

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 7113 PCB HIS 14-01 Health Care

SPONSOR(S): Health & Human Services Committee; Health Care Appropriations Subcommittee; Health Innovation Subcommittee; Brodeur and others

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	11 Y, 2 N, As CS	Pridgeon	Pridgeon
2) Health & Human Services Committee	15 Y, 2 N, As CS	Poche	Calamas

SUMMARY ANALYSIS

CS/CS/HB 7113 addresses several areas of health care, including hospital obstetrical services, trauma centers, telehealth, the certificate of need review process, and advanced practice registered nurses. The bill:

- Requires a hospital to provide 120 days' notice to privileged obstetrical physicians before closing its obstetrical department or ending obstetrical services at the hospital.
- Permits a Level I, Level II, or pediatric trauma center to continue operating at the same level for a 7-year approval period if it has been in continuous operation for a 12-month period following the enactment of ch. 2004-259, Laws of Fla., is in operation at the time the bill becomes law, files an application with the American College of Surgeons by April 1, 2015, for a site visit by its Committee of Trauma for the purpose of obtaining a trauma center consultation report, and meets statutory trauma center standards and patient outcome requirements.
- Caps, for one year, the amount of a trauma activation fee charged by a trauma center to a patient at \$15,000.
- Requires each trauma center to post its trauma activation fee within the trauma center and on its website home page.
- Merges Trauma Service Area (TSA) 17 (Collier County), with TSA 15 (Charlotte, Glades, Hendry, and Lee Counties).
- Authorizes all Florida licensed health care professionals to use telehealth, from any location, to deliver health care services within their respective scopes of practice.
- Allows out-of-state health care professionals to use telehealth, within the relevant scope of practice established by Florida law and rule, to provide health care services to Florida patients, requires them register with the Department of Health or the applicable board, and establishes eligibility requirements for registration.
- Provides an exemption from the certificate of need review process for the transfer of not more than 15 percent of the acute care beds of a licensed hospital to another location in the county where the hospital located, if certain criteria are met.
- Allows certified nurse practitioners who meet certain criteria to register with the Board of Nursing to practice specified advanced or specialized nursing practices without physician supervision or a protocol as "independent nurse practitioners" (INPs) and authorizes them to, among other things, administer, dispense, order, and prescribe controlled medicinal drugs, provide a signature, certification, stamp, verification, affidavit, or other endorsement that is otherwise required by law to be signed by a physician; act as a patient's primary care provider; and certify involuntarily examinations under the Baker Act.
- Sets standards for controlled substance prescribing by INPs.
- Includes a non-substantive rewrite and reorganization of the prescription drug monitoring program (PDMP) statute.
- Requires a physician to access the PDMP and view a patient's prescription drug history prior to issuing a prescription for a controlled substance at the patient's first visit.
- Requires a law enforcement agency seeking information from the PDMP to enter into a user agreement with the program which outlines terms of use, contains access control provisions, and requires an annual self-audit by the agency to ensure compliance with the agreement and applicable laws and rules.
- Directs Enterprise Florida, Inc., and Visit Florida to promote medical tourism and market the state as a healthcare destination.
- Requires Visit Florida to include medical tourism in the 4-year marketing plan and showcase Florida providers.
- Requires Visit Florida to create a matching grant program for local and regional economic development organizations to create targeted medical tourism marketing initiatives.
- Authorizes a public health trust to execute a contract with a labor union or other labor organization without first obtaining approval from the Board of County Commissioners or other governing body of the county.

The bill has an indeterminate positive fiscal impact on state government and an indeterminate, but likely insignificant, negative fiscal impact on state government. The bill also appropriates \$500,000 in nonrecurring funds to the Department of Health for the administration of the PDMP.

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

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h7113b.HHSC

DATE: 4/18/2014

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Obstetrical Services in Hospitals

Hospitals are required to report the emergency services they will provide on the application form to the Agency for Health Care Administration (AHCA).¹ These services, such as obstetrics, are then listed on the hospital's license,² and must be displayed conspicuously.³ Hospitals must notify AHCA of any change of service that affects information on their license by submitting a revised licensure application, between 60 and 120 days in advance of the change.⁴ The list of services is also used for the inventory of hospital emergency services maintained by AHCA.⁵ There are currently 139 hospitals in Florida that are licensed to offer emergency obstetrical services.⁶

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.⁷ 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.⁸

¹ Agency for Health Care Administration, *Health Care Licensing Application: Hospitals*, at 12, available at http://ahca.myflorida.com/mchq/Health_Facility_Regulation/Hospital_Outpatient/Hospitals/SupportingForms.shtml#licap (last visited April 9, 2014).

² S. 408.806(4)(b), F.S.

³ S. 408.804, F.S.

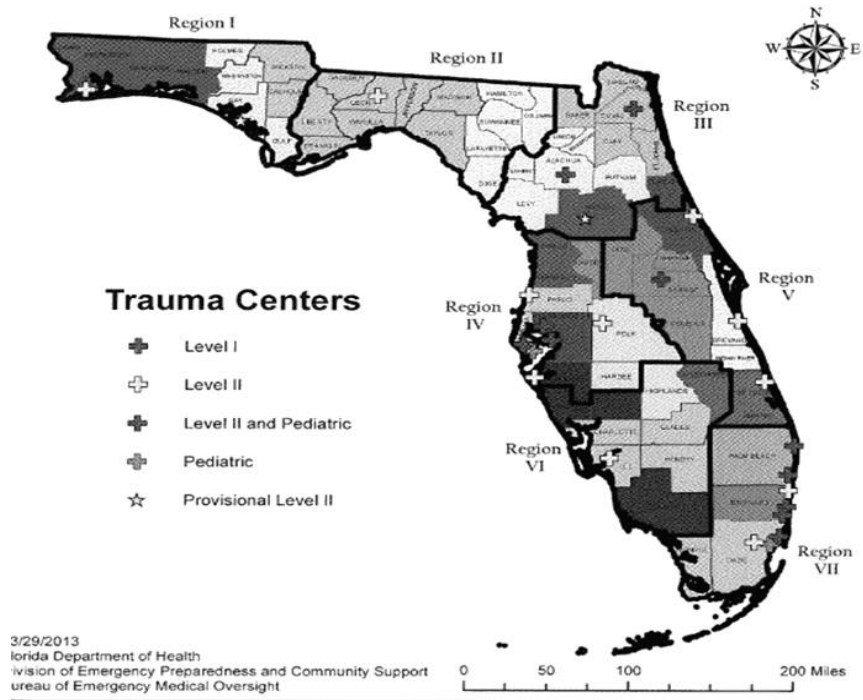
⁴ S. 408.806(2)(c), F.S.

⁵ S. 395.1041(2), F.S.

⁶ Agency for Health Care Administration, *Facility/Provider Locator*, available at <http://www.floridahealthfinder.gov/facilitylocator/FacilitySearch.aspx> (report generated February 21, 2014).

⁷ S. 395.4015, F.S.,

⁸ 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 and Human Services Committee staff).



Florida is divided into nineteen TSAs, detailed below:⁹

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.¹⁰ Each Level I and Level II trauma

⁹ S. 395.402(4)(a), F.S.

¹⁰ S. 395.402(4)(b) and (c), F.S.

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.¹¹ 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.¹² Currently, TSA 17 (Collier) is not directly covered by a trauma center.¹³

The DOH is required to apportion, by rule, the number of trauma centers needed for each TSA.¹⁴ 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.¹⁵

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 trauma center standards.¹⁶ 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:¹⁷

¹¹ S. 395.402(1), F.S.

¹² Id.

¹³ 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 April 9, 2014).

¹⁴ S. 395.402(4)(b), F.S., and Rule 64J-2.010, F.A.C.

¹⁵ S. 395.401(2), F.S., and Rule 64J-2.011, F.A.C.

¹⁶ 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.

¹⁷ Florida Department of Health, *Florida Trauma Centers*, available at www.floridahealth.gov/licensing-and-regulation/trauma-system/documents/%20traumacenterlisting2014.pdf (last viewed on April 9, 2014).

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.¹⁸ 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.¹⁹ 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.²⁰ A Level I trauma center:²¹

- 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.
- 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.

¹⁸ S. 395.4001(10), F.S.

¹⁹ S. 395.4025(3), (5), and (6), F.S.

²⁰ S. 395.4001(6)(b), F.S.

²¹ 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 April 9, 2014).

A Level II trauma center serves as a resource facility to general hospitals through shared outreach, education, and quality improvement activities.²² A Level II trauma center:²³

- 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:²⁴

- Must have a minimum of five qualified trauma surgeons²⁵, 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.²⁶

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.²⁷ 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.²⁸

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.²⁹ 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 assessment of the effectiveness of the trauma system and report its findings to the Governor and Legislature by February 1, 2005. The assessment included:³⁰

- Consideration of aligning trauma service areas within the trauma region boundaries as established July 2004.

²² S. 395.4001(7)(b), F.S.

²³ See supra, FN 21 at pages 3.2-3.33

²⁴ Id. at pages 4.2-4.36

²⁵ 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.

²⁶ S. 395.404(1)(a), F.S.

²⁷ 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 and Human Services Committee staff).

²⁸ Id. at page 11.

²⁹ Ch. 2004-259, Laws of Fla.

³⁰ S. 395.402(2), F.S.

- 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:³¹

- 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.³² 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.

Based on the DOH Trauma Service Area Assessment from January 2014,³³ 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

³¹ S. 395.402(3), F.S.

³² S. 3, ch. 2013-153, Laws of Fla.

³³ See supra, FN 13.

- Okaloosa
- Walton
- TSA 11-
 - Hardee
 - Highlands

As of April 17, 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 hospitals³⁴ challenged the DOH approval of new trauma centers in Pasco,³⁵ Manatee,³⁶ and Clay³⁷ 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.³⁸ 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:³⁹

- 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.
- 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).

³⁴ Bayfront Medical Center in St. Petersburg, Tampa General Hospital, St. Joseph’s Hospital in Tampa, and Shands Jacksonville.

³⁵ Blake Medical Center in Bradenton.

³⁶ Regional Medical Center Bayonet Point in Hudson.

³⁷ 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.

³⁸ 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.

³⁹ See *Department of Health v. Bayfront Medical Center*, 2012 WL 5971201 (Fla.App. 1 Dist.).

- 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,"⁴⁰ which is recognized as a guide to

⁴⁰ A copy of this publication is on file with Health and Human Services Committee staff.

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.⁴¹ ACS awards Level I-IV verifications:⁴²

- 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:⁴³

- 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.⁴⁴

⁴¹ As of March 28, 2014, ACS verifies trauma centers in 47 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 April 9, 2014).

⁴² American College of Surgeons, *Description of Hospital Levels*, available at: <http://www.facs.org/trauma/hospitallevels.pdf> (last viewed on April 9, 2014).

⁴³ 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 April 9, 2014).

⁴⁴ 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 quality for performance improvement. The Plan is available at www.floridahealth.gov/licensing-and-regulation/trauma-system/documents/state-trauma-system-plan-final.pdf.

- 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.⁴⁵

Regional Domestic Security Task Forces (RDSTFs)

The RDSTFs were codified by the Legislature because of a perceived need to develop and implement a statewide strategy to address preparation and response efforts by federal, state, and local law enforcement agencies, emergency management agencies, fire and rescue departments, first-responder personnel and others in dealing with potential or actual terrorist acts within or affecting Florida.⁴⁶

The Florida Department of Law Enforcement (FDLE) is required to establish an RDSTF in each of its seven operational regions, and to dedicate employees to support the function of each task force.⁴⁷ Each task force is co-chaired by FDLE's regional director and by a local sheriff or chief of police from within the operational region.⁴⁸ Each RDSTF may also include representatives from the Department of Emergency Management, the DOH, local emergency planning committees, state and local law enforcement agencies, fire and rescue departments, first-responder personnel, and other persons deemed appropriate by the co-chairs.⁴⁹

Section 395.402, F.S., requires the DOH to review, in its assessment of the statewide trauma system, the RDSTF structure and determine whether integrating trauma system planning with the structure is feasible. The DOH is also required to identify any duplication of effort by the RDSTF structure and the trauma system.

Telehealth

Health Care Professional Shortage

There is currently a physician shortage in the U.S.⁵⁰ This shortage is predicted to continue into the foreseeable future and will likely worsen with the aging and growth of the U.S. population⁵¹ and the passage of the Patient Protection and Affordable Care Act.⁵² Aging populations create a disproportionately higher health care demand.⁵³ Additionally, as more individuals qualify for health care

⁴⁵ See supra, FN 43 at pages 12-14.

⁴⁶ S. 943.0312, F.S.

⁴⁷ S. 943.0312(1), F.S.; the RDSTFs are located in Pensacola, Tallahassee, Jacksonville, Orlando, Tampa, Ft. Myers, and Miami.

⁴⁸ S. 943.0312(1)(b), F.S.

⁴⁹ S. 943.0312(1)(c), F.S.

⁵⁰ 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 April 9, 2014).

⁵¹ There will be a significant increase in the U.S. population, estimated to grow 20 percent (to 363 million) between 2008-2030.

⁵² *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 April 9, 2014).

⁵³ 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.annfam.org/content/10/6/503.full.pdf+html> (last visited on April 9, 2014).

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:⁵⁴

- 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 physicians⁵⁵ and an unmet demand of over 1,500 physical therapists.⁵⁶

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.⁵⁷ 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 professionals⁵⁸ and more efficient utilization of our existing workforce through the expanded use of telehealth.⁵⁹

Telehealth in General

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, treatment⁶⁰ and prevention of disease and injuries⁶¹, 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.⁶²

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.⁶³ There are however common elements among the varied definitions of telehealth.

⁵⁴ *Telemedicine: An Important Force in the Transformation of Healthcare*, Matthew A. Hein, June 25, 2009.

⁵⁵ 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 April 9, 2014).

⁵⁶ Florida Department of Economic Opportunity's presentation to the Florida House of Representative's Select Committee on Health Care Workforce Innovation, January 15, 2014.

⁵⁷ See supra, FN 55.

⁵⁸ Id.

⁵⁹ *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 April 9, 2014).

⁶⁰ 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 April 9, 2014).

⁶¹ 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 April 9, 2014).

⁶² *Telemedicine: Opportunities and Developments in Member States, Global Observatory for Ehealth Series- Volume 2*, Section 1.2, page 9.

⁶³ *State Telehealth Laws and Reimbursement Policies*, Center for Connected Health Policy, The National Telehealth Policy Resource Center, November 2013.

Telehealth generally consists of synchronous and/or asynchronous transmittal of information.⁶⁴ Synchronous refers to the live⁶⁵ transmission of information between patient and provider during the same time period.⁶⁶ Asynchronous telehealth is the transfer of data over a period of time, and typically in separate time frames.⁶⁷ 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.⁶⁸ Telehealth more broadly includes non-clinical services, such as patient and professional health-related education, public health and health administration.⁶⁹

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,⁷⁰ started in the 1960s in large part driven by the military and space technology sectors.⁷¹ 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.⁷² In fact, there are currently about 200 telehealth networks, with 3,500 service sites in the U.S.⁷³

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.⁷⁴ This occurs in both rural areas and urban communities.⁷⁵ Telehealth reduces the impact of this issue by providing a mechanism to

⁶⁴ The majority of telehealth definitions allow for both synchronous and asynchronous transmittal of information. Some definitions however omit asynchronous from the definition of telehealth.

⁶⁵ This is also referred to as “real time” or “interactive” telehealth.

⁶⁶ *Telemedicine Nomenclature*, American Telemedicine Association, located at <http://www.americantelemed.org/practice/nomenclature#.Uu1G6qNOncs> (last visited on April 9, 2014). The use of live video to evaluate and diagnosis a patient would be considered synchronous telehealth.

⁶⁷ 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.

⁶⁸ *Glossary and Acronyms*, U.S. Department of Health and Human Services <http://www.hrsa.gov/ruralhealth/about/telehealth/glossary.html#t> (last visited on April 9, 2014).

⁶⁹ Id.

⁷⁰ 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.

⁷¹ See supra, FN 62.

⁷² *What is Telemedicine*, American Telemedicine Association, <http://www.americantelemed.org/learn/what-is-telemedicine#.Uu6eGqNOncs> (last visited on April 9, 2014).

⁷³ *Telemedicine Frequently Asked Questions*, American Telemedicine Association, <http://www.americantelemed.org/learn/what-is-telemedicine/faqs#.Uu5vyaNOncs> (last visited on April 9, 2014).

⁷⁴ See supra, FN 55.

⁷⁵ Id.

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.⁷⁶ 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 patient⁷⁷ or a chronic condition.⁷⁸ 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.

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.⁷⁹ However, the Ryan Haight Online Pharmacy Consumer Protection Act,⁸⁰ 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 telehealth⁸¹ 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.⁸² To qualify for Medicare reimbursement, the originating site must be:

- Located in a federally defined rural county;
- Designated rural;⁸³ or
- Identified as a participant in a federal telemedicine demonstration project as of December 21, 2000.⁸⁴

⁷⁶ Id.

⁷⁷ 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.

⁷⁸ For example, diabetes is a chronic condition which can benefit by treatment through telehealth.

⁷⁹ 21 CFR §829(e)(2)

⁸⁰ Ryan Haight Online Consumer Protection Act of 2008, Public Law 110-425.

⁸¹ 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.

⁸² Only two states have a federal demonstration project that meets these qualifications: Hawaii and Alaska.

⁸³ 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).

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.⁸⁵

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:

- 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).⁸⁶ 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.⁸⁷ HITECH was intended to strengthen existing HIPAA security and privacy rules.⁸⁸ It expanded HIPAA to entities not previously covered; specifically, "business associates" now includes Regional Health Information Organizations, and Health Information Exchanges.⁸⁹ Similarly, it made changes to the privacy rule to better protect personal health information held, transferred, or used by covered entities.⁹⁰

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.

⁸⁴ 42 U.S.C. §1395(m)(m)(4)(C)(i)

⁸⁵ 42 U.S.C. §1395(m)(m)(4)(C)(ii).

⁸⁶ "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 on April 9, 2014).

⁸⁷ Id.

⁸⁸ Id.

⁸⁹ Id.

⁹⁰ Id.

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.⁹¹ 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 2014.⁹²

Telehealth Barriers

There are several barriers which impede the use of telehealth. These barriers include:⁹³

- 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.

Standardized Definition

Lack of a standard definition⁹⁴ 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 states⁹⁵ do not have a statutory structure for the delivery of health care services through telehealth.⁹⁶ 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.⁹⁷ Many times an exception is expressly contained within the regulation which allows the in-person requirement to be met

⁹¹ Federation of State Medical Boards, *Interstate Compact for Physician Licensure Moves Forward with Consensus Principles* (October 7, 2013), available at http://www.fsmb.org/pdf/nr_interstate_compact.pdf (last visited on April 9, 2014).

⁹² Federation of State Medical Boards, *State Medical Board Effort to Streamline Medical Licensing Gains Support in U.S. Senate* (January 14, 2014), available at http://www.fsmb.org/pdf/interstate_compact_senators_january13C.pdf (last visited on April 9, 2014).

⁹³ *State Telehealth Laws and Reimbursement Policies*, Center for Connected Health Policy, The National Telehealth Policy Resource Center, November 2013.

⁹⁴ 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.

⁹⁵ This includes Florida.

⁹⁶ *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.

⁹⁷ *State Telehealth Laws and Reimbursement Policies*, Center for Connected Health Policy, The National Telehealth Policy Resource Center, November 2013.

through telehealth.⁹⁸ 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.⁹⁹ Most states have exceptions to this requirement, applicable only in certain limited circumstances, which include:¹⁰⁰

- 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.

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.¹⁰¹ 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.¹⁰² 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.

⁹⁸ Id.

⁹⁹ Id.; this includes Florida.

¹⁰⁰ *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 April 9, 2014).

¹⁰¹ *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.

¹⁰² 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.

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.¹⁰³

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).¹⁰⁴ The Rule sets forth requirements and restrictions for physicians and physician assistants prescribing medications.¹⁰⁵ The Rule also states that telemedicine “shall include, but is not limited to, prescribing legend drugs to patients through the following modes of communication: (a) Internet; (b) Telephone; and (c) Facsimile.”¹⁰⁶ 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.¹⁰⁷

The Board recently adopted a new rule¹⁰⁸ setting forth standards for telemedicine.¹⁰⁹ 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.¹¹⁰ 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.¹¹¹ 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.¹¹²

The new rule however prohibits prescribing controlled substances through telemedicine.¹¹³

¹⁰³ Agency for Health Care Administration, Florida Medicaid, “Practitioner Services Coverage and Limitations Handbook,” December 2012, pg. 2-119, available at: http://portal.flhmmis.com/FLPublic/Tab/125/content/public/handbooks/cl_12_12-12-01_practitioner_services_handbook.pdf.spage (last visited on April 9, 2014).

¹⁰⁴ 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.

¹⁰⁵ Rule 64B8-9.014, F.A.C.

¹⁰⁶ Id.

¹⁰⁷ The Board of Osteopathic Medicine rule only applies to osteopathic physicians.

¹⁰⁸ The Board of Medicine and the Board of Osteopathic Medicine rules for telemedicine are identical.

¹⁰⁹ Rule 64B8-9.0141, F.A.C.

¹¹⁰ Rule 64B8-9.0141, F.A.C.

¹¹¹ The Board of Osteopathic Medicine definition only applies to osteopathic physicians.

¹¹² Id.

¹¹³ Id.

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.¹¹⁴ 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.¹¹⁵

Florida Medicaid Program

Florida's Medicaid program reimburses for a limited number of services provided by designated practitioners using telehealth.¹¹⁶ Medicaid limits the use of telehealth to behavioral health, dental, and 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.¹¹⁷

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.¹¹⁸

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.¹¹⁹ The new contract additionally eliminates numerous prior restrictions related to types of services and the type of providers who may utilize telehealth.¹²⁰

¹¹⁴ Florida Department of Health, *Child Protection Teams*, http://www.floridahealth.gov/AlternateSites/CMS-Kids/families/child_protection_safety/child_protection_teams.html (last visited April 9, 2014).

¹¹⁵ 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 on April 9, 2014).

¹¹⁶ S. 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.

¹¹⁷ *Id.*

¹¹⁸ S. 1, ch. 2013-150, Laws of Fla.

¹¹⁹ 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 on April 9, 2014).

¹²⁰ *Id.*

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.¹²¹ FETTN allows for multiple interface options and currently 7 out of 25 trauma centers are part of the network.¹²² 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-Jacksonville, and Orlando Health.¹²³

Other Department of Health Initiatives

The DOH utilizes tele-radiology through the Tuberculosis (TB) Physician's Network.¹²⁴ 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:

- 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.¹²⁵

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.¹²⁶ These acts include:¹²⁷

- 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.¹²⁸ 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.¹²⁹ An action against a non-resident may be brought in any county of the state.¹³⁰

¹²¹ 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).

¹²² Id.

¹²³ Florida Department of Health, *Long Range Program Plan* (September 28, 2012).

¹²⁴ Id.

¹²⁵ *Venetian Salami Company v. Parthenais*, 554 So.2d 499 (Fla. 1989).

¹²⁶ S. 48.193, F.S.

¹²⁷ Id.

¹²⁸ *Metnick & Levy v. Seuling*, 123 So.3d 639 (Fla. 4th DCA 2013).

¹²⁹ S. 47.011, F.S.

¹³⁰ See supra, FN 128; this is subject to the doctrine of forum non conveniens.

Certificate of Need

A certificate of need (CON) is a written statement issued by the Agency for Health Care Administration (AHCA) evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility, health service, or hospice.¹³¹

Florida's CON program has been in operation since July 1973. From 1974 through 1986, the specifics of the program were largely dictated by the federal National Health Planning and Resources Development Act, which established minimum requirements regarding the type of services subject to CON review, review procedures, and review criteria. Each state was required to have a CON program in compliance with those standards as a condition for obtaining federal funds for health programs. The federal health planning legislation was repealed in 1986.

The Florida CON program has three levels of review: full, expedited and exempt.¹³² Unless, a hospital project is exempt from the CON process, it must undergo a full comparative review. Expedited review is primarily targeted towards nursing home projects.

Full Review

Some hospital projects are required to undergo a full comparative review under the statute, including:

- Construction of a new hospital;
- Replacement of a hospital;
- Increasing the number of beds for acute care in a hospital that is located in a low-growth¹³³ county;
- Increasing the number of beds for comprehensive rehabilitation; and
- Establishing tertiary health services¹³⁴.

Review Exemptions

Section 408.036(3), F.S., provides several exemptions to CON review for certain hospital projects, including:

- Adding swing beds¹³⁵ in a rural hospital in a number that does not exceed one-half of its licensed beds.
- Converting licensed acute care hospital beds to Medicare and Medicaid certified skilled nursing beds in a rural hospital, as defined in s. 395.602, F.S., so long as the conversion of the beds does not involve the construction of new facilities. The total number of skilled nursing beds, including swing beds, may not exceed one-half of the total number of licensed beds in the rural hospital as of July 1, 1993. Certified skilled nursing beds designated under this provision, excluding swing beds, shall be included in the community nursing home bed inventory. A rural hospital which subsequently decertifies any acute care beds exempted under this provision shall notify the agency of the decertification, and the agency shall adjust the community nursing home bed inventory accordingly.

¹³¹ S. 408.032(3), F.S.

¹³² S. 408.036, F.S.

¹³³ Rule 59C-1.004(1)(g), F.A.C.

¹³⁴ S. 408.032(17), F.S., defines "tertiary health service" as a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of such service. Examples of such service include, but are not limited to, pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care units, comprehensive rehabilitation, and medical or surgical services which are experimental or developmental in nature to the extent that the provision of such services is not yet contemplated within the commonly accepted course of diagnosis or treatment for the condition addressed by a given service. The agency shall establish by rule a list of all tertiary health services.

¹³⁵ S. 395.602(2)(g), F.S., defines "swing bed" as a bed which can be used interchangeably as either a hospital, skilled nursing facility (SNF), or intermediate care facility (ICF) bed pursuant to 42 C.F.R. parts 405, 435, 440, 442, and 447.

- Adding hospital beds licensed under chapter 395, F.S., for comprehensive rehabilitation in a number that may not exceed 10 total beds or 10 percent of the licensed capacity, whichever is greater.
- Establishing a level II neonatal intensive care unit (NICU) if the unit has at least 10 beds, and if the hospital had a minimum of 1,500 births during the previous 12 months.
- Establishing a level III NICU if the unit has at least 15, and if the hospital had a minimum of at least 3,500 births during the previous 12 months.
- Establishing a level III NICU if the unit has at least 5 beds, and is a verified trauma center, as defined in s. 395.4001(14), F.S., and if the hospital applicant has a level II NICU.
- Establishing an adult open-heart-surgery program in a hospital located within the boundaries of a health service planning district, which: has experienced an annual net out-migration of at least 600 open-heart-surgery cases for 3 consecutive years; has a population that exceeds the state average of population per licensed and operational open-heart programs by at least 25 percent.
- For the provision of percutaneous coronary intervention for patients presenting with emergency myocardial infarctions in a hospital that does not have an approved adult open-heart-surgery program.

Advanced Practice Registered Nurses

Health Care Workforce Supply and Demand

Due to the aging and growth of the U.S. population and implementation of the Patient Protection and Affordable Care Act (PPACA), demand of the national health care workforce will outpace supply through 2025 and beyond.¹³⁶ Such demand will be magnified even further in Florida where there is a more abundant aging population, and consequently, both a disproportionately higher health care demand and a larger retiring health care workforce. Future shortages will likely result in longer wait times for medical appointments, increased travel distances to access care, shorter visit times with practitioners, and increased costs of care.¹³⁷

Some states are acting to counter health care workforce shortages in their respective states. For example, New Mexico's Governor proposed on November 13, 2013, that the state streamline the requirements for nurses licensed in other states to become licensed in New Mexico and proposed that almost \$220,000 in recurring marketing and advertising funds be used to recruit certified nurse practitioners to the state.¹³⁸ Other states have formed advisory councils and task forces to conduct workforce studies, have funded educational and training programs to recruit and retain health care workers, and have used resources to aggregate comprehensive workforce data to link workforce supply to demand.¹³⁹

In 2008, the Robert Wood Johnson Foundation and the Institute of Medicine launched a two-year initiative to research and analyze the nursing profession and how it may be reformed in order to combat the current and projected workforce shortage. The effort resulted in a report, which included as its

¹³⁶ The Association of American Medical Colleges (AAMC), "The Complexities of Physician Supply and Demand: Projections Through 2025," available at <https://members.aamc.org/eweb/upload/The%20Complexities%20of%20Physician%20Supply.pdf> (last visited on April 9, 2014); see also American Association of Colleges of Nursing, "Nursing Shortage," available at <https://www.aacn.nche.edu/media-relations/fact-sheets/nursing-shortage> (last visited on April 9, 2014).

¹³⁷ Id., AAMC, "The Complexities of Physician Supply and Demand: Projections Through 2025," at pg. 7.

¹³⁸ State of New Mexico, Office of the Governor, Susana Martinez, Press Release, "Governor Susana Martinez Proposes Streamlining Licensure for Nurses Relocating to New Mexico," available at http://www.governor.state.nm.us/uploads/PressRelease/191a415014634aa89604e0b4790e4768/Governor_Susana_Martinez_Propose_s_Streamlining_Licensure_for_Nurses_Relocating_to_New_Mexico.pdf (last visited on April 9, 2014).

¹³⁹ Association of Academic Health Centers, "State Actions and the Health Workforce Crisis," available at http://www.aahcdc.org/policy/reddot/AAHC_Workforce_State_Actions.pdf (last visited on April 9, 2014).

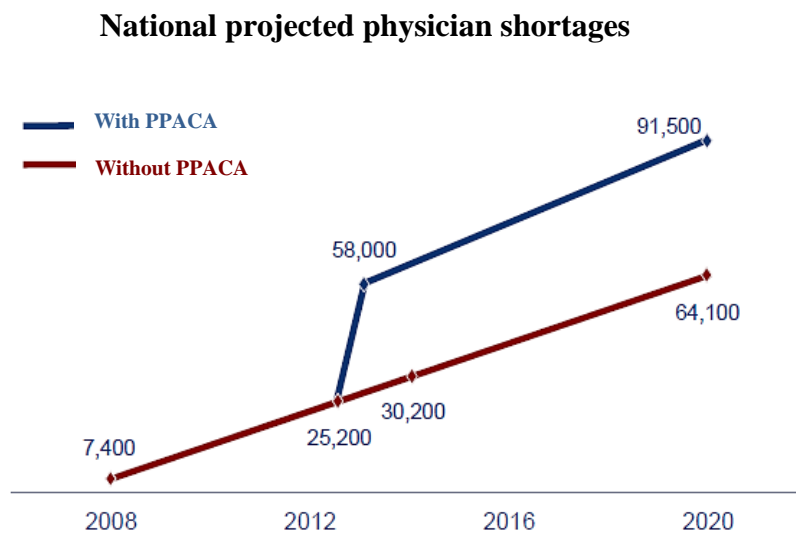
number one recommendation that scope of practice barriers should be removed for advanced practice nurses and they should be able to practice to the full extent of their education and training.¹⁴⁰

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 2025.¹⁴¹

In 2012, there were 260.5 physicians¹⁴² 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.¹⁴³ Regarding primary care physicians, there were 90.1 per 100,000 population.¹⁴⁴

The following chart illustrates the projected physician shortage, nationally, with and without full implementation of the PPACA.



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,¹⁴⁵ it ranks as having the 23rd highest physician to population ratio.¹⁴⁶ In 2012, Florida had a ratio of 84.8 primary care physicians per 100,000 population, ranking Florida 30th compared to other states.¹⁴⁷

¹⁴⁰ Institute of Medicine of the National Academies, "The Future of Nursing: Leading Change, Advancing Health," "Report Recommendations," available at <http://www.iom.edu/~media/Files/Report%20Files/2010/The-Future-of-Nursing/Future%20of%20Nursing%202010%20Recommendations.pdf> (last visited on April 9, 2014).

¹⁴¹ 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 April 9, 2014).

¹⁴² These totals include allopathic and osteopathic doctors.

¹⁴³ 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 April 9, 2014).

¹⁴⁴ Id. at pg. 5.

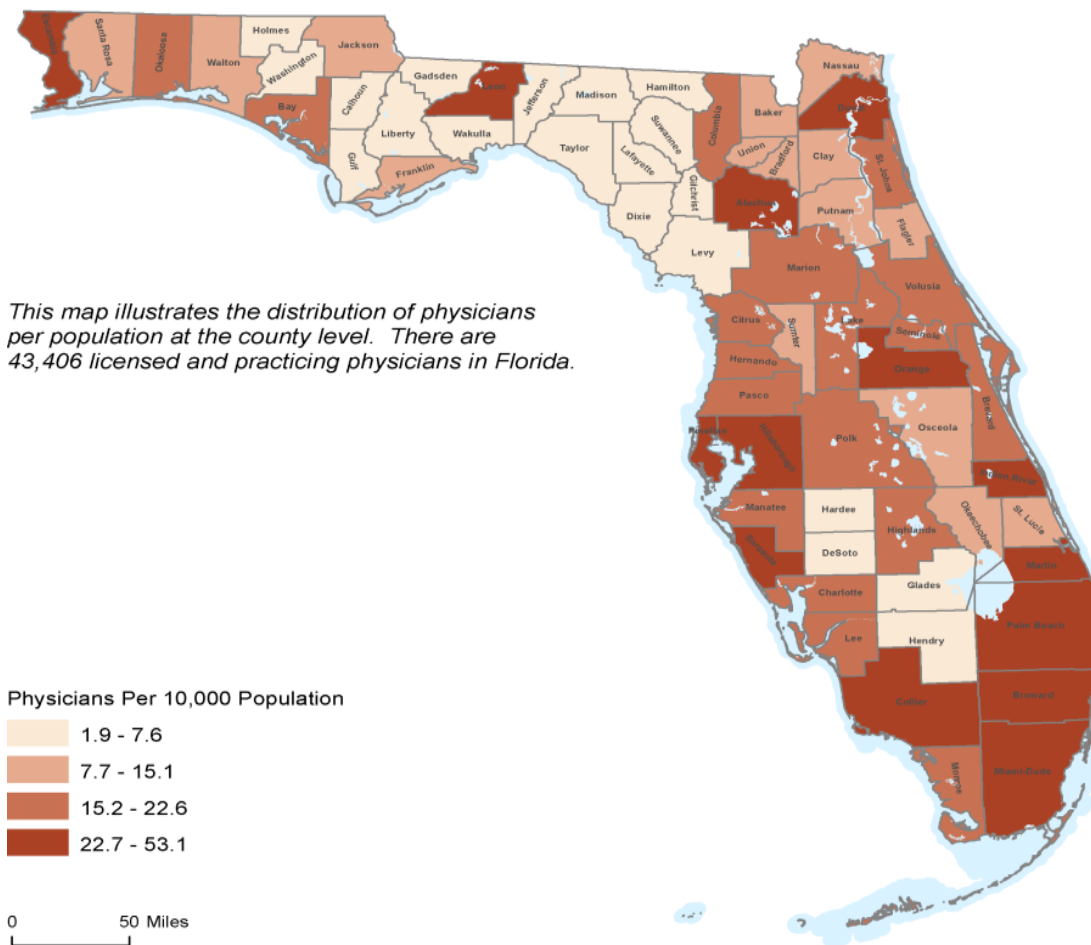
¹⁴⁵ The U.S. Census Bureau estimated Florida to have 19,552,860 residents in 2013, behind California (38,332,521), Texas (26,448,193), and New York (19,651,127). U.S. Census Bureau, "Annual Estimates of the Resident Population: 2013 Population Estimates," available at <http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk> (last visited on April 9, 2014).

¹⁴⁶ See supra, FN 143, at pg. 9.

¹⁴⁷ Id. at pg. 13.

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.¹⁴⁸ The following map¹⁴⁹ illustrates that not only does Florida have a shortage of physicians, but there is a maldistribution of physicians and they are generally concentrated in urban areas.

Florida's Physician Workforce by County 2012-2013



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).¹⁵⁰ 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.¹⁵¹

¹⁴⁸ 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 April 9, 2014).

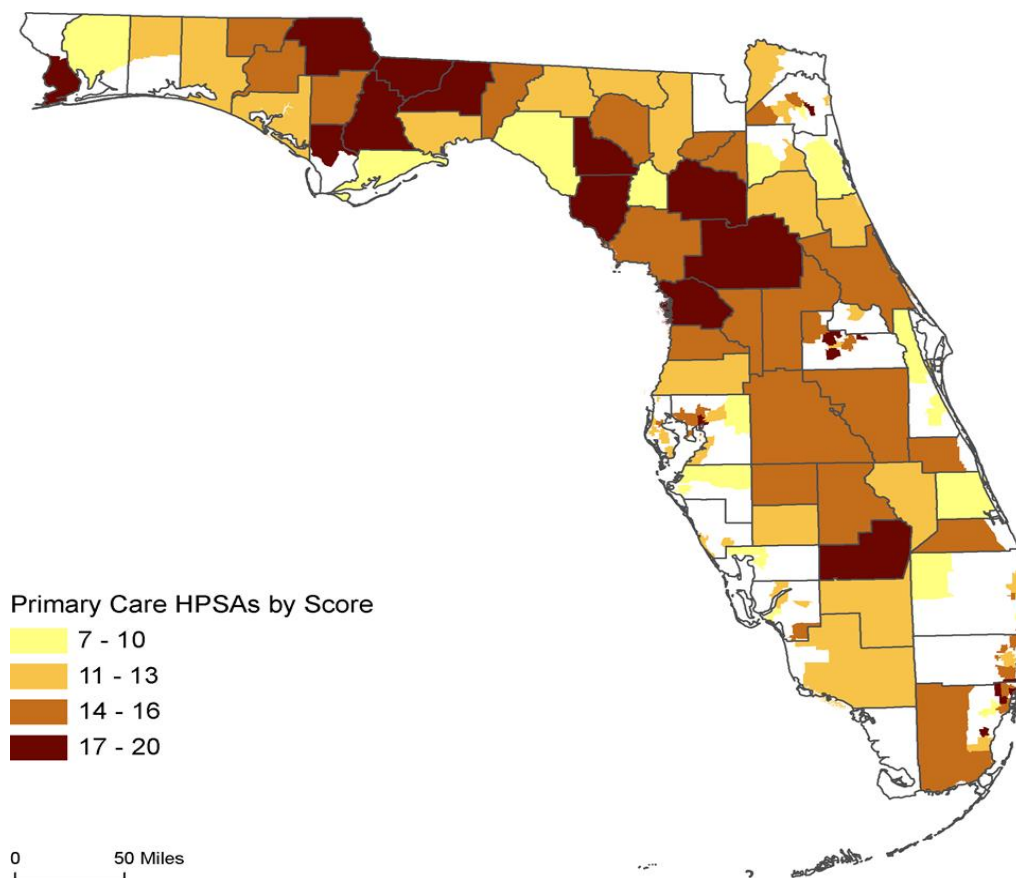
¹⁴⁹ Id. at pg. 8.

¹⁵⁰ 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 April 9, 2014).

¹⁵¹ 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

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.

Florida Primary Care Health Professional Shortage Areas



Source: Health Resources and Services Administration, October 2013.

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.¹⁵²

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 2025.¹⁵³ The table below illustrates the study's findings.

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 April 9, 2014).

¹⁵² Florida Department of Health, Presentation on Health Care Workforce: Physician Workforce and Florida CHARTS Data, November 6, 2013 (on file with Health and Human Services Committee staff).

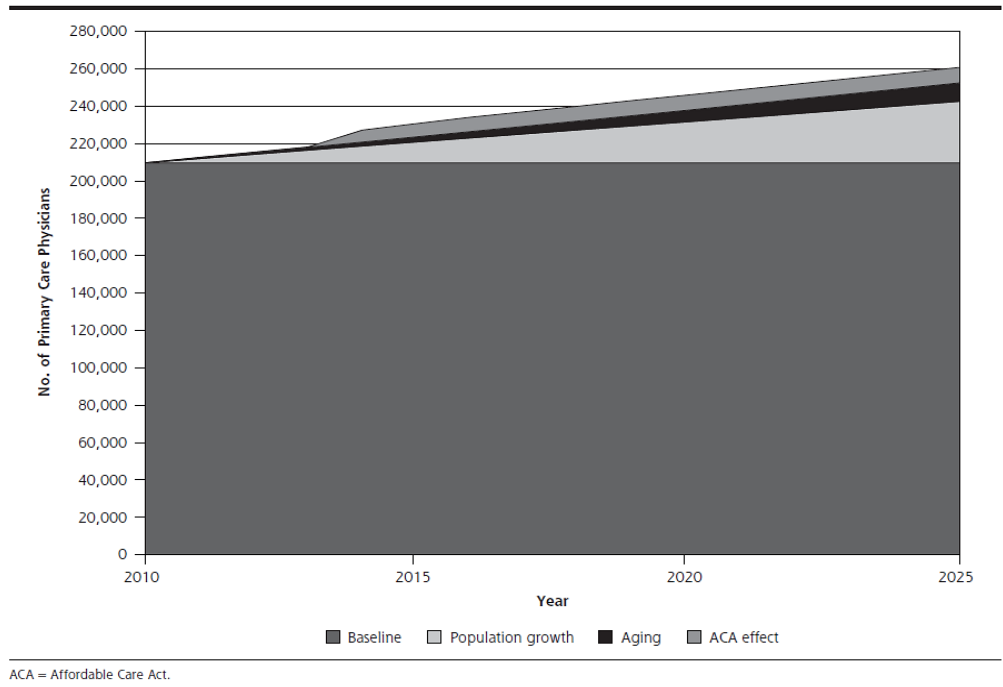
¹⁵³ Petterson, Stephen M., et al., "Projecting U.S. Primary Care Physician Workforce Needs: 2010-2025", *Annals of Family Medicine*, vol. 10, No. 6, Nov./Dec. 2012, available at <http://www.annfam.org/content/10/6/503.full.pdf+html> (last visited on April 9, 2014).

STORAGE NAME: h7113b.HHSC

DATE: 4/18/2014

PAGE: 25

Figure 2. Growing need for primary care physicians, 2010-2025.



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.¹⁵⁴ 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).¹⁵⁵ It is estimated that 86% of the medical school graduating class of 2013 will have education-related debt.¹⁵⁶ With an average medical student debt of \$169,901, debt plays a major role in medical students' career decisions.¹⁵⁷

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.¹⁵⁸ 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.¹⁵⁹

¹⁵⁴ 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/rqcmo-specialty-geographic.Par.0001.File.tmp/Specialty-geography-compressed.pdf> (last visited on April 9, 2014).

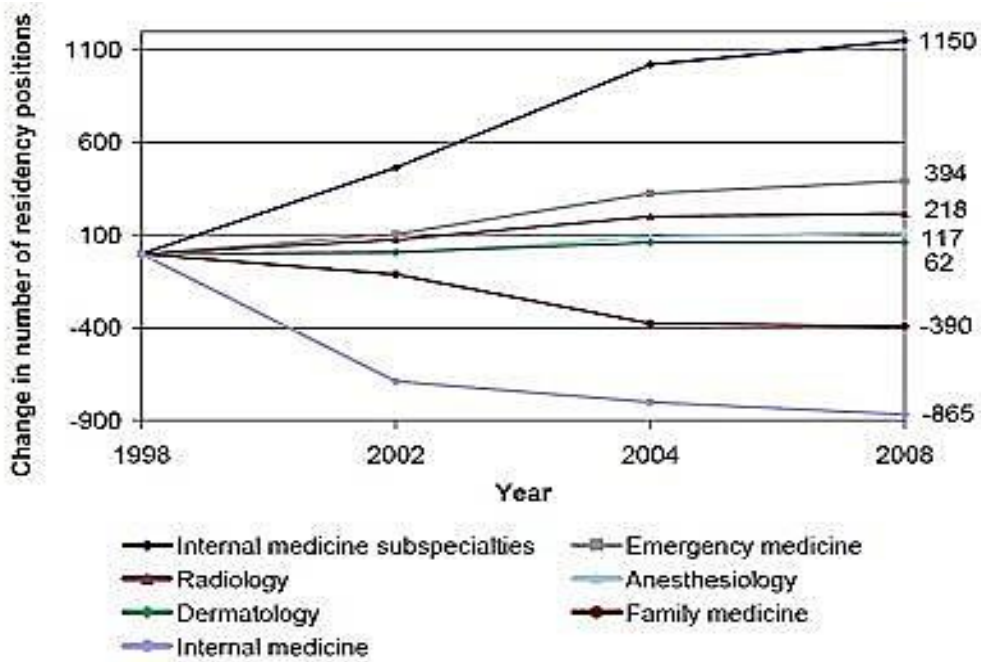
¹⁵⁵ Grayson, M., Newton, D., Thompson, L., "Payback time: the associations of debt and income with medical student career choice," *Medical Education*, Vol. 46, Issue 10, pg. 984, October 2012 (on file with Health and Human Services Committee staff).

¹⁵⁶ 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 April 9, 2014).

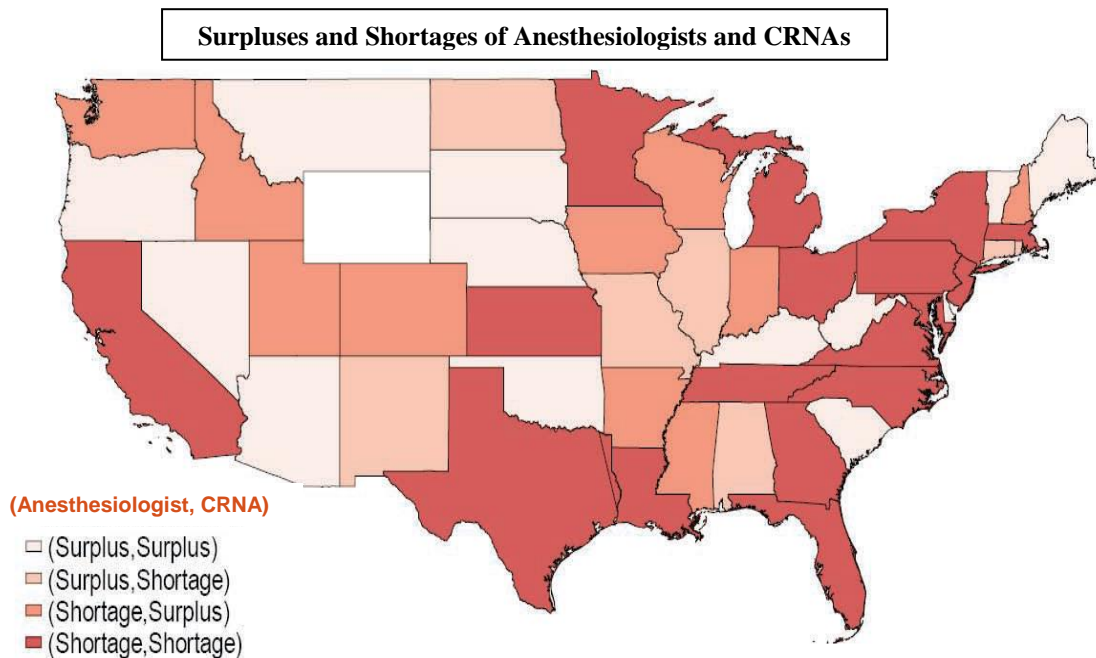
¹⁵⁷ Id.

¹⁵⁸ Weida NA, Phillips RL Jr, Bazemore AW, Doodoo 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 April 9, 2014).

¹⁵⁹ Id.



In 2010, the RAND Corporation published a study reporting that Florida, Alabama, and North Carolina had the least number of anesthesiologists in the nation.¹⁶⁰ Overall, the study found that 27 states are experiencing a shortage of anesthesiologists, which is reflected in the chart below.¹⁶¹



Source: RAND Corporation

¹⁶⁰ Daugherty, L., Fonseca, R., Kumar, K., Michaud, P.; "An Analysis of the Labor Markets for Anesthesiology," RAND Corp., available at http://www.rand.org/content/dam/rand/pubs/technical_reports/2010/RAND_TR688.pdf (last visited on April 9, 2014).

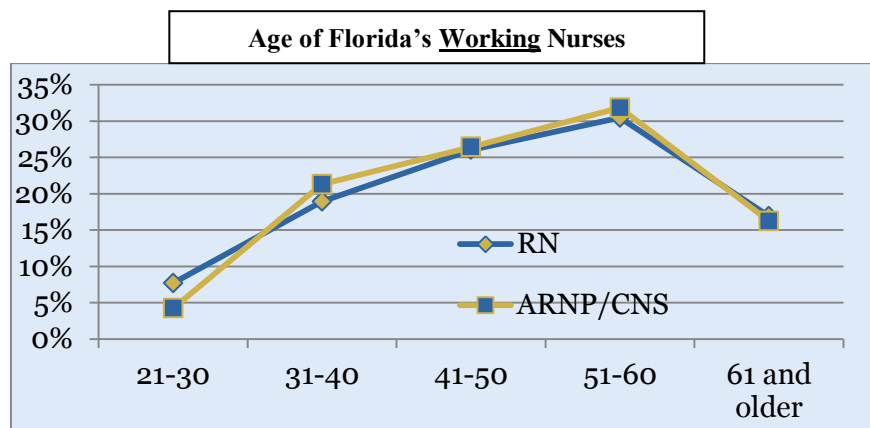
¹⁶¹ Id.; note that some states are not provided or are not shaded because they were not included in the study due to an inadequate number of observations on which to base an analysis.

Nurse Workforce Data

In 2012, there were approximately 110,200 certified nurse practitioners (CNP), 35,200 certified registered nurse anesthetists (CRNAs), 6,000 certified nurse midwives (CNMs), and 2,711,000 registered nurses (RNs) employed in the U.S.¹⁶² There were 34.8 CNPs, 1.89 CNMs, 11.1 CRNAs, and 857.3 RNs per 100,000 population in 2012.¹⁶³

As of January 2014, there were 18,843 advanced registered nurse practitioners (ARNPs) holding a certificate to practice in Florida, including 13,590 CNPs, 4,550 CRNAs, and 703 CNMs. There were also 246,397 RNs with active licenses as of January 2014.¹⁶⁴ Based on those figures, Florida has approximately the following number of nurses per 100,000 population: 69.5 CNPs, 3.6 CNMs, 23.2 CRNAs, and 1,260.4 RNs.^{165,166}

The Florida Center for Nursing (center) projects that there will be a shortage of approximately 20,600 RNs in 2025, and if PPACA were to be fully implemented Florida would have a shortage of approximately 50,300 RNs.¹⁶⁷ The center has also reported that over 30 percent of Florida's ARNPs and RNs are 51 to 60 years old, meaning there will be a large sector of Florida's nursing workforce retiring in the near future.¹⁶⁸



¹⁶² U.S. Department of Labor, Bureau of Labor Statistics, "Employment Projections," available at <http://data.bls.gov/projections/occupationProj> (last visited on April 9, 2014).

¹⁶³ These ratios were calculated using the U.S. Census Bureau's population estimate for 2012 was 316,266,000, which is available at <https://www.census.gov/prod/2011pubs/12statab/pop.pdf> (last visited on April 9, 2014) and the U.S. Bureau of Labor Statistics 2012 data on employment projections available at <http://data.bls.gov/projections/occupationProj> (last visited on April 9, 2014).

¹⁶⁴ The Florida Department of Health, Division of Medical Quality Assurance, provided the licensee information, which is on file with committee staff.

¹⁶⁵ These ratios were calculated using population estimates for FY 2013-2014 provided by the Florida Office of Economic & Demographic Research and available at <http://edr.state.fl.us/Content/conferences/population/ComponentsofChange.pdf> (last visited on April 9, 2014).

¹⁶⁶ Although it appears from this data that Florida has a higher ratio of nurses than the national ratio, the national data used to calculate the ratios only considers the number of nurses "employed" in the U.S. No similar employment data exists in Florida for 2012 to correlate with the national numbers. The numbers used to calculate Florida's ratios includes all active licensees, whom may not necessarily be employed, hence the larger ratios.

¹⁶⁷ The estimates are based on full-time equivalent (FTE) registered nurses. The Florida Center for Nursing, "RN and LPN Supply and Demand Forecasts, 2010-2025: Florida's Projected Nursing Shortage in View of the Recession and Healthcare Reform," October 2010, available at: http://www.flcenterfornursing.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=17&PortalId=0&TabId=151 (last visited on April 9, 2014).

¹⁶⁸ Florida Center for Nursing, Presentation on Florida's Nurse Workforce, November 6, 2013 (on file with Health and Human Services Committee staff).

Advanced Practice Nurses

The term advanced practice nurse (APN) refers to registered nurses who have completed rigorous training and advanced education, usually resulting in a master's degree or higher. The titles of APNs vary from state to state. The National Council of State Boards of Nursing encourages states to use the term "advanced practice registered nurse" (APRN) to promote uniformity and title recognition across the nation.¹⁶⁹

Florida APNs

In Florida, an APN is titled as an "advanced registered nurse practitioner" (ARNP)¹⁷⁰ and is categorized as a certified nurse practitioner (CNP), certified nurse midwife (CNM), or certified registered nurse anesthetist (CRNA).¹⁷¹ As of January 2014, Florida had 13,590 CNPs, 4,550 CRNAs, and 703 CNMs.¹⁷²

ARNPs are regulated under part I of ch. 464, F.S., the Nurse Practice Act. The Board of Nursing (Board), established under s. 464.004, F.S., provides by rule the eligibility criteria for applicants to be certified as ARNPs and the applicable regulatory standards for ARNP nursing practices. Additionally, the Board is responsible for administratively disciplining an ARNP who commits an act prohibited under ss. 464.018 or 456.072, F.S.

Section 464.003(2), F.S., defines the term "advanced or specialized nursing practice" to include, in addition to practices of professional nursing that registered nurses are authorized to perform, advanced-level nursing acts approved by the Board as appropriate for APRNs to perform by virtue of their post-basic specialized education, training, and experience. Advanced or specialized nursing acts may only be performed if authorized under a supervising physician's protocol.

In addition to advanced or specialized nursing practices, ARNPs are authorized to practice certain medical acts, as opposed to nursing acts, approved by a joint committee, formed pursuant to s. 464.003(2), F.S. The joint committee consists of three members appointed by the Board of Nursing, two of whom must be ARNPs; three members appointed by the Board of Medicine, two of whom must have had work experience with ARNPs; and the State Surgeon General or the State Surgeon General's designee.¹⁷³ The joint committee has not met since 1999 and has never approved a medical act. Currently, there are no members appointed to the joint committee.¹⁷⁴

For an applicant to be eligible to be certified as an ARNP, the applicant must be licensed as a registered nurse, must have a master's degree, and must submit to the Board proof that the applicant holds a current national advanced practice certification from a board-approved nursing specialty board.¹⁷⁵ A nursing specialty board must attest to the competency of nurses in a clinical specialty area, require nurses to take a written examination prior to certification, require nurses to complete a formal program prior to eligibility of examination, maintain program accreditation, and identify standards or scope of practice statements appropriate for each nursing specialty.

Pursuant to s. 456.048, F.S., all ARNPs must carry malpractice insurance or demonstrate proof of financial responsibility. Any applicant for certification is required to submit proof of coverage or financial responsibility within sixty days of certification and prior to each biennial certification renewal. The ARNP must have professional liability coverage of at least \$100,000 per claim with a minimum annual

¹⁶⁹ National Council of State Boards of Nursing, "APRN Talking Points: Consensus Model for APRN Regulation," available at: https://www.ncsbn.org/2010_APRN_TalkingPoints_web.pdf (last visited on April 9, 2014).

¹⁷⁰ S. 464.003(3), F.S.

¹⁷¹ S. 464.012(4), F.S.

¹⁷² See supra, FN 164.

¹⁷³ S. 464.003(2), F.S.

¹⁷⁴ Email correspondence from DOH, February 20, 2014 (on file with Health and Human Services Committee staff).

¹⁷⁵ S. 464.012(1), F.S., and Rule 64B9-4.002, F.A.C.

aggregate of at least \$300,000 or an unexpired irrevocable letter of credit in the amount of at least \$100,000 per claim with a minimum aggregate availability of at least \$300,000 and which is payable to the ARNP as beneficiary.¹⁷⁶ By comparison, physicians are required by Florida law to establish some method of financial responsibility, and can choose one of three options for doing so (malpractice insurance, an escrow account, or a letter of credit). However, physicians who agree to pay adverse judgments, up to certain statutory limits, are exempt from this requirement, and must notify patients that they have chosen not to carry malpractice insurance.¹⁷⁷

Autonomy of Practice

APN autonomy of practice varies widely by state. Generally, states align with four types of autonomy:

1. Independent nursing practice;
2. Collaborative nursing practice that requires physician collaboration without a specific requirement for a written agreement;
3. Supervised nursing practice that requires physician supervision with a written agreement, protocol, notice, or plan signed by the physician, who has discretion as to what practices are authorized, including controlled substance prescribing; or
4. Supervised nursing practice that requires physician supervision with a written agreement, protocol, notice, or plan signed by the physician, who has discretion as to what practices are authorized, except controlled substance prescribing which is statutorily prohibited.¹⁷⁸

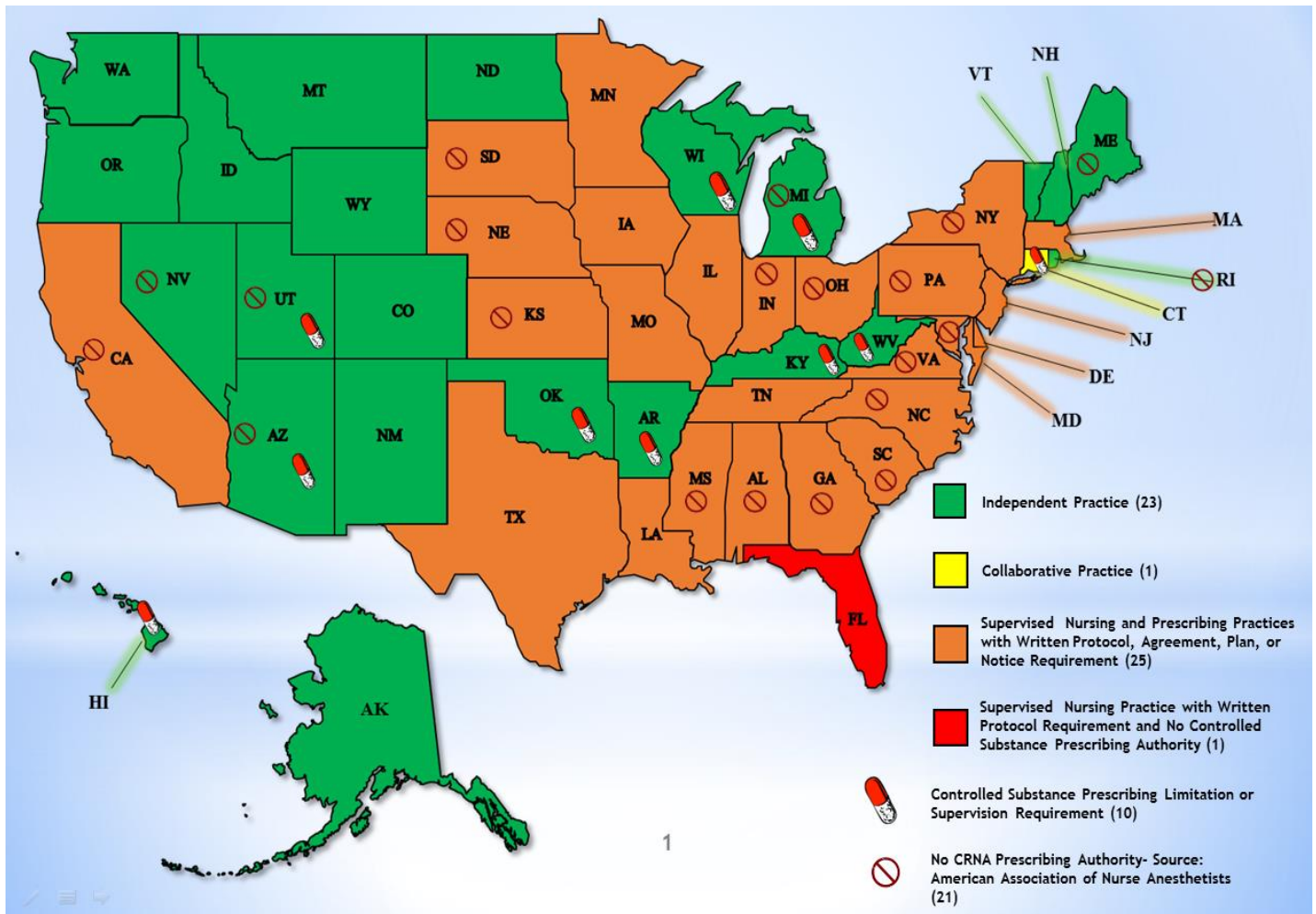
Within these four categories, a total of 23 states allow an APN to diagnose and treat a patient without physician supervision. One state requires a collaborative arrangement (without a written agreement or protocol). Twenty-six states require supervision, in which the APN must enter into or file with a regulatory board a written protocol, agreement, plan, or notice signed by a physician.¹⁷⁹ The following map illustrates the different levels of autonomy of practice for APNs throughout the U.S.

¹⁷⁶ Rule 64B9-4.002(5), F.A.C.

¹⁷⁷ If allopathic and osteopathic physicians meet certain eligibility criteria and post signage at their medical office disclosing to the public that they do not carry medical malpractice insurance, they are exempt from medical malpractice or proof of financial responsibility requirements provided in ss. 458.320 and 459.0085, F.S., respectively.

¹⁷⁸ Findings based on research conducted in 2013 by staff of the Select Committee on Health Care Workforce Innovation.

¹⁷⁹ *Id.*



APN Autonomy in Veterans Health Administration Facilities

The Veterans Health Administration (VHA) of the U.S. Department of Veterans Affairs is drafting a new Nursing Handbook to recognize APNs as “Licensed Independent Practitioners” in all VHA facilities and allow such nurses to practice to the full extent of their education and training without physician supervision.¹⁸⁰ In Florida, there are 56 VHA medical centers and health care clinics that would be affected by this policy change.¹⁸¹

APN Autonomy in Florida

Florida is a supervisory state. Under s. 464.012(3), F.S., APNs may only perform nursing practices delineated in a written physician protocol filed with the Board.¹⁸²

Florida law allows a physician providing primary health care services to supervise APNs in up to four medical offices,¹⁸³ in addition to the physician’s primary practice location. If the physician provides

¹⁸⁰ U.S. Department of Veterans Affairs, Office of Nursing Services, “APRN Practice,” updated February 20, 2013, on file with committee staff. Although APRNs will be able to practice independently in VHA facilities, they may not be able to prescribe controlled substances because they must adhere to the laws in the state in which they are licensed regarding prescribing authority for controlled substances. Under current law, Florida-licensed ARNPs practicing in the VHA cannot prescribe controlled substances while working alongside APN peers who can.

¹⁸¹ U.S. Department of Veterans Affairs, Veterans Health Administration, “Locations: Florida,” available at <http://www.va.gov/directory/guide/state.asp?STATE=FL&dnum=1> (last visited on April 9, 2014).

¹⁸² Allopathic and osteopathic physicians are also required to provide notice of the written protocol and the supervisory relationship to the Board of Medicine or Board of Osteopathic Medicine, respectively. SS. 458.348 and 459.025, F.S.

¹⁸³ The supervision limitations do not apply in certain facilities such as hospitals, colleges of medicine or nursing, nonprofit family-planning clinics, rural and federally qualified health centers, nursing homes, assisted living facilities, continuing care facilities, retirement

specialty health care services, then only two medical offices in addition to the physician's primary practice location may be supervised.¹⁸⁴ Furthermore, a special limitation applies to dermatology services. If the physician offers services primarily related to dermatologic or skin care services (including aesthetic skin care services other than plastic surgery), at a medical office that is not the physician's primary practice location, then the physician may only supervise one medical office.¹⁸⁵

Scope of Practice

State laws vary as to the scope within which an APN may practice, which is often determined by whether the APN is a CNP, CNM, or CRNA, and often relates to the authority to prescribe drugs and sign documents.

Eleven of the 23 independent practice states authorize an APN to prescribe controlled substances to a patient without physician supervision. Two of the 23 independent practice states, Kentucky and Michigan, require APNs to enter into a collaboration or delegation agreement with a physician in order to prescribe controlled substances.¹⁸⁶ Only one state, Florida, both requires APNs to practice under written physician protocols and also prohibits APNs from prescribing controlled substances. Twenty-one states specifically prohibit CRNAs from prescribing drugs.¹⁸⁷ The map on p. 11 illustrates the varying controlled substance prescribing requirements throughout the U.S.

At least 4 states grant APNs authority to sign or certify any document that is required by law to be signed by a physician.¹⁸⁸ This authority is often referred to as "global signature authority." Many states specify in law the types of things an APN may sign, such as death certificates, handicapped license designations, and advanced directives.

Nineteen states statutorily recognize APNs as "primary care providers."¹⁸⁹ Recognizing APNs as primary care providers assists them with being able to directly bill public or private payers for services provided, order certain tests, and establish independent primary care practices.¹⁹⁰ Insurers may be unwilling to contract directly with a provider who is supervised by another provider.¹⁹¹

APN Scope of Practice in Florida

Within the framework of the written protocol, an APN may:

- Monitor and alter drug therapies;
- Initiate appropriate therapies for certain conditions;
- Perform additional functions as may be determined by Board rule;
- Order diagnostic tests and physical and occupational therapy;
- Perform certain acts within his or her specialty; and

communities, clinics providing anesthesia services, rural health clinics, community-based health care settings, student health care centers, school health clinics, or other government facilities. SS. 458.348(4)(e), and 459.025(3)(e), F.S.

¹⁸⁴ SS. 458.348, and 459.025, F.S.

¹⁸⁵ Id.

¹⁸⁶ The remaining 10 states have some type of restriction or limitation on prescribing controlled substances regardless of supervision.

¹⁸⁷ American Association of Nurse Anesthetists, Presentation on "Current State Legislative and Regulatory Trends," November 9, 2013, available at http://www.aana.com/meetings/meeting-materials/Fall%20Leadership%20Academy/Documents/Chacko_Conover_Current%20State%20Legislative%20and%20Regulatory%20Trends%20FLA%202013.pdf (last visited on April 9, 2014).

¹⁸⁸ The states with global signature authority are Hawaii, Maine, Rhode Island, and Vermont.

¹⁸⁹ Office of Program Policy Analysis & Government Accountability, "States Vary in Their Treatment of Advanced Registered Nurse Practitioners as Primary Care Providers," October 2013, (on file with Health and Human Services Committee staff).

¹⁹⁰ National Nursing Centers Consortium, "Insurers' contracting policies on nurse practitioners as primary care providers: the current landscape and what needs to change," *Policy, Politics & Nursing Practice*, 7(3), 216-226, August 2006, abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/17071708> (last visited on April 9, 2014).

¹⁹¹ ARNP services are mandatory services in the current Florida Medicaid program, and are required minimum services in the Managed Medical Assistance program being implemented this year. SS. 409.905, 409.973, F.S. Florida law does not require Medicaid managed care plans to contract directly with ARNPs.

STORAGE NAME: h7113b.HHSC

DATE: 4/18/2014

- Perform medical acts authorized by a joint committee.¹⁹²

However, Florida law does not authorize APNs to prescribe, administer, or dispense controlled substances.¹⁹³ Florida is the only state in the U.S. that requires an APN to be supervised by a physician, authorizes APNs to only perform those nursing practices delineated under a physician's written protocol, and *a/so* prohibits an APN from prescribing, administering, dispensing, mixing or otherwise preparing controlled substances.¹⁹⁴

Additionally, APNs in Florida are not authorized to sign certain documents; rather, Florida law requires them to be signed by a physician. For example, APNs are not authorized to sign a certificate to initiate the involuntary examination of a person under the Baker Act, to sign for the release of persons in receiving facilities under the Baker Act, or to sign death certificates.¹⁹⁵

Reports and Studies Related to Advanced Practice Nurses

Patient Health Care Outcomes

Despite concerns that APNs provide a different quality of care than physicians,¹⁹⁶ a multitude of reports and studies suggest treatment by an APN is just as safe, if not safer, than treatment by a physician. In 2009, the Cochrane Collaboration published a review of the findings of 25 articles comparing physician and APN patient outcomes. The review found that, in general, there are no appreciable differences between physicians and APNs in health outcomes for patients, process of care, resource utilization, or cost.¹⁹⁷

Certified Nurse Practitioners

Similar to the Cochrane review, the National Governors Association performed a review of various studies to determine whether there were differences in the quality of care provided by CNPs compared to physicians. The studies measured quality of care components such as patient satisfaction, time spent with patients, and prescribing accuracy. The review of those studies found that CNPs provided at least equal quality of care to patients as compared to physicians and, in fact, CNPs were found to have equal or higher patient satisfaction rates and tended to spend more time with patients during clinical visits.¹⁹⁸

A 2013 study, found that allowing CNPs to practice and prescribe drugs without physician oversight leads to increased primary health care utilization and improvements in health outcomes.¹⁹⁹

Cost Savings

The rising cost of health care is a concern for individuals, families, businesses, government entities, and society as a whole. These rising costs will only be intensified by the increasing number of persons

¹⁹² SS. 464.012(3),(4), and 464.003, F.S.

¹⁹³ SS. 893.02(21), and 893.05(1), F.S.

¹⁹⁴ SS. 464.012, 893.02(21), and 893.05(1), F.S.

¹⁹⁵ SS. 394.463(2) and 382.008, F.S.

¹⁹⁶ When 972 clinicians, including 467 nurse practitioners and 505 physicians, were surveyed in a study as to whether physicians provide a higher quality of examination and consultation, the respondents were diametrically opposed. Approximately 66.1% of physicians agreed with the statement and 75.3% of nurse practitioners disagreed with the statement. Donelan, K., Sc.D., DesRoches, C., Dr. P.H., Dittus, R., M.D., M.P.H., and Buerhaus, P., R.N., Ph.D., "Perspectives of Physicians and Nurse Practitioners on Primary Care Practice," *N. Engl. J. Med.* 2013, 368:1898-1906, available at <http://www.nejm.org/doi/full/10.1056/NEJMsa1212938#t=articleTop> (last visited on April 9, 2014).

¹⁹⁷ Laurant, M., et al., The Cochrane Collaboration, "Substitution of doctors by nurses in primary care," October 18, 2004, (on file with Health and Human Services Committee staff).

¹⁹⁸ National Governors Association, "*The Role of Nurse Practitioners in Meeting Increasing Demand for Primary Care*," December 2012, available at <http://www.nga.org/files/live/sites/NGA/files/pdf/1212NursePractitionersPaper.pdf> (last visited on April 9, 2014).

¹⁹⁹ Udalova, V., Traczynski, J., "*Nurse Practitioner Independence, Health Care Utilization, and Health Outcomes*," March 15, 2013, available at http://www.lafollette.wisc.edu/research/health_economics/Traczynski.pdf (last visited on April 9, 2014).

with health care coverage resulting from implementation of the PPACA and the shortage of health care workers.²⁰⁰

In 2012, the Perryman Group conducted a study to determine whether Texas could achieve any cost-savings by increasing the utilization of APNs. A report of the study's findings concluded that greater utilization of APNs would improve patient outcomes, reduce overall health care costs, and increase access to health care. The estimated savings were \$16.1 billion in total expenditures and \$8 billion in output (gross product) each year. Additionally, it was estimated that 97,205 permanent jobs would be added to Texas' workforce. Finally, the report estimated that Texas would receive additional tax receipts of up to \$483.9 million to the state and \$233.2 million to local government entities each year.²⁰¹

Another study found that states that allow APRNs to practice and prescribe without physician supervision experience 16-35% increases in health care utilization, increases in care quality, and reductions in inappropriate emergency room use. The researchers concluded these advances were primarily due to elimination of supervision time (10%) and lower indirect costs (such as better appointment availability and lower patient travel costs).²⁰²

The U.S. Federal Trade Commission (FTC) has authored several letters to states regarding the negative effects of restrictive scope of practice laws for APNs. The main concern of the FTC is that scope of practice restrictions are anti-competitive and that they, in effect, reduce competitive market pressures, increase out-of-pocket prices, allow for more limited service hours, and reduce the distribution of services. The FTC poses that if such constraints were eliminated, not only would access to services be increased, but there would be benefits to price competition that would help contain health care costs.²⁰³

Prescription Drug Monitoring Program

In General

Chapter 2009-197, Laws of Fla., established the Prescription Drug Monitoring Program (PDMP) within the Department of Health (DOH) in s. 893.055, F.S. The PDMP uses a comprehensive electronic system/database to monitor the prescribing and dispensing of certain controlled substances.²⁰⁴ The PDMP database became operational on September 1, 2011, when it began receiving prescription data, retroactive to December 1, 2010, from pharmacies and dispensing practitioners.²⁰⁵

Dispensers of controlled substances listed in Schedule II, III, or IV must report specified information to the PDMP database, including the name of the prescriber, the date the prescription was filled and dispensed, and the name, address, and date of birth of the person to whom the controlled substance is dispensed.²⁰⁶ Dispensers must report the dispensing of a specified controlled substance to the PDMP database within seven days of dispensing the controlled substance.²⁰⁷ As of February 2014, over 100

²⁰⁰ The Perryman Group, "The Economic Benefits of More Fully Utilizing Advanced Practice Registered Nurses in the Provision of Health Care in Texas," May 2012, available at <http://c.ymcdn.com/sites/www.texasnp.org/resource/resmgr/Advocacy/Perryman%20APRN%20Utilization%20Economic%20Impact%20Report%20May%202012.pdf> (last visited on April 9, 2014).

²⁰¹ Id.

²⁰² See supra, FN 199.

²⁰³ U.S. Federal Trade Commission, Office of Policy Planning, Bureau of Competition and Bureau of Economics, letters to the Illinois State Senate, Connecticut House of Representatives, and Texas State Senate (on file with Health and Human Services Committee staff).

²⁰⁴ S. 893.055(2)(a), F.S.

²⁰⁵ Florida Department of Health, *Overview and Status Update of the PDMP*, PowerPoint presentation before Health Quality Subcommittee, Sept. 24, 2013, page 3 (on file with Health Quality Subcommittee staff).

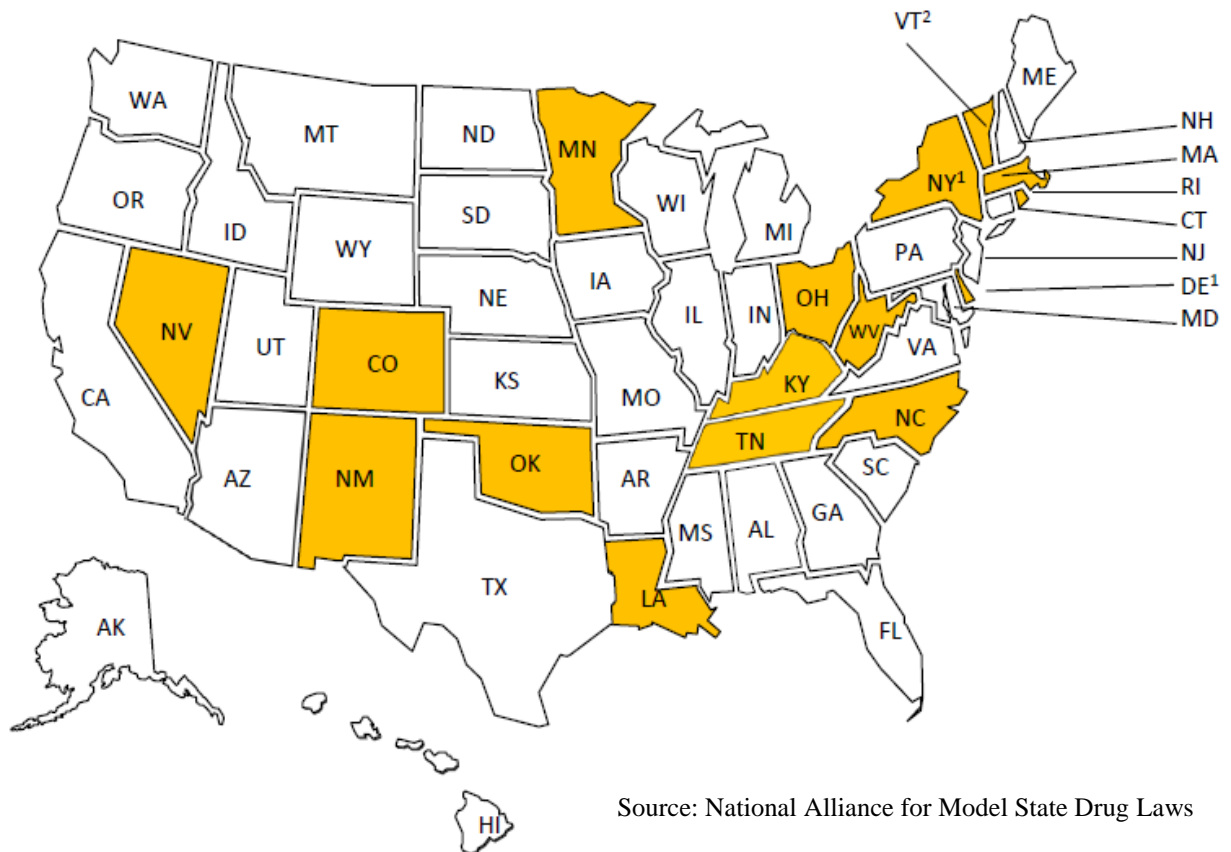
²⁰⁶ S. 893.055(3)(a)-(c), F.S.; controlled substances listed in Schedule II, III, or IV can be found in s. 893.03(2)-(4), F.S.

²⁰⁷ S. 893.055(4), F.S.

million dispensing records have been reported to the PDMP by more than 6,100 dispensers since the program became operational.²⁰⁸

Direct access to the PDMP database is presently limited by law²⁰⁹ to medical doctors, osteopathic physicians, dentists, podiatric physicians, advanced registered nurse practitioners, physician assistants, and pharmacists.²¹⁰ More than 24,000 prescribers and pharmacists have registered with the PDMP, and over 19,200 of those practitioners, or 79% of all registered practitioners, have queried the database.²¹¹

Although Florida law does not require physicians to access the PDMP database to review a patient's controlled substance prescription history prior to prescribing the patient a controlled substance, many other states' laws contain such a requirement. The following map²¹² shows the states (in yellow) that require prescribers or dispensers to access a "prescription management program" database, in certain circumstances.²¹³



Source: National Alliance for Model State Drug Laws

²⁰⁸ Memorandum from Rebecca Poston, Program Manager for PDMP, and Bob MacDonald, Executive Director, The Florida PDMP Foundation, Inc., to Marco Paredes, Director of Legislative Planning, Florida Department of Health, February 6, 2014, page 1 (responding to request for updated information from Health Quality Subcommittee staff, on file with subcommittee).

²⁰⁹ S. 893.055(7)(b), F.S.

²¹⁰ Health care practitioners began accessing the PDMP database on October 17, 2011. Florida Department of Health, Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), 2012-2013 Prescription Drug Monitoring Program Annual Report, December 1, 2013, page 2, available at www.floridahealth.gov/reports-and-data/e-forcse/news-reports/documents/2012-2013pdmp-annual-report.pdf (last viewed on March 14, 2014).

²¹¹ See supra, FN 208 at page 1.

²¹² National Alliance for Model State Drug Laws, Prescription Drug Monitoring Programs, *States that Require Prescribers and/or Dispensers to Access PMP In Certain Circumstances*, Map, July 2013, available at www.namsdl.org/library/15016036-1C23-D4F9-74B7207D8ED67C96 (last viewed on March 14, 2014).

²¹³ The New York law went into effect in August 2013. Delaware began requiring dispensers to check the database in March 2014. Vermont began requiring mandatory use for replacement prescriptions in October 2013 and in other circumstances in November 2013.

In Florida, indirect access to the PDMP database is provided to:

- The DOH or its relevant health care regulatory boards;
- The Attorney General for Medicaid fraud cases;
- A law enforcement agency;²¹⁴ and
- A patient or the legal guardian, or designated health care surrogate of an incapacitated patient.²¹⁵

Entities with indirect access to the PDMP database may request information from the PDMP program manager that is confidential and exempt under s. 893.0551, F.S., which is discussed below. A law enforcement agency, for example, may request such information during an active investigation regarding potential criminal activity, fraud, or theft relating to prescribed controlled substances.²¹⁶ As of February 2014, law enforcement agencies queried the PDMP database more than 36,000 times in conjunction with active criminal investigations.²¹⁷

Florida law only requires the PDMP program manager to verify that a request from a law enforcement agency to query the database is authentic and that it is related to an active investigation, but no supporting documentation is required to be submitted to the PDMP program manager to query the database. The following map, by state, shows what documentation, if any, law enforcement agencies across the U.S. are required to submit before information from the PDMP database is released to those agencies.²¹⁸

²¹⁴ Law enforcement agencies began requesting data from the PDMP in support of active criminal investigations on November 14, 2011. See *supra*, FN 210.

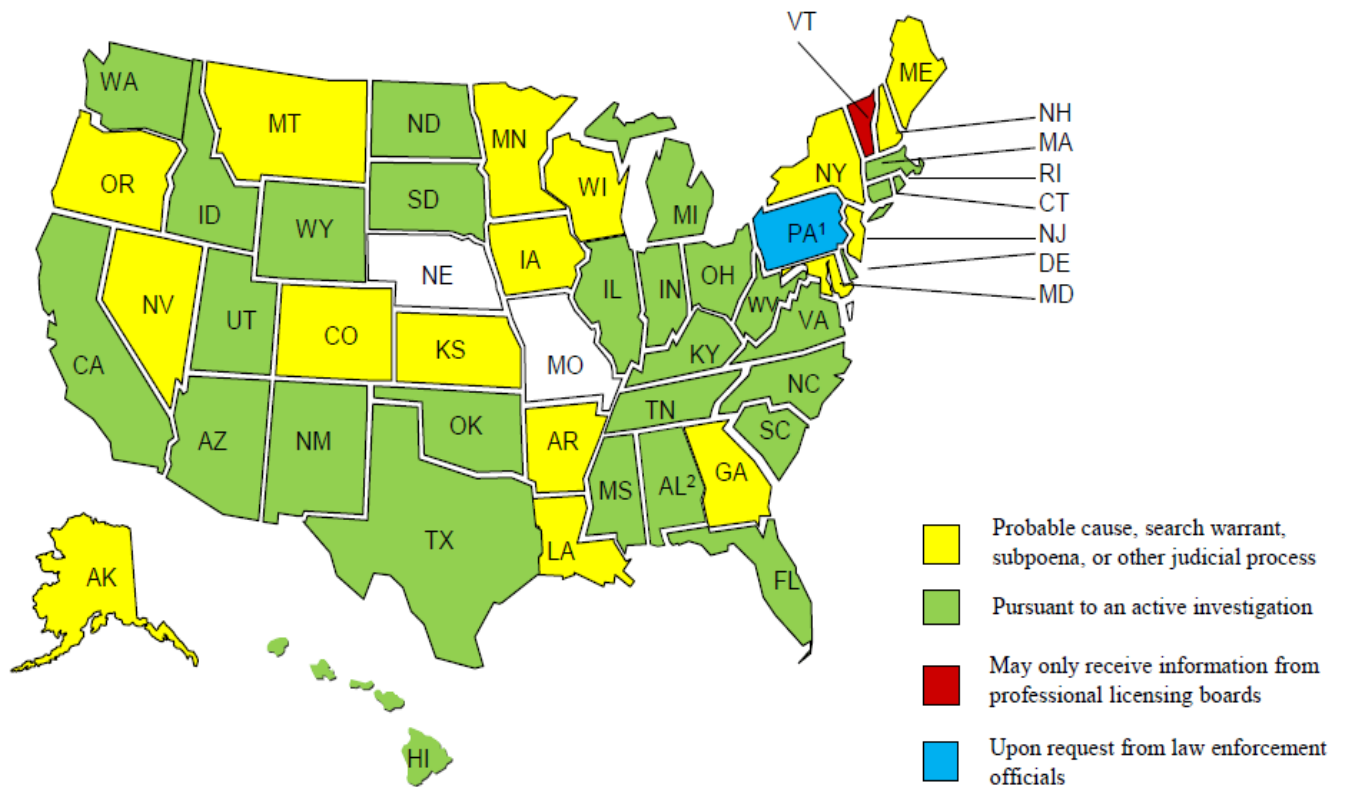
²¹⁵ S. 893.055(7)(c)1.-4., F.S.

²¹⁶ S. 893.055(7)(c)3., F.S.; see also 64K-1.003(2)(c), F.A.C.

²¹⁷ See *supra*, FN 208 at page 2.

²¹⁸ National Alliance for Model State Drug Laws, Prescription Drug Monitoring Programs, *Law Enforcement Access*, Map, July 2013, available at www.namsdl.org/library/17AEB855-1C23-D4F9-7464F56193EA3DEC (last viewed on March 14, 2014).

Types of Authorized Recipients – Law Enforcement Officials



Source: National Alliance for Model State Drug

Funding for the PDMP

Restrictions on how the DOH may fund implementation and operation of the PDMP are also included in statute. The DOH is prohibited from using state funds and any money received directly or indirectly from prescription drug manufacturers to implement the PDMP.²¹⁹ Since 2010, the PDMP has spent \$1,519,297 for system and database infrastructure, personnel, and facility expenses.²²⁰ Funding for the PDMP comes from three funding sources²²¹:

1. Donations procured by the Florida PDMP Foundation, Inc. (Foundation), the direct-support organization authorized by s. 893.055(11), F.S., to fund the continuing operation of the PDMP. The following amounts have been donated to the Foundation since its inception²²²:

FY 2009-2010	\$125,000
FY 2010-2011	\$339,443
FY 2011-2012	\$120,010

²¹⁹ S. 893.055(10) and (11)(c), F.S.

²²⁰ Florida Department of Health, Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), 2012-2013 Prescription Drug Monitoring Program Annual Report, December 1, 2013, page 8, available at www.floridahealth.gov/reports-and-data/e-forcse/news-reports/documents/2012-2013pdmp-annual-report.pdf (on file with Health Quality Subcommittee staff); information also came from Florida Department of Health documents detailing the funding history of the PDMP, also on file with Health Quality Subcommittee staff.

²²¹ See supra, FN 208 at pages 2-4.

²²² Information contained in a document received from Florida Department of Health, on file with subcommittee staff.

FY 2012-2013	\$73,910
FY 2013-2014	\$134,625
TOTAL	\$792,988

2. Federal Grants. The PDMP has been awarded four Harold Rogers Prescription Drug Monitoring Program (“Rogers”) grants from the U.S. Department of Justice and one additional federal grant. The amount and purpose of each grant follows:

- A Rogers "Implementation" grant of \$400,000 to implement the prescription drug monitoring system. The grant project period ended August 31, 2012.
- A Rogers "Enhancement" grant of \$400,000 for system enhancements. The grant period ended March 31, 2013.
- A second Rogers “Enhancement” grant of \$399,300 to enhance collaborations with law enforcement agencies, enhance the PDMP’s ability to analyze collected data to identify drug abuse trends and identify and address sources of prescription drug diversion, and increase the number of PDMP users. The grant period ends September 30, 2014.
- A third Rogers “Enhancement” grant of \$399,950 to form multi-disciplinary and multi-jurisdictional groups to identify areas of greatest risk for prescription drug abuse and diversion and create data-driven responses to these areas at the local level. The grant period ends March 31, 2015.
- A grant of \$240,105 from the Substance Abuse and Mental Health Services Administration to integrate PDMP data into existing clinical workflow and technology and to expand interoperability. The grant period ends September 30, 2014.

The total amount of federal grants received is \$1,839,355.

3. Private grants and donations. The DOH has been awarded three private grants from the National Association of State Controlled Substance Authorities. These grants, totaling \$49,952, were used to create a website, to purchase office equipment, and to purchase promotional items. The grant period ended on June 30, 2011, and \$44,886 was drawn down by the PDMP.

The following chart illustrates the breakdown of costs for the PDMP from FY 2012-13 through FY 2014-15.²²³

COST	FY 2012-13	FY 2013-14*	FY 2014-15*
Infrastructure	\$240,086	\$240,087	\$240,087
Personnel (2 FTEs)	\$211,016	\$209,454	\$209,454
Facilities	\$26,186	\$12,858	\$12,858
PDMP Enhancements	\$0	\$0	\$37,601
TOTAL	\$477,288	\$494,699	\$500,000

*Projected

The PDMP is currently funded through fiscal year 2013-2014.²²⁴

Public Records Exemption for Information in the PDMP Database

Section 893.0551, F.S.,²²⁵ provides an exemption from public records for personal information of a patient and certain information concerning health care professionals outlined in the statute.²²⁶ The statute details exceptions for disclosure of information after the DOH ensures the legitimacy of the

²²³ See supra, FN 208 at page 4.

²²⁴ See s. 10, Ch. 2013-153, Laws of Fla. (appropriating \$500,000 for FY 2013-2014 for the general administration of the PDMP).

²²⁵ The public records exemption was established in 2009 in conjunction with the PDMP. See s. 1, ch. 2009-197, Laws of Fla.

²²⁶ S. 893.0551(2)(a)-(h), F.S.

person's request for the information.²²⁷ The statute makes confidential and exempt from the Public Records Law²²⁸ and s. 24(a), Art. 1 of the State Constitution identifying information, including, but not limited to, the name, address, telephone number, insurance plan number, government-issued identification number, provider number, Drug Enforcement Administration number, or any other unique identifying number of a patient, patient's agent, health care practitioner or practitioner as defined in s. 893.055, or an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, a pharmacist, or a pharmacy, which is contained in the PDMP database.

The DOH is required to disclose the confidential and exempt information to the following entities after verifying that entity's request for the information is legitimate:

- The Attorney General or his or her designee when working on Medicaid fraud cases involving prescription drugs or when the Attorney General has initiated a review of specific identifiers of Medicaid fraud regarding prescription drugs.
- Any relevant health care regulatory board within the DOH which is responsible for the licensure, regulation, or discipline of a practitioner, pharmacist, or other person who is authorized to prescribe, administer, or dispense controlled substances and is involved in a specific controlled substances investigation for prescription drugs involving a designated person.
- A law enforcement agency as defined in s. 119.011(4)(a), F.S., which enforces the laws of this state or the United States relating to controlled substances and which has initiated an ongoing and active investigation, as defined in ss. 119.011 and 893.07, F.S., involving a specific violation of law regarding prescription drug abuse or diversion of prescribed controlled substances.
- A health care practitioner who certifies that the information is necessary to provide medical treatment to a current patient in accordance with ss. 893.05 and 893.055, F.S.
- A pharmacist, as defined in s. 465.003, F.S., who certifies that the requested information is to be used to dispense controlled substances to a current patient in accordance with ss. 893.04 and 893.055, F.S.
- A patient or the legal guardian or designated health care surrogate for an incapacitated patient, if applicable making a request as provided in s. 893.055(7)(c), F.S.
- The patient's pharmacy, prescriber, or dispenser, as defined in s. 893.055, who certifies that the information is necessary to provide medical treatment to his or her current patient in accordance with s. 893.055, F.S.
- The program manager of the PDMP, the program and support staff, and individuals designated by the program manager as necessary to process validated requests for information or to perform database administrative tasks necessary to support the monitoring program.

Any agency that obtains information pursuant to s. 893.0551, F.S., must maintain the confidential and exempt status of that information.²²⁹ However, a law enforcement agency with lawful access to such information is permitted to disclose confidential and exempt information received from the DOH to a criminal justice agency as part of an active investigation of a specific violation of law.²³⁰

A person who willfully and knowingly violates the restrictions on the use of the confidential and exempt information commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.803, or s. 775.084, F.S.²³¹

The exemption is subject to future review and repeal on October 2, 2014, in accordance with the Open Government Sunset Review Act.²³²

²²⁷ S. 893.0551(3)(a)-(g), F.S.

²²⁸ Ch. 119, F.S.

²²⁹ S. 893.0551(5), F.S.

²³⁰ S. 893.0551(4), F.S.

²³¹ S. 893.0551(6), F.S.

²³² The Open Government Sunset Review Act provides for the systematic review, through a 5-year cycle ending October 2 of the 5th year following enactment, of an exemption from the Public Records Act or the Sunshine Law. See s. 119.15, F.S.

Recent Disclosure of PDMP Database Information

In May 2013, members of a drug task force investigating prescription drug fraud and trafficking in central Florida queried the PDMP database for the prescription medication history of doctors and their pharmacies, and six individuals accused of forging prescriptions. The response to the query contained 3,300 patient names and prescription drug histories. The investigators uncovered, through verification by the doctors whose names were queried, 63 fictitious names and the stolen identities of seven other people. The six individuals were alleged to be using fictitious names and stolen identities to fraudulently obtain prescription drugs to be illegally distributed.

The State Attorney's Office in the Seventh Judicial Circuit of Florida, which was responsible for prosecuting the six individuals, provided defense counsel for five of the six accused persons with computer disks containing the 3,300 names and prescription drug histories. One defense counsel reviewed the information, recognized the name of a colleague, and disclosed the 3,300 names and prescription drug histories to the colleague, who was not involved in any of the six criminal cases resulting from the investigation.

The colleague, who was also a defense attorney, filed a lawsuit against the State Attorney seeking an injunction preventing the reviewing, revealing, copying, distributing, or discussing his private prescription medication history and seeking an order to require the State Attorney to notify the remaining 3,299 individuals that their names and prescription drug histories were published or disclosed by the State Attorney's Office. The lawsuit was dismissed by the circuit court in February 2014. However, the colleague refiled the lawsuit in March 2014, asking the court to declare unconstitutional s. 893.055(7)(c), F.S., and any other related provision which allows law enforcement agencies to access information in the PDMP database without a court order or search warrant. Litigation remains ongoing.

Public Health Trusts

Each county is authorized to create a public corporate body known as a public health trust.²³³ 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.²³⁴ 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).²³⁵

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.²³⁶ Designated facilities include:²³⁷

- Sanatoriums;
- Clinics;
- Ambulatory care centers;
- Primary care centers;
- Hospitals;
- Rehabilitation centers;
- Health training facilities;
- Nursing homes;

²³³ Section 154.07, F.S.

²³⁴ Id.

²³⁵ Section 154.08, F.S., and s. 154.09, F.S.

²³⁶ Section 154.08, F.S.

²³⁷ Id.

- 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.²³⁸ The board is selected by the governing body of the county where the trust is located and consists of between 7 and 21 members.²³⁹ 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.²⁴⁰ The members serve without compensation, but are entitled to necessary expenses incurred in the discharge of their duties.²⁴¹

The board of each public health trust is deemed to exercise a public and essential governmental function of both the state and the county.²⁴² 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:²⁴³

- 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).²⁴⁴ The Trust's designated facilities include Jackson Memorial Hospital and all related facilities and real and personal property. The related facilities include:²⁴⁵

²³⁸ Id.

²³⁹ Section 154.09, F.S.

²⁴⁰ Id.

²⁴¹ Id.

²⁴² Section 154.11, F.S.

²⁴³ Id.

²⁴⁴ Chapter 25A of the Miami-Dade County Code.

²⁴⁵ *About Jackson Health System: Overview*, <http://www.jacksonhealth.org/about.asp> (last visited on March 1, 2014)

- 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.

Medical Tourism

Medical tourism is a term used to describe when consumers travel to receive medical treatment. Traditionally, the term meant to travel across international boundaries but consumer travel across state lines has increased and is referred to as domestic medical tourism. Medical tourism can include sophisticated treatments such as cardiac surgery and orthopedics, as well as elective or routine procedures for dental care or cosmetic surgeries. Medical tourism seems to be occurring for a variety of reasons including the globalization of healthcare services and increases in geriatric populations in the United States and Europe. The industry has “medical tourism facilitators” that market medical tourism “models” to consumers. The function of facilitators is comparable to travel agents and presents legal uncertainties in the interaction between facilitators and providers.

Medical tourism occurs for a variety of reasons. Consumer preference in medical care will depend on factors that a consumer normally applies when purchasing a good. These factors can include cost, income, substitutions, or complimentary goods. Due to the size and scope of the healthcare industry, there is no one “trend” in medical tourism.

Medical tourism is often presented as a way to lower costs for medical treatment. Cost savings is an incentive for some employers to adopt domestic medical tourism practices within the United States. Changes to healthcare law in the United States have brought medical treatment cost disparity into the spotlight. In May 2013, NPR reported on data released by the Federal Department of Health and Human Services on hospital charges for treatment of Medicare patients.²⁴⁶ NPR reported that there were large differences in the costs of the 100 most common treatments that require hospitalization. Differences occurred across states and hospitals miles from each other. The differences in cost ranged in multiples of 5 to 40. Similar reports found supporting examples including a joint replacement procedure that cost \$297,000 at Centinela Hospital and \$84,000 at St. John’s Health Center, two California hospitals about 12 miles apart.²⁴⁷ The reports suggest similar levels of disparity in costs to private insurers and uninsured patients.

Visit Florida

Visit Florida is the state’s public/private partnership for tourism marketing. Enterprise Florida, Inc. (EFI), contracts with Visit Florida to promote the state for tourism. EFI’s Division of Tourism Marketing supports Visit Florida in its activities. Visit Florida is also required to adopt a 4-year tourism marketing plan.²⁴⁸ According to Visit Florida, tourism in Florida was responsible for 91.5 million tourists in 2012 that spent more than \$71.8 billion, generated 23 percent of the state’s sales tax revenue and employed more than one million Floridians.²⁴⁹ The Fiscal Year 2013-14 General Appropriations Act appropriated

²⁴⁶ NPR, *Government Data Reveals Wild Disparity in Health Care Costs* (May 8, 2013), available at: <http://www.npr.org/templates/story/story.php?storyId=182337915> (Last visited March 28, 2014).

²⁴⁷ Christian Science Monitor, *New report reveals stunning disparities in health-care costs* (May 8, 2013), available at: <http://www.csmonitor.com/Business/2013/0508/New-report-reveals-stunning-disparities-in-health-care-costs> (Last visited March 28, 2014).

²⁴⁸ Section 288.923(4), F.S.

²⁴⁹ Visit Florida, available at: <http://www.visitflorida.com/en-us/about-visit-florida.html> (Last visited March 28, 2014).

over \$63 million to Visit Florida.²⁵⁰ Visit Florida raises matching funds from the private sector, and in 2012 achieved an almost 2:1 ratio, dollar per dollar.²⁵¹

Effect of Proposed Changes

Obstetrical Services in Hospitals

The bill amends s. 395.1051, F.S., to require hospitals to notify obstetrical physicians at least 120 days before closing an obstetrical department or ceasing to provide obstetrical services.

Trauma Centers

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 consecutive 12-month period after enactment of ch. 2004-259, remains in operation for the consecutive 12-month period immediately preceding the effective date of the bill, and submits an application by April 1, 2015, to the ACS COT for a site visit to obtain a consultation report to continue to operate as a verified trauma center at the same level, 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.

Further, the bill caps the amount a trauma center may charge for its trauma activation fee at \$15,000 for one year. The bill requires each trauma center to post the trauma activation fee within the center and in a prominent position on the trauma center's website home page.

The bill also amends s. 395.402, F.S., to remove any reference to the RDSTF structure and trauma regions, which mirror the regions established in the RDSTF structure, as factors to be considered by the DOH in an assessment of the statewide trauma system.

Finally, the bill eliminates current Trauma Service Area (TSA) 17, which consists of Collier county, and moves Collier county to TSA 15, which consists of Charlotte, Glades, Hendry, and Lee counties. Currently TSA 17 does not have a trauma center within its boundaries. Residents of Collier county in need of trauma care most often seek such care in Lee county. The bill reduces the total number of TSAs by one, to 18 TSAs.

²⁵⁰ Fiscal Year 2013-14 General Appropriations Act, Line Item 2228, ch. 2013-40, L.O.F.

²⁵¹ Visit Florida, available at: <http://www.visitflorida.com/en-us/about-visit-florida.html> (Last visited March 28, 2014).

Telehealth

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.²⁵²

- Acupuncturist;
- Allopathic physician;
- Osteopathic physician;
- Chiropractor;
- Podiatrist;
- 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 in this state. 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

²⁵² 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.
STORAGE NAME: h7113b.HHSC
DATE: 4/18/2014

relevant scope of practice, as established by Florida law and rule, may not be interpreted as practicing medicine without a license. The bill prohibits a telehealth provider from using telehealth to prescribe a controlled substance for chronic nonmalignant pain unless the controlled substance is ordered for inpatient treatment at a hospital licensed under ch. 395.

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 in this state. 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 the DOH or the applicable board to provide telehealth services, within the relevant scope of practice established by Florida law and rule, to patients in this state. To register as an out-of-state telehealth provider, the health care professional must:

- Submit an application to the DOH;
- Pay a \$150 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 also requires out-of-state telehealth providers to notify the applicable board or the DOH of restrictions placed on the health care professional's license to practice or disciplinary actions taken against the health care practitioner.

The bill authorizes the DOH to revoke an out-of-state telehealth provider's registration if the registrant:

- Fails to immediately notify the department of any adverse actions taken against his or her license;
- Has restrictions placed on or disciplinary action taken against his or her license in any state or jurisdiction; or
- Violates any of the requirements for the registration of out-of-state telehealth providers.

The bill requires the DOH to publish on its website the name of each registered out-of-state telehealth provider. It must also include the following background information for each registrant:

- Health care occupation;
- Completed health care training and education, including completion dates and any certificates or degrees obtained;
- Out-of-state health care license with license number;
- Florida telehealth provider registration number;
- Specialty;
- Board certification;
- 5 year disciplinary history, including sanctions and board actions; and
- Medical malpractice insurance provider and policy limits, including whether the policy covers claims which arise in this state.

The bill establishes, for jurisdictional purposes, that any act that constitutes the delivery of health care services shall be deemed to occur at the place where the patient is located at the time the act is performed. This will assist a patient in establishing jurisdiction and venue in Florida in the event he or she pursues a legal action against the telehealth provider.

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

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

Certificate of Need (CON) Review Exemption

The bill creates an exemption from CON review for the relocation of less than 15 percent of a hospital's current licensed beds within the same county, if the hospital:

- Has 500 or more licensed beds.
- Provides care to more Medicaid recipients and uninsured individuals than other hospitals operating in the same county.
- Receives least 40% of its gross revenues from services provided to Medicaid recipients and uninsured individuals.
- Has an investment grade bond rating.

The hospital must also certify that relocation of the beds is for the purpose of enhancing the fiscal stability of the hospital.

It appears that Shands Jacksonville Medical Center could meet the criteria to relocate beds.

Advanced Practice Registered Nurses

To address the current and impending health care workforce shortage in Florida, this bill expands the scope of practice for certified nurse practitioners (CNPs) and authorizes certain qualified CNPs to practice autonomously.

Certified Nurse Practitioners

The bill authorizes CNPs to prescribe, dispense, order, or administer controlled substances, if allowed under a supervising physician's protocol and only to the extent the supervising physician is authorized to prescribe, dispense, order, or administer those controlled substances.

Independent Nurse Practitioners

The bill allows a CNP who meets certain eligibility criteria to register as an "Independent Nurse Practitioner" (INP). The bill establishes title protection for this new title.

To register as an INP, the applicant must hold an active and unencumbered ARNP certificate and a national nurse practitioner certificate, pay an application fee set by the Board (not to exceed \$100), and must have:

- Completed, in any U.S. jurisdiction, at least 2,000 clinical practice hours within a three-year period immediately prior to applying for registration;
- Not been subject to any disciplinary action during the five years immediately preceding the application; and
- Completed a graduate level course in pharmacology.

To maintain their registration, INPs must complete at least 10 hours of continuing education approved by the Board in pharmacology prior to biennial renewal, unless an exception applies for the first biennial renewal. ARNPs registered as INPs must also ensure that their practitioner profiles created by the Department of Health reflect their registration as an INP.

INPs are authorized to perform any act currently authorized for CNPs, but may perform such acts without the supervision of a physician or a written protocol. In addition to those acts, an INP may independently and without supervision or a written protocol perform the following acts:

- Admit, discharge, or manage the care of, a patient requiring the services of a health care facility.
- Provide a signature, certification, stamp, verification, affidavit, or other endorsement that is otherwise required by law to be provided by a physician.
- Certify causes of death and sign, correct, and file death certificates.
- Act as a patient's primary care provider.
- Execute a certificate to subject a person to involuntary examination under the Baker Act.²⁵³
- Examine, and approve the release of, a person admitted into a receiving facility under the Baker Act, if the INP holds a national certification as a psychiatric-mental health advanced practice nurse.

The bill imposes safeguards to ensure INPs safely prescribe controlled substances and are held accountable if they do otherwise. Specifically, INPs:

- Must report adverse incidents attributable to the prescription of a controlled substance. Adverse incidents are only those events that require the transfer of a patient to a hospital or cause permanent physical injury or death.
- May be administratively disciplined for several delineated prohibited acts related to inappropriate prescribing practices.
- Are required to register as prescribers of controlled substances for chronic nonmalignant pain, if they prescribe such substances, and must meet statutory requirements related to treatment plans, recordkeeping, patient examinations, written agreements, and referrals.
- Must comply with the prescribing and dispensing requirements and limitations under the Florida Comprehensive Drug Abuse Prevention and Control Act.²⁵⁴

In addition, the bill provides for several other accountability measures for INPs by:

- Requiring INPs to maintain malpractice insurance or prove financial responsibility as provided by Board rule to ensure claims due to malpractice are covered;
- Authorizing the Board to administratively discipline INPs for several delineated prohibited acts related to relationships with patients, business practices, and nursing practices; and
- Subjecting INPs to accountability provisions included in the Florida Patient's Bill of Rights and Responsibilities.²⁵⁵

The bill also revises the membership of the joint committee currently established in law under s. 464.03(2), F.S., to replace the Surgeon General's appointee with a Board of Pharmacy appointee. The joint committee, which is currently responsible for determining the medical acts that may be performed by ARNPs, is tasked with establishing a formulary of controlled substances that INPs may not prescribe, administer, or dispense.

²⁵³ The Baker Act is also titled the "Florida Mental Health Act" under s. 394.451, F.S.

²⁵⁴ Chapter 893, F.S.

²⁵⁵ S. 381.026, F.S., requires health care providers to provide patients with certain information related to qualifications, diagnosis, treatment, grievance procedures, and service charges. Also, health care providers are prohibited from discriminating against a patient for specified reasons and must respect a patient's privacy under this law.

Prescription Drug Monitoring Program

The bill makes comprehensive, but non-substantive, changes to the current law by reorganizing and rewording s. 893.055, F.S. All of the substantive provisions governing the establishment, maintenance, and operation of the PDMP that are currently in the statute are included in the bill.

However, the bill makes two substantive changes to current law. First, the bill requires a physician to access the PDMP database and review a new patient's prescription drug history prior to issuing a prescription for a Schedule II, III, or IV controlled substance at the initial visit with the patient. The bill also makes any failure to comply with this requirement grounds for discipline against the license of the physician. Physicians are not required to access the PDMP database under current law. The bill takes into account the possibility that the PDMP database may not be accessible at the time a physician is about to issue a prescription for a controlled substance to a patient at that patient's visit. If that occurs, and the inability to access the PDMP database is through no fault of the physician, the physician may issue the prescription to the patient and view the patient's prescription drug history after the initial visit once accessibility is restored.

Second, the bill requires a law enforcement agency to enter into a user agreement with the PDMP before it can receive information from the PDMP database. The user agreement, which will be created by the DOH, must, at a minimum:

- Provide access control and information security to maintain confidentiality;
- Contain training requirements for the authorized users of the law enforcement agency;
- Require an annual attestation from the head of the law enforcement agency stating that the agency is complying with the agreement and disclosing any issues and corrective action to maintain compliance;
- Require biennially updates to the PDMP database regarding the status of any case for which information was received from the database;
- Require a law enforcement agency to appoint an agency administrator who will appoint authorized users and ensure compliance with the agreement and applicable laws;
- Require each authorized user to attest that each request for information from the PDMP database is related to an active investigation;
- Require a law enforcement agency to conduct an annual self-audit, completed by the agency's internal affairs or professional standards division, to ensure compliance with the agreement. The results of the audit must be reported to the PDMP manager within 7 days of completion; and
- Allow the PDMP manager to restrict, suspend, or terminate an agency administrator's or authorized user's access to the PDMP database for failing to comply with the agreement.

The bill also limits the release of PDMP information shared with a state attorney to responses to a discovery demand only if the information is directly related to the criminal case for which the information is requested from the PDMP database. If the information is not related to the criminal case, the state attorney must inform the party demanding discovery that unrelated information exists. Information that is unrelated to the criminal case can only be released upon an order of a court of competent jurisdiction.

Public Health Trusts

The bill gives authority to a public health trust to execute a contract with a labor union or any other labor organization without first obtaining approval from the governing body of the county.

Medical Tourism

The bill directs EFI to market the state as a health care destination and to promote quality health care services in Florida. It also requires the inclusion of promotion of medical tourism as a part of Visit Florida's 4-year tourism marketing plan.

The bill requires Visit Florida to include specific initiatives to advance Florida as a healthcare destination within the 4-year marketing plan. The marketing plan must:

- Promote national and international awareness of the qualifications, scope of services, and specialized healthcare expertise of providers in Florida; and
- Include an initiative that showcases select qualified providers offering bundled healthcare packages and support services.

The showcased providers must be selected through a solicitation of proposals from licensed providers for plans. The plans should include available services, provider qualifications, logistic arrangements, and other services and amenities to be provided to patients and their families. Single proposals may include offers made through a network of providers.

Visit Florida shall assess the qualifications and credentials of providers submitting proposals. To the extent funding is available, all qualified providers must be selected to be in the showcase.

To be qualified for the showcase, a provider must:

- Ensure that all providers in a proposal must have full, active, and unencumbered Florida licenses;
- Unconditional accreditation from a nationally recognized accrediting body;
- Be recognized as a Cancer Center of Excellence or have a current national or international recognition in a specialty area; and
- Meet other criteria established by Visit Florida in collaboration with the Florida Agency for Health Care Administration (AHCA) and the Department of Health.

Visit Florida is also required to create a matching grant program to provide funding to local or regional economic development organizations for targeted medical tourism marketing initiatives. The initiatives must promote Florida as a destination for healthcare service. Providers involved in the local initiative must meet the criteria specified for qualified providers in the showcase. The local or regional economic development organization must show an ability to involve a variety of businesses to collaboratively welcome and support patients and their families who travel to Florida for medical services. The cash or in-kind services available from the local or regional economic development board must be at least equal to the amount of state financial support. Proposals must be submitted by November 1 of each year. Funds must be equally divided among all selected applicants.

The bill requires \$3.5 million of the funds appropriated in the GAA to Visit Florida to be allocated annually for the development and implementation of the medical tourism marketing plan. An additional \$1.5 million must be allocated annually for the matching grant program.

The bill provides an effective of July 1, 2014, except as otherwise indicated.

B. SECTION DIRECTORY:

Section 1: Amends s. 395.1051, F.S., relating to duty to notify patients.

Section 2: Creates an unnumbered section of law related to legislative findings regarding the state trauma system and trauma centers.

Section 3: Creates an unnumbered section of law related to becoming a verified Level I, Level II, or pediatric trauma center, notwithstanding any other provision of law.

- Section 4:** Creates an unnumbered section of law related to the provision of a trauma center consultation report by a trauma center to the Department of Health and the use of the report in any assessment of the state trauma system.
- Section 5:** Amends s. 395.401, F.S., relating to trauma services system plans; approval of trauma centers and pediatric trauma centers; procedures; renewal.
- Section 6:** Amends s. 395.402, F.S., relating to trauma service areas; number and location of trauma centers.
- Section 7:** Amends s. 395.4025, F.S., relating to trauma centers; selection; quality assurance; records.
- Section 8:** Creates s. 456.47, F.S., relating to use of telehealth to provide services.
- Section 9:** Amends s. 408.036, F.S., relating to projects subject to review; exemptions.
- Section 10:** Amends s. 381.026, F.S., relating to Florida Patient's Bill of Rights and Responsibilities.
- Section 11:** Amends s. 382.008, F.S., relating to death and fetal death registration.
- Section 12:** Amends s. 394.463, F.S., relating to involuntary examination.
- Section 13:** Amends s. 456.048, F.S., relating to financial responsibility requirements for certain health care practitioners.
- Section 14:** Amends s. 456.44, F.S., relating to controlled substance prescribing.
- Section 15:** Amends s. 464.003, F.S., relating to definitions.
- Section 16:** Amends s. 464.012, F.S., relating to certification of advanced registered nurse practitioners; fees.
- Section 17:** Creates s. 464.0125, F.S., relating to registration of independent advanced practice registered nurses; fees.
- Section 18:** Amends s. 464.015, F.S., relating to titles and abbreviations; restrictions; penalty.
- Section 19:** Creates s. 464.0155, F.S., relating to reports of adverse incidents by independent advanced practice registered nurses.
- Section 20:** Amends s. 464.018, F.S., relating to disciplinary actions.
- Section 21:** Amends s. 893.02, F.S., relating to definitions.
- Section 22:** Amends s. 960.28, F.S., relating to payment for victims' initial forensic physical examinations.
- Section 23:** Amends s. 288.901, F.S., relating to Enterprise Florida, Inc.
- Section 24:** Amends s. 288.923, F.S., relating to Division of Tourism Marketing; definitions; responsibilities.
- Section 25:** Creates s. 288.924, F.S., relating to medical tourism.
- Section 26:** Amends s. 456.072, F.S., relating to grounds for discipline; penalties; enforcement.
- Section 27:** Amends s. 893.055, F.S., relating to prescription drug monitoring program.
- Section 28:** Amends s. 893.0551, F.S., relating to public records exemption for the prescription drug monitoring program.
- Section 29:** Amends s. 154.11, F.S., relating to powers of board of trustees.
- Section 30:** Creates an unnumbered section of law making an appropriation of \$500,000 in nonrecurring funds from the General Revenue Fund to the Department of Health for the general administration of the prescription drug monitoring program.
- Section 31:** Provides an effective date of July 1, 2014, except as otherwise provided.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Advanced Practice Registered Nurses

Applicants for registration as an INP will have to pay an initial application fee, and registered INPs will have to pay a biennial renewal fee, to the DOH. The total amount the DOH will receive from

such fees is indeterminate, because the number of APRNs who choose to register as INPs is not predictable.

2. Expenditures:

Advanced Practice Registered Nurses

The Board of Nursing may incur indeterminate, but nominal, costs associated with rulemaking, which can be absorbed within existing resources.

PDMP

The bill appropriates \$500,000 in nonrecurring funds from the General Revenue Fund to the DOH for the general administration of the PDMP for fiscal year 2014-2015.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Trauma Centers

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.²⁵⁶ Review teams consist of two trauma surgeons and one nurse supervisor.²⁵⁷ A four person review team adds a specialist with additional trauma experience.²⁵⁸ Any additional member of the review team costs \$3,000.²⁵⁹ 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 \$19,500.²⁶⁰

Advanced Practice Registered Nurses

Applicants for registration as an INP will have to pay an application fee and INPs renewing their registration will be subject to renewal fees. The bill authorizes the Board to set the application and biennial renewal fees, but they may not exceed \$100 and \$50 respectively.

The bill requires INPs to obtain medical malpractice insurance. The Board may require INPs to have more coverage and therefore a more expensive policy than what is required for APRNs.

²⁵⁶ 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).

²⁵⁷ Telephone conference between Molly Lozada, Verification/Consultation Programs Program Administrator, and Health Innovation Subcommittee staff on January 30, 2014.

²⁵⁸ Id.

²⁵⁹ Id.

²⁶⁰ See supra, FN 257.

ARNPs who have paid physicians in order to be supervised under a protocol achieve some cost-savings if they register as an INP and practice without a written protocol.

Medical Tourism

The bill could result in an increase in medical tourism in the state, increasing both tourism dollars spent and spending on health care.

D. FISCAL COMMENTS:

Medical Tourism

The bill reallocates some of the appropriation to Visit Florida for the purpose of including medical tourism in its 4-year marketing plan and showcasing Florida providers. The bill also allocates \$1.5 million annually for Visit Florida to create a matching grant program for local and regional economic development organizations to create targeted medical tourism marketing initiatives.

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:

Trauma Centers

The Florida Constitution provides that the Legislature shall not enact any special law unless notice is first published.²⁶¹ 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.²⁶² Laws which arbitrarily affect one subdivision of the state, but which fail to encompass other similarly situated subdivisions may be classified as special laws.²⁶³ 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.²⁶⁴ 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.²⁶⁵

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."²⁶⁶ 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.²⁶⁷ Police power is the sovereign right of the state to enact laws

²⁶¹ Florida Const. Art. III, s. 10; notice may be avoided if a referendum is conducted among those citizens affected by the law.

²⁶² *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).

²⁶³ *Dept. of Bus. Regulation v. Classic Mile, Inc.*, 541 So.2d 1155 (Fla. 1989).

²⁶⁴ *Id.*; see also *Anderson v. Board of Pub. Instruction for Hillsborough Cnty.*, 136 So. 334 (Fla. 1931).

²⁶⁵ Florida Const. Art. III, s. 11.

²⁶⁶ *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)).

²⁶⁷ *Id.* at 1336-37.

for the protection of lives, health, morals, comfort and general welfare.²⁶⁸ 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.²⁶⁹

In General

The bill may implicate the provision of Article III, Section 6 of the Florida Constitution which requires every law to embrace one subject and matter properly connected therewith.

B. RULE-MAKING AUTHORITY:

Where necessary, the bill provides sufficient rule-making authority to the appropriate department or agency to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On April 10, 2014, the Health and Human Services Committee adopted six amendments and reported the bill favorably as a committee substitute. The amendments made the following changes to the bill:

- Clarified that a trauma center must be in operation for the consecutive 12-month period immediately preceding the effective date of the act to be eligible for verification as a trauma center.
- Removed any reference to the RDSTF structure or trauma regions, which mirror the regions established under the RDSTF structure, as factors that must be considered by the DOH in an assessment of the statewide trauma system.
- Eliminated TSA 17 and moved Collier county to TSA 15 with Charlotte, Glades, Hendry, and Lee counties.
- Added provisions relating to the PDMP which:
 - Contains a comprehensive and nonsubstantive rewrite of s. 893.055, F.S.;
 - Requires a physician to access the PDMP and view a patient's prescription drug history prior to issuing a prescription for a controlled substance at the patient's first visit or face disciplinary action;
 - Requires the DOH to develop a user agreement to be executed by a law enforcement agency prior to obtaining information from the PDMP; and
 - Specifies the terms of the user agreement, including annual attestation by the agency head that the agreement, laws, and rules are being followed and an annual self-audit by the agency internal affairs or professional standards division to ensure the agreement, law, and rules are being followed.
- Added provisions relating to medical tourism which:
 - Directs Enterprise Florida, Inc., and Visit Florida to promote medical tourism and market the state as a healthcare destination;

²⁶⁸ *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).

²⁶⁹ *Id.* (citing *Scarborough v. Newsome*, 7 So.2d 321 (1942); *Holley*, 238 So.2d at 407).

- Requires Visit Florida to include medical tourism in the 4-year marketing plan and showcase Florida providers; and
- Requires Visit Florida to create a matching grant program for local and regional economic development organizations to create targeted medical tourism marketing initiatives.
- Authorized a public health trust to execute a contract with a labor union or other labor organization without first seeking approval from the governing body of the county where the public health trust is located.
- Removed the provisions of the bill which permitted the use of telehealth to diagnose and treat the human eye and its appendages under certain conditions and if certain criteria were met.

The analysis is drafted to the committee substitute as passed by the Health and Human Services Committee.