College of Surgeons Committee on Trauma, and complies with s. 395.4025(6), F.S.; making a hospital that complies with such requirements eligible for renewal of its 7-year approval period under s. 395.4025(6), F.S.; requiring a hospital that obtains a trauma center consultation report following the site visit to provide the report to the Department of Health; requiring the department to use the trauma center consultation reports in any assessment of the state trauma system; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. The Legislature finds that an integrated, comprehensive, and superior quality trauma system is necessary to protect the health, safety, and welfare of the residents of Florida and visitors to this state. The Legislature further finds that each trauma center operating in the state is an

integral part of the trauma system and fulfills a critical need for trauma care in the area in which it is located. A disruption in the operational status of a trauma center may disrupt the availability of needed trauma services for residents of and visitors to Florida. The Legislature finds that all currently operating trauma centers in the state are contributing to an inclusive trauma system and are delivering needed trauma services so that optimal trauma care is available and accessible throughout the state.

Section 2. Notwithstanding any other provision of law, a hospital that has operated continuously as a Level I, Level II, or pediatric trauma center for a consecutive 12-month period after the enactment of chapter 2004-259, Laws of Florida, and that submits an application for a site visit by the American College of Surgeons Committee on Trauma on or before June 30, 2015, for the purpose of obtaining a trauma center consultation report may continue to operate as a verified Level I, Level II, or pediatric trauma center until the approval period in s. 395.4025(6), Florida Statutes, expires and so long as the hospital continues to meet the other requirements of s. 395.4025(6), Florida Statutes, related to trauma center standards and patient outcomes. A hospital that meets the requirements of this section shall be eligible for renewal of its 7-year approval period pursuant to s. 395.4025(6), Florida Statutes.

Section 3. Each hospital that obtains a trauma center

consultation report from the American College of Surgeons Committee on Trauma shall provide a copy of the report to the Department of Health. The department shall use the report in any assessment of the state trauma system.

Section 4. This act shall take effect July 1, 2014.

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Care Appropriations Subcommittee

Representative Brodeur offered the following:

Amendment (with title amendment)

Remove lines 40-57 and insert:

remains operational as of the effective date of this act, and submits an application for a site visit by the American College of Surgeons Committee on Trauma on or before April 1, 2015, for the purpose of obtaining a trauma center consultation report, may continue operating at the same trauma center level as a verified Level I, Level II, or pediatric trauma center until the approval period in s. 395.4025(6), Florida Statutes, expires as long as the hospital continues to meet the other requirements of s. 395.4025(6), Florida Statutes, related to trauma center standards and patient outcomes. A hospital that meets the requirements of this section shall be eligible for renewal of

its 7-year approval period pursuant to s. 395.4025(6), Florida Statutes.

Section 3. Each hospital that obtains a trauma center consultation report from the American College of Surgeons Committee on Trauma shall provide a copy of the report to the Department of Health. The department shall use each report in any assessment of the state trauma system.

Section 4. This act shall take effect upon becoming a law.

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

Remove lines 4-7 and insert:
trauma center to continue operating as a Level I, Level II, or pediatric trauma center if it has been in continuous operation after the enactment of chapter 2004-259, Laws of Florida, for at least a consecutive 12-month period, remains operational as of the effective date of the act, submits an application by April 1, 2015, for a