

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 7087 PCB SCAHA 16-01 Telehealth

SPONSOR(S): Health & Human Services Committee; Health Care Appropriations Subcommittee; Select Committee on Affordable Healthcare Access; Sprowls

TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Select Committee on Affordable Healthcare Access	14 Y, 0 N	McElroy	Calamas
1) Health Care Appropriations Subcommittee	9 Y, 0 N, As CS	Garner	Pridgeon
2) Health & Human Services Committee	17 Y, 0 N, As CS	McElroy	Calamas

SUMMARY ANALYSIS

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

The bill authorizes Florida licensed health care professionals to use telehealth to deliver health care services within their respective scopes of practice. The bill also authorizes out-of-state health care professionals to use telehealth to deliver health care services to Florida patients if they register, and renew registration biennially, with the Department of Health (DOH) or the applicable board, meet certain eligibility requirements, and pay a fee. A registered telehealth provider is prohibited from opening an office in Florida and from providing in-person health care services to patients located in Florida.

The bill requires a telehealth provider to use the same standard of care applicable to health care services provided in person. Additionally, the telehealth provider must conduct an in-person physical examination of the patient prior to providing services through telehealth, unless the telehealth provider is capable of conducting a patient evaluation using telehealth in a manner consistent with the applicable standard of care sufficient to diagnose and treat the patient. Both the telehealth provider and the patient may be in any location at the time the services are rendered.

The bill allows health care providers who are authorized to prescribe a controlled substance to use telehealth to do so. Telehealth may not be used to prescribe a controlled substance to treat chronic nonmalignant pain, except in certain limited circumstances. The bill requires registered telehealth providers, who are pharmacists, to use only pharmacies that hold a Florida permit or registration to dispense drugs to patients in Florida.

The bill requires a telehealth provider to document the services rendered in the patient's medical records according to the same standard as that required for in-person services. The bill requires those records to be confidential in accordance with the current confidentiality requirements placed upon health care facilities and health care professionals providing in-person services.

The bill requires a registered telehealth provider to notify the appropriate professional board, or DOH if there is no board, when the telehealth provider's license is restricted or when a disciplinary action has been taken or is pending, within 5 days of such occurrence. The bill authorizes the board, or DOH if there is no board, to revoke a telehealth provider's registration for failure to provide such notification, for having a restriction placed on the telehealth provider's license in another state or jurisdiction, and for violating any of the requirements outlined in the bill.

The bill excludes a product used to deliver services through telehealth from the definition of discount medical plan.

The bill requires the Agency for Health Care Administration (AHCA), with assistance from DOH and the Office of Insurance Regulation (OIR), to survey health care providers, facilities and insurers on telehealth utilization and coverage. The bill requires AHCA to report on the surveys to the Governor, Senate President and Speaker of the House of Representatives. These departments can absorb the impact of conducting the survey within existing resources.

The bill provides an appropriation of \$261,389 recurring and \$15,528 nonrecurring from the Medical Quality Assurance Trust Fund and four full time equivalent positions and \$145,870 in salary rate to utilize the funds generated from the registration fee to offset the workload increase anticipated from additional licenses. The bill does not appear to have a fiscal impact on local government.

The bill provides an effective date of July 1, 2015.

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

STORAGE NAME: h7087c.HHSC

DATE: 2/19/2016

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Health Care Professional Shortage

There is currently a health care provider shortage in the U.S.¹ For example, as of June 19, 2014, the U.S. Department of Health and Human Services has designated 6,100 Primary Care Health Professional Shortage Area (HPSA) (requiring 8,200 additional primary care physicians to eliminate the shortage), 4,900 Dental HPSAs (requiring 7,300 additional dentists to eliminate the shortage), and 4,000 Mental Health HPSAs (requiring 2,800 additional psychiatrists to eliminate the shortage). Similarly, according to a 2010 report prepared by the Florida Center for Nursing, Florida is projected to experience a shortage of more than 62,800 nurses by 2025.²

This shortage is predicted to continue into the foreseeable future and will likely worsen with the aging and growth of the U.S. population³ and the passage of the Patient Protection and Affordable Care Act.⁴ Aging populations create a disproportionately higher health care demand.⁵ Additionally, as more individuals qualify for health care benefits, there will necessarily be a greater demand for more health care professionals to provide these services. There are several other factors which will likely increase the demand for a larger health care workforce. These include:⁶

- Shortage of health care 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 for just primary care, dental care and mental health there are 615 federally designated Health Professional Shortage Areas (HPSA) within the state.⁷ It would take 916 primary care⁸, 860 dental care⁹ and 83 mental health¹⁰ practitioners to eliminate these shortage areas.

¹ For example, as of June 19, 2014, the U.S. Department of Health and Human Services has designated 6,100 Primary Care Health Professional Shortage Area (HPSA) (requiring 8,200 additional primary care physicians to eliminate the shortage), 4,900 Dental HPSAs (requiring 7,300 additional dentists to eliminate the shortage), and 4,000 Mental Health HPSAs (requiring 2,800 additional psychiatrists to eliminate the shortage). This information is available at the U.S. Department of Health and Human Services' Health Resources and Services Administration's website, <http://www.hrsa.gov/shortage/> (last visited on February 17, 2016).

² 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* (Oct. 2010), available at <https://www.flcenterfornursing.org/ForecastsStrategies/FCNForecasts.aspx> (last visited February 17, 2016).

³ There will be a significant increase in the U.S. population, estimated to grow 20 percent (to 363 million) between 2008-2030.

⁴ *Department of Health and Human Services Strategic Plan: Goal 5: Strengthen the Nation's Health and Human Service Infrastructure and Workforce*, U.S. Department of Health and Human Services, <http://www.hhs.gov/secretary/about/goal5.html> (last visited on February 17, 2016).

⁵ One 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. Petterson, Stephen M., et al., "Projecting U.S. Primary Care Physician Workforce Needs: 2010-2025", *Annals of Family Medicine*, vol. 10, No. 6, Nov./Dec. 2012, available at: <http://www.annfammed.org/content/10/6/503.full.pdf+html> (last visited on February 17, 2016).

⁶ *Telemedicine: An Important Force in the Transformation of Healthcare*, Matthew A. Hein, June 25, 2009.

⁷ *Providers & Service Use Indicators*, Kaiser Family Foundation. <http://kff.org/state-category/providers-service-use/access-to-care/> (last visited on February 17, 2016).

⁸ *Primary Care Health Professional Shortage Areas (HPSAs)*, Kaiser Family Foundation. <http://kff.org/other/state-indicator/primary-care-health-professional-shortage-areas-hpsas/> (last visited on February 17, 2016).

⁹ *Dental Care Health Professional Shortage Areas (HPSAs)*, Kaiser Family Foundation. <http://kff.org/other/state-indicator/dental-care-health-professional-shortage-areas-hpsas/> (last visited on February 17, 2016).

¹⁰ *Mental Health Professional Shortage Areas (HPSAs)*, Kaiser Family Foundation. <http://kff.org/other/state-indicator/mental-health-care-health-professional-shortage-areas-hpsas/> (last visited on February 17, 2016).

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.¹¹ 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 professionals¹² and more efficient utilization of our existing workforce through the expanded use of telehealth.¹³

Telehealth

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

The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment¹⁴ and prevention of disease and injuries¹⁵, 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.¹⁶

More specific definitions vary by country and state, and occasionally by profession.¹⁷ There are, however, common elements among the varied definitions of telehealth.

Telehealth generally consists of synchronous and/or asynchronous transmittal of information.¹⁸ Synchronous refers to the live¹⁹ transmission of information between patient and provider during the same time period.²⁰ Asynchronous telehealth is the transfer of data over a period of time, and typically in separate time frames.²¹ 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 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

¹¹ U.S. Department of Health and Human Services, *supra* note 4.

¹² *Id.*

¹³ *Department of Health and Human Services Strategic Plan: Goal 1: Strengthen the Nation's Health and Human Service Infrastructure and Workforce*, U.S. Department of Health and Human Services, <http://www.hhs.gov/secretary/about/goal5.html> (last visited on February 17, 2016).

¹⁴ The University of Florida's Diabetes Center of Excellence utilizes telehealth to deliver treatment to children with diabetes and other endocrine problems who live in Volusia County. This allows the children to receive specialized treatment without the necessity of traveling from Volusia County to Gainesville. The Florida Department of Health's Children's Medical Services underwrites the program. <https://ufhealth.org/diabetes-center-excellence/telemedicine> (last visited on February 17, 2016).

¹⁵ The University of South Florida has partnered with American Well to provide health care services to the residents of the Villages via telehealth. The goal is to reduce hospital admissions, readmission rates, and pharmacy costs, while maintaining Medicare beneficiaries in their homes rather than long-term care settings. <http://hscweb3.hsc.usf.edu/blog/2012/06/22/usf-health-and-american-well-to-bring-telehealth-to-seniors-living-at-the-villages/> (last visited on February 17, 2016).

¹⁶ *Telemedicine: Opportunities and Developments in Member States, Global Observatory for Ehealth Series- Volume 2*, Section 1.2, page 9.

¹⁷ *State Telehealth Laws and Reimbursement Policies*, Center for Connected Health Policy, The National Telehealth Policy Resource Center, February 2015.

¹⁸ The majority of telehealth definitions allow for both synchronous and asynchronous transmittal of information. Some definitions however omit asynchronous from the definition of telehealth.

¹⁹ This is also referred to as “real time” or “interactive” telehealth.

²⁰ *Telemedicine Nomenclature*, American Telemedicine Association, located at <http://www.americantelemed.org/resources/nomenclature#.VOuc1KNOncs> (last visited on February 17, 2016). The use of live video to evaluate and diagnosis a patient would be considered synchronous telehealth.

²¹ *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.

health status of a patient from a distance.²² Telehealth more broadly includes non-clinical services, such as patient and professional health-related education, public health and health administration.²³

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.²⁴

Telehealth, in its modern form,²⁵ started in the 1960s in large part driven by the military and space technology sectors.²⁶ 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.²⁷ In fact, there are currently an estimated 200 telehealth networks, with 3,500 service sites in the U.S.²⁸

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.²⁹ This occurs in both rural areas and urban communities.³⁰ Telehealth reduces the impact of this issue by providing a mechanism to deliver quality health care, irrespective of the location of a patient or a health care professional. Cost is another barrier to obtaining quality health care.³¹ 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 patient³² or a chronic condition.³³ 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 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:

²² American Telemedicine Association, *Telemedicine/Telehealth Terminology*, <http://www.americantelemed.org/docs/practice-telemedicine/glossaryofterms.pdf> (last visited February 18, 2016).

²³ Id.

²⁴ *What is Telehealth?* U.S. Department of Health and Human Services, <http://www.hrsa.gov/healthit/toolbox/RuralHealthITToolbox/Telehealth/whatistelehealth.html> (last visited February 18, 2016).

²⁵ 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.

²⁶ *Telemedicine: Opportunities and Developments in Member States*, *supra* note 15.

²⁷ *What is Telemedicine*, American Telemedicine Association, <http://www.americantelemed.org/learn/what-is-telemedicine#.Uu6eGqNOncs> (last visited on February 18, 2016).

²⁸ *Telemedicine Frequently Asked Questions*, American Telemedicine Association, <http://www.americantelemed.org/learn/what-is-telemedicine/fags#.Uu5vyaNOncf> (last visited on February 18, 2016).

²⁹ U.S. Department of Health and Human Services, *supra* note 4.

³⁰ Id.

³¹ Id.

³² 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.

³³ For example, diabetes is a chronic condition which can benefit by treatment through telehealth.

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.³⁴ However, the Ryan Haight Online Pharmacy Consumer Protection Act,³⁵ 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 telehealth³⁶ 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.³⁷ To qualify for Medicare reimbursement, the originating site must be:

- Located in a federally defined rural county;
- Designated rural;³⁸ or
- Identified as a participant in a federal telemedicine demonstration project as of December 21, 2000.³⁹

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.⁴⁰

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 2002.⁴¹ These rules address the use and disclosure of an individual's personal health information as well as create standards for information security.

³⁴ 21 CFR §829(e)(2).

³⁵ Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Public Law 110-425 (H.R. 6353).

³⁶ 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.

³⁷ Only two states have a federal demonstration project that meets these qualifications, Hawaii and Alaska.

³⁸ 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).

³⁹ See 42 U.S.C. sec. 1395(m)(m)(4)(C)(i).

⁴⁰ See 42 U.S.C. sec. 1395(m)(m)(4)(C)(ii).

⁴¹ *The Privacy Rule*, U.S. Department of Health and Human Services. <http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/> (last visited February 18, 2016).

Only certain entities are subject to HIPAA's provisions. These "covered entities" include⁴²:

- 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).⁴³ 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.⁴⁴ HITECH was intended to strengthen existing HIPAA security and privacy rules.⁴⁵ It expanded HIPAA to entities not previously covered; specifically, "business associates" now includes Regional Health Information Organizations, and Health Information Exchanges.⁴⁶ Similarly, it made changes to the privacy rule to better protect personal health information held, transferred, or used by covered entities.⁴⁷

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.

Telehealth Barriers

There are several barriers which impede the use of telehealth. These barriers include:⁴⁸

- 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 definition⁴⁹ 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

⁴² For Covered Entities and Business Associates, U.S. Department of Health and Human Services.

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/> (last visited February 18, 2016).

⁴³ U.S. Department of Health & Human Services, *HITECH Act Enforcement Interim Final Rule*, <http://www.hhs.gov/hipaa/for-professionals/special-topics/HITECH-act-enforcement-interim-final-rule/index.html>, (last visited February 18, 2016).

⁴⁴ Id.

⁴⁵ Id.

⁴⁶ Id.

⁴⁷ Id.

⁴⁸ *State Telehealth Laws and Medicaid Program Policies: A Comprehensive Scan of the 50 States and District of Columbia*, Center for Connected Health Policy, The National Telehealth Policy Resource Center, July 2015, <http://cchpca.org/sites/default/files/resources/STATE%20TELEHEALTH%20POLICIES%20AND%20REIMBURSEMENT%20REPORT%20FINAL%20%28c%29%20JULY%202015.pdf> (last visited February 18, 2016).

⁴⁹ No two states define telehealth exactly alike, although some similarities exist between certain states. See Id.

The absence of a uniform regulatory structure governing the use of telehealth presents another barrier to its use. Currently, 7 states⁵⁰ do not have a statutory structure for the delivery of health care services through telehealth.⁵¹ 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 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.⁵² Many times an exception is expressly contained within the regulation which allows the in-person requirement to be met through telehealth.⁵³ This exception, however, can vary by profession 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. Currently, 37 states prohibit a health care professional from using telehealth to provide health care services unless the professional is licensed in the state where the patient is located.⁵⁴ Most states have exceptions to this requirement, applicable only in certain limited circumstances, which include:⁵⁵

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

Seven states require out-of-state licensed health care professionals to acquire a special telehealth license or certificate to provide health care services through telehealth to patients in those states.⁵⁶ Two of these states (Tennessee and Texas), however, only offer the telehealth license to physicians who are 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 must 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, states impose 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

⁵⁰ This includes Florida.

⁵¹ Even amongst states with telehealth statutory regulations, no two states regulate telehealth in exactly the same manner. *Supra* note 48.

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.* This includes Florida.

⁵⁵ *Licensure and Scope of Practice FAQs*, Telehealth Resource Centers, <http://www.telehealthresourcecenter.org/toolbox-module/licensure-and-scope-practice> (last visited on February 18, 2016).

⁵⁶ These states are AL, LA, MN, NM, 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. *Supra* note 48.

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.⁵⁷ Under this model, “hub” refers to the location to where the health care professional must be located while “spoke” refers to the location where the patient must be located.

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

Telehealth in Florida

Florida does not have a statutory structure for the delivery of health care services through telehealth.⁵⁸ References to telehealth in the Florida Administrative Code relate to the Board of Medicine, the Board of Osteopathic Medicine, the Child Protection Team program and the Florida Medicaid program.⁵⁹

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).⁶⁰ The Rule sets forth requirements and restrictions for physicians and physician assistants prescribing medications.⁶¹ 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.”⁶² The Rule, however, fails to fully define telemedicine and does not regulate its use in any other way. The Board only regulates allopathic physicians, so this rule does not apply to any other profession.⁶³

In 2014 the Board adopted a new rule⁶⁴ setting forth standards for telemedicine.⁶⁵ 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.⁶⁶ 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.⁶⁷ The new rule provides that:⁶⁸

- 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

⁵⁷ 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.

⁵⁸ The only references to telehealth in the Florida Statutes are in ss. 364.0135, F.S. and 381.885, F.S. Section 364.0135, F.S., relates to broadband internet services and does not define or regulate telehealth in any manner. Section 381.885, F.S., relates to epinephrine auto-injectors and expressly states that consultation for the use of the auto-injector through electronic means does not constitute the practice of telemedicine.

⁵⁹ See Agency for Health Care Administration, Florida Medicaid, “Practitioner Services Coverage and Limitations Handbook,” December 2012, pg. 2-119, available at:

<http://portal.flmmis.com/FLPublic/HiddenStaticSearchPage/tabid/55/Default.aspx?publicTextSearch=practioners%20services%20handbook> (last visited on February 18, 2016).

⁶⁰ 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.

⁶¹ Rule 64B8-9.014, F.A.C.

⁶² Id.

⁶³ The Board of Osteopathic Medicine rule only applies to osteopathic physicians.

⁶⁴ The Board of Medicine and the Board of Osteopathic Medicine rules for telemedicine are identical.

⁶⁵ Rule 64B8-9.0141, F.A.C.

⁶⁶ Rule 64B8-9.0141, F.A.C.

⁶⁷ The Board of Osteopathic Medicine definition only applies to osteopathic physicians.

⁶⁸ See footnote 68 *supra*.

- The same patient confidentiality and record-keeping requirements applicable to in-person services are applicable to services provided through telemedicine.

The new rule prohibits physicians and physician's assistants from providing treatment recommendations, including issuing a prescription, through telemedicine unless the following has occurred:⁶⁹

- A documented patient evaluation, including history and physical examination to establish the diagnosis for which any legend drug is prescribed;
- A discussion between the physician or the physician assistant and the patient regarding treatment options and the risks and benefits of treatment; and
- Contemporaneous medical records are maintained.

The new rule, however, prohibits prescribing controlled substances through telemedicine but does not preclude physicians from ordering controlled substances through the use of telemedicine for patients hospitalized in a facility licensed pursuant to 395, F.S.⁷⁰

Child Protection Teams

A Child Protection Team (CPT) is a medically directed multi-disciplinary group that works with local sheriffs' offices and the Department of Children and Families to supplement investigative activities in cases of child abuse and neglect.⁷¹ The CPT program within the Children's Medical Services (CMS) program utilizes a telehealth network to perform child assessments. The use of telemedicine⁷² under this program requires the presence of a CMS approved physician or advanced registered nurse practitioner at the hub site and a registered nurse at the remote site to facilitate the evaluation.⁷³ In 2014, CPT telehealth services were available at 9 sites and 667 children were provided medical or other assessments via telehealth technology.⁷⁴

Florida Emergency Trauma Telemedicine Network

Various designated trauma centers participate in the Florida Emergency Trauma Telemedicine Network (FETTN). Coordinated by the Department of Health (DOH), the FETTN facilitates the treatment of trauma patients between trauma centers and community or rural hospitals.⁷⁵ The FETTN allows for multiple interface options and currently 7 out of 25 trauma centers are part of the network.⁷⁶ 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.⁷⁷

Tuberculosis Physician's Network

⁶⁹ Id.
⁷⁰ Id.
⁷¹ Florida Department of Health, *Child Protection Teams*, http://www.floridahealth.gov/AlternateSites/CMS-Kids/families/child_protection_safety/child_protection_teams.html (last visited February 18, 2016).
⁷² Rule 64C-8.001(5), F.A.C., 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."
⁷³ Rule 64C-8.003(3), F.A.C.
⁷⁴ Florida Department of Health, *Maternal and Child Health Block Grant Narrative for 2014*, <http://www.floridahealth.gov/healthy-people-and-families/womens-health/pregnancy/mch-fl-2013-1narrative.pdf> p.21, (last visited: February 18, 2016).
⁷⁵ 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).
⁷⁶ Id.
⁷⁷ Florida Department of Health, *Long Range Program Plan* (September 28, 2012), on file with the Health and Human Services Committee.

The DOH utilizes tele-radiology through the Tuberculosis Physician's Network.⁷⁸ 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 DOH. This service is not currently reimbursed by Medicaid.

Florida Medicaid Program

Under the Medicaid Medical Assistance (MMA) Program implemented in 2014, the vast majority of Medicaid recipients are covered through managed care. Medicaid MMA contracts contain broader allowance for telehealth than in the pre-MMA managed care contracts and fee-for-service program rules.⁷⁹ Not only may MMA plans use telehealth for behavioral health, dental, and physician services as before but, upon approval by AHCA, may also use telehealth to provide other covered services.⁸⁰ The MMA contract eliminates numerous prior restrictions related to types of services and the type of providers who may utilize telehealth, but retains the requirement to use hub and spoke model.⁸¹

Discount Medical Plans

A discount medical plan is a business arrangement or contract in which a person, in exchange for fees, dues, charges, or other consideration, provides access for plan members to providers of medical services and the right to receive medical services from those providers at a discount.⁸² The term does not include any product regulated under ch. 627, ch. 641, or part I of ch. 636, F.S.⁸³ A discount medical plan organization is an entity which, in exchange for fees, dues, charges, or other consideration, provides access for plan members to providers of medical services and the right to receive medical services from those providers at a discount.⁸⁴ Plans offered by such organizations commonly include:

- A monthly enrollment fee ranging, for example, from \$8 to \$45 per month.
- Access to a wide variety of health services including doctor and clinic visits, specialist visits and treatment, hospital services, prescription medications, and medical devices, all at reduced rates.
- Discounts ranging from 5 percent to 70 percent on various services.⁸⁵

Section 636.204, F.S., requires that any entity doing business in this state as a discount medical plan organization must be licensed by the Office of Insurance Regulation and must renew its license annually.

Effect of Proposed Changes

The bill creates 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 and treatment, monitoring transfer of medical data, patient and professional health-related education, public health services and health administration. The definition of telehealth does not include audio-only telephone calls, e-mail messages or facsimile transmissions. Thus, health care professionals can use telehealth to provide services to patients through both “live”

⁷⁸ Id.

⁷⁹ In Florida's Medicaid program the state reimburses physicians on a fee-for-service basis for health care services provided through telemedicine. The use of telemedicine to provide these services is limited to the hospital outpatient setting, inpatient setting, and physician office.

⁸⁰ Model Agreement, Attachment II, Exhibit II A, Medicaid Managed Medical Assistance Program, Agency for Health Care Administration, November 2015, available at http://ahca.myflorida.com/Medicaid/statewide_mc/plans.shtml (last viewed February 18, 2016).

⁸¹ Id.

⁸² Section 636.202(1), F.S.

⁸³ Chapter 627, F.S., includes annuity and life insurance policies, health insurance policies, Medicare supplement policies, disability insurance policies, property insurance contracts, motor vehicle and casualty insurance contracts, surety insurance contracts, title insurance contracts, and long-term care insurance policies; chapter 641, F.S., includes certain health care policies or contracts; and part I of chapter 636, F.S., includes prepaid limited health service contracts.

⁸⁴ Section 636.202(2), F.S.

⁸⁵ National Conference of State Legislatures, Health Care Discount Plans: State Roles and Regulation, available at <http://www.ncsl.org/research/health/health-care-discount-plans-state-roles.aspx> (last viewed on February 18, 2016).

and “store and forward” methods. It also authorizes the use of telemonitoring. The definition does not place any additional limitations on the type of technology that can be used in telehealth. However, both HIPAA and HITECH continue to apply to covered entities.

The bill excludes a product used to deliver services through telehealth from the definition of discount medical plan under s. 636.202, F.S. This ensures that such a product is not regulated as a discount medical plan.

Telehealth Providers

The bill defines “telehealth provider” as any person who provides health care related services using telehealth and who is licensed in Florida or is an out-of-state health care registered and is in compliance with the requirements of this bill. Florida licensed telehealth providers must be one of the following professionals:⁸⁶

- Behavior analyst;
- Acupuncturist;
- Allopathic physician;
- Osteopathic physician;
- Chiropractor;
- Podiatrist;
- Optometrist;
- Nurse;
- Pharmacist;
- Dentist;
- Dental Hygienist;
- Midwife;
- Speech therapist;
- Occupational therapist;
- Radiology technician;
- Electrologist;
- Orthotist;
- Pedorthist;
- Prosthetist;
- Medical physicist;
- Emergency Medical Technician;
- Paramedic;
- Massage therapist;
- Optician;
- Hearing aid specialist;
- Clinical laboratory personnel;
- Respiratory therapist;
- Physical therapist;
- Psychologist;
- Psychotherapist;
- Dietician/Nutritionist;
- Athletic trainer;
- Clinical social worker;
- Marriage and family therapist; or
- Mental health counselor.

⁸⁶ These are professionals licensed under s. 393.17; part III, ch. 401; 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, part IV, ch. 483; ch. 484; ch. 486; ch. 490; or ch. 491.

Out-of-state telehealth providers must register biennially with 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 or renew registration as an out-of-state telehealth provider, the health care professional must:

- Submit an application to 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 have had a license revoked in any U.S. state or jurisdiction.

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

The bill requires out-of-state telehealth providers to notify the applicable board or DOH of restrictions placed on the health care professional’s license to practice or disciplinary actions taken against the health care practitioner within 5 days after such occurrence.

The bill authorizes a board, or DOH if there is no board, to revoke an out-of-state telehealth provider’s registration if the registrant:

- Fails to notify DOH of any adverse actions taken against his or her license within 5 days after such adverse action;
- 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 DOH to publish on its website the name of each registered out-of-state telehealth provider. It must also include the following background information, to the extent applicable, 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.

Telehealth Provider Standards

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.

Under the bill a telehealth provider is not required to research a patient’s medical history or conduct a physical examination of the patient before providing telehealth services to the patient if the telehealth provider is capable of conducting a patient evaluation in a manner consistent with the applicable standard of care sufficient to diagnose and treat the patient when using telehealth. The bill also allows the evaluation to be performed using telehealth.

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 allows health care providers who are authorized to prescribe a controlled substance to use telehealth to prescribe controlled substances. Telehealth may not be used to prescribe a controlled substance to treat chronic nonmalignant pain, unless ordered by a physician for an inpatient admitted to a facility licensed under ch. 395, F.S., prescribed for a patient receiving hospice services as defined under s. 400.601, F.S., or prescribed for a resident of a nursing home facility as defined under s. 400.021(12), F.S.

The bill requires that a telehealth provider document the telehealth services rendered in the patient's medical records according to the same standard as that required for in-person services. The bill requires that such medical records be kept confidential consistent 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 (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 provides that a non-physician telehealth provider using telehealth and acting within the applicable scope of practice, as established under Florida law, may not be interpreted as practicing medicine without a license.

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 for consultations between health care practitioners.

The bill requires a registered telehealth provider, who is a pharmacist, to use a pharmacy holding a Florida permit, a nonresident pharmacy registered in Florida, or a nonresident pharmacy or outsourcing facility holding a nonresident sterile compounding permit to dispense medicinal drugs to Florida patients.

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

Telehealth Survey

The bill requires AHCA, DOH and OIR, within existing resources, to survey health care facilities, health maintenance organizations, health care practitioners, and health insurers to determine:

- National and state utilization of telehealth;
- Types of health care services provided via telehealth;
- Costs and cost savings associated with using telehealth to provide health care services; and
- Insurance coverage for providing health care services via telehealth.

The bill authorizes AHCA, DOH and OIR to assess fines to enforce participation and completion of the surveys.

The bill requires DOH to survey health care practitioners upon and as a condition of licensure renewal and requires DOH and OIR to submit their findings and research to AHCA. AHCA is then required to submit a report to the Governor, the President of the Senate and the Speaker of the House of Representatives on telehealth utilization and insurance coverage by June 30, 2018.

The bill provides an effective date of July 1, 2016.

B. SECTION DIRECTORY:

Section 1: Creates s. 456.47, F.S., relating to the use of telehealth to provide services.

Section 2: Amends s. 636.202, F.S., relating to definitions.

Section 3: Requires AHCA to report on telehealth utilization and insurance coverage.

Section 4: Provides an appropriation.

Section 5: Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The bill authorizes DOH to assess a \$150 registration and registration renewal fee for out-of-state telehealth providers. The revenue generated is anticipated to be \$769,182 biennially, assuming that the number of out-of-state registrants will be comparable to the experience of a similar program in Texas. Utilizing the Texas Medical Board experience of a 0.58% licensure rate would generate 5,128 Florida telehealth registrants.⁸⁷

2. Expenditures:

The bill requires out-of-state health care professionals to register with DOH prior to providing any health care services through telehealth to individuals located in Florida. The State of Texas offers a comparable telehealth license to physicians and physician's assistants out of state. There are currently 416 active telehealth licensed physicians in the state of Texas and a total 71,935 active in-state physicians licensed.⁸⁸ Applying the ratio found in Texas of telehealth physicians compared to the total in-state physicians of 0.58% to the current active in-state physicians in the state of Florida, 66,468, an anticipated 384 physicians will seek telehealth licensure in Florida. Applying the same rate to the 820,248 additional medical professionals identified in the bill, an anticipated 4,743 will register as out-of-state telehealth providers in Florida.⁸⁹ The Florida Medical Quality Assurance Division currently employs 570 positions to regulate 886,716 active in-state licenses.

The bill provides an appropriation of \$261,389 recurring and \$15,528 nonrecurring from the Medical Quality Assurance Trust Fund and four full time equivalent positions and \$145,870 in salary rate to utilize the funds generated from the bill's \$150 registration fee to offset the workload increase anticipated from an additional 5,128 licenses.

The bill also requires AHCA, DOH and OIR to conduct a survey on various telehealth and insurance issues, and requires AHCA to compile and prepare the report for the Governor and the Legislature. DOH is required to survey health care practitioners upon and as a condition of licensure renewal in order to compile the information required. The departments will be able to conduct the survey within existing resources as specified in the bill.⁹⁰

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

⁸⁷ Physician Statistics, Physicians In and Out of State Report, Texas Medical Board, September 2015, available at <http://www.tmb.state.tx.us/showdoc/statistics> (last viewed February 18, 2016).

⁸⁸ Id.

⁸⁹ Florida Department of Health, *Annual Report and Long-Range Plan*, Division of Medical Quality Assurance, Fiscal Year 2014-2015, available at <http://mqawebteam.com/annualreports/1415/> Table 15: Revenue, Expenditures and Cash Balances (last viewed February 18, 2016).

⁹⁰ Florida Department of Health, 2016 Agency Legislative Bill Analysis of HB 7087, on file with the Health and Human Services Committee (January 26, 2016).

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

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

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 8, 2016, the Health Care Appropriations Subcommittee adopted two amendments and reported the bill favorably as a committee substitute. The amendments:

- Required DOH to survey the health care practitioners upon and as a condition of licensure renewal to compile the information required; and
- Provided an appropriation of \$276,917 from the Medical Quality Assurance Trust Fund and four full time equivalent positions for the purpose of implementing the provisions of this act.

This analysis is drafted to the committee substitute as passed by the Health Care Appropriations Subcommittee.

On February 17, 2016, the Health and Human Services Committee adopted an amendment to CS/HB 7087 and reported the bill favorably as a committee substitute. The amendment:

- Required biennial, rather than annual, registration for out-of-state telehealth providers.
- Required a telehealth provider to notify DOH or the appropriate board a license restriction or disciplinary action within 5 business days after such action, rather than “immediately”.
- Included outsourcing facilities and nonresident pharmacies holding a nonresident sterile compounding permit as entities from which a registered telehealth provider pharmacist may dispense drugs.
- Allowed a board, instead of DOH, to revoke a telehealth provider’s registration, when applicable.
- Excluded from the definition of “discount medical plan” any product used to deliver services through telehealth.

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