

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Communications, Energy, and Public Utilities

BILL: SB 1646

INTRODUCER: Health Policy Committee

SUBJECT: Telemedicine

DATE: March 24, 2014

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
	<u>Lloyd</u>	<u>Stovall</u>	<u>HP</u>	HP SPB 7128 as introduced
1.	<u>Caldwell</u>	<u>Caldwell</u>	<u>CU</u>	Pre-meeting
2.	_____	_____	<u>AHS</u>	_____
3.	_____	_____	<u>AP</u>	_____

I. Summary:

SB 1646 creates the Florida Telemedicine Act (the act) and defines the key components for the practice of telemedicine. The act establishes telemedicine as the practice of medicine through advanced communications technology by a telemedicine provider at a distant site. A telemedicine provider is a physician licensed under chapter 458 or chapter 459 or an out of state physician who meets the specific requirements for an exemption from Florida licensure. The act also provide exclusions from licensure for consultations and for emergency services, as defined under the act.

Physicians practicing telemedicine are required at license renewal to identify themselves as a telemedicine provider on their practitioner profile and to complete 2 hours of continuing education related to telemedicine.

The standard of care for telemedicine service coincides with health care services provided in-person. The nonemergency prescribing of a legend drug based solely on an online questionnaire is specifically prohibited and a controlled substance may not be prescribed through telemedicine for chronic non-malignant pain.

The act requires a telemedicine provider to be responsible for the quality of his or her equipment or technology and to maintain records in accordance with federal and state laws. Each telemedicine provider must identify himself or herself to the patient and their location prior to each encounter.

Regulatory boards, or the Department of Health (DOH) if there is not an applicable board, may adopt rules to administer the act. Rules prohibiting telemedicine that are inconsistent with this act must be repealed. Venue for any civil or administrative action is based on the location of the patient or in Leon County.

Telemedicine services to diagnose and treat the human eye may be used if certain standards are met, including minimum automated equipment requirements. The act prohibits the prescription of spectacles or contact lenses based on a telemedicine service or solely on the use of a computer controlled device.

The Medicaid program must reimburse providers for telemedicine services in the same manner as provided for in-person services. Reimbursement amounts must be negotiated between the parties, to the extent permitted under federal law. Regardless of the amount negotiated, reimbursement for both the originating and the distant site should be considered based on the services provided during the encounter. A process for discontinuation of reimbursement for a Medicaid service through telemedicine is provided if the Agency for Health Care Administration (AHCA) can document a specific telemedicine service is not cost effective or does not meet the clinical needs of Medicaid recipients. The Medicaid provisions sunset on June 30, 2017. The AHCA is required to submit a report on the usage and costs, including any savings, of telemedicine services provided to Medicaid recipients by January 1, 2017, to the President of the Senate, the Speaker of the House of Representatives, and the minority leaders of the House and Senate.

The bill's effective date is October 1, 2014.

II. Present Situation:

Telemedicine utilizes various advances in communication technology to provide healthcare services through a variety of electronic mediums. Telemedicine is not a separate medical specialty and does not change what constitutes proper medical treatment and services. According to the American Telemedicine Association, services provided through telemedicine include¹:

- **Primary Care and Specialist Referral Services** - that involves a primary care or allied health professional providing consultation with a patient or specialist assisting the primary care physician with a diagnosis. The process may involve live interactive video or the use of store and forward transmission of diagnostic images, vital signs, and/or video clips with patient data for later review.
- **Remote patient monitoring** - that includes home telehealth, using devices to remotely collect and send data to home health agencies or remote diagnostic testing facilities.
- **Consumer medical and health information** - that offers consumers specialized health information and online discussion groups for peer to peer support.
- **Medical education** - that provides continuing medical education credits.

The term telehealth is also sometimes used interchangeably with telemedicine. Telehealth, however, generally refers to a wider range of health care services that may or may not include clinical services². Telehealth often collectively defines the telecommunications equipment and

¹ American Telemedicine Association, *What is Telemedicine?*, <http://www.americantelemed.org/learn/what-is-telemedicine> (last visited Jan. 6, 2014).

² Majerowicz, Anita; Tracy, Susan, "Telemedicine: Bridging Gaps in Healthcare Delivery," *Journal of AHIMA* 81, no. 5, (May 2010): 52-53, 56, http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_047324.hcsp?dDocName=bok1_047324 (last visited Jan. 27, 2014).

technology that is used to collect and transmit the data for a telemedicine consultation or evaluation.

Board of Medicine Rulemaking

Florida's Board of Medicine convened a Telemedicine Workgroup in 2013 to review its rules on telemedicine which had not been amended since 2003. The 2003 rule focused on standards for the prescribing of medicine via the internet. Last month, the Board adopted new rules specific to standards for telemedicine practice for allopathic and osteopathic physicians. These new rules define telemedicine, establish a standard of care, prohibit the prescription of controlled substances, permit the establishment of a doctor-patient relationship via telemedicine, and exempt emergency medical services³.

Telemedicine in Other States

As of January 2014, at least 20 states and the District of Columbia have mandated that private insurance plans cover telemedicine services at reimbursement rates equal to an in-person consultation.⁴ Forty-four states reimburse under Medicaid for limited services, some restricting reimbursement to only rural or low provider access areas.⁵ The breadth of state telemedicine laws vary from the very limited of authorizing store and forward services to mandating private insurance coverage and payment equivalency between face-to-face visits and telemedicine encounters. While nine states specifically issue a special-telemedicine-only license or certificate, several others may allow physicians from contiguous states to practice under certain conditions.⁶

States have used telemedicine in correctional systems to eliminate the need to transport inmates in both Colorado and Wyoming.⁷ In some cases, the health care professional is located in another location at the same facility and is able to interact with the inmate. This option addresses situations with violent inmates or handicap accessibility issues. Some jails use this same technology for online visits in place of face-to-face visitation, including the Alachua County jail in Florida.⁸

Rural counties have utilized telemedicine to fill the void for specialty care in their emergency rooms and to avoid costly and time consuming transfers of patients from smaller hospitals to the larger tertiary centers for care. In a California project, the rural hospitals' emergency rooms received video conference equipment to facilitate the telemedicine consultations as part of the

³ See Notice of Final Rule 64B8-9.0141, F.A.C., published February 20, 2014 and Notice of Final Rule 64B15-14.0081, F.A.C., published February 20, 2014. Both rules are effective March 12, 2014.

⁴ American Telemedicine Association, *2014 State Telemedicine Legislative Tracking*, <http://www.americantelemed.org/docs/default-source/policy/state-telemedicine-legislation-matrix.pdf> (last visited Jan. 24, 2014).

⁵ Id.

⁶ Center for Connected Health Policy, *State Telehealth Laws and Reimbursement Policies*, (November 2013), p.6, <http://telehealthpolicy.us/sites/telehealthpolicy.us/files/uploader/50%20State%20Medicaid%20Update%20Nov.%202013%20-%20Rev.%2012-20.pdf> (last visited Jan. 24, 2014).

⁷ Government Computing News, *Prisons Turn to Telemedicine for Treating Inmates*, (May 21, 2013), <http://gcn.com/blogs/pulse/2013/05/prisons-telemedicine-treating-inmates.aspx> (last visited Jan. 28, 2014)

⁸ Gainesville, Sun, *Now You Can Visit an Inmate From Home*, (Jan. 9, 2014), <http://www.gainesville.com/article/20140109/ARTICLES/140109711?p=1&tc=pg#gsc.tab=0> (last visited Jan. 28, 2014).

study. The rural hospital physicians, nurses, and parents were linked with pediatric critical care medicine specialists at the University of California, Davis.⁹ Researchers at the university found that parents' satisfaction and perception of the quality of care received was significantly greater with telemedicine than with telephone guidance.¹⁰

Federal Provisions for Telemedicine

Federal laws and regulations address telemedicine from several angles, from prescribing controlled substances and setting hospital emergency room guidelines, to establishing reimbursement guidelines for the Medicare program.

Prescribing Via the Internet

Federal law specifically prohibits the issue of controlled substances prescribed 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.¹¹ However, the Ryan Haight Online Pharmacy Consumer Protection Act,¹² signed into law in October 2008, created an exception for the in-person medical evaluation for telemedicine 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.

The Drug Enforcement Administration (DEA) of the federal Department of Justice issued its own definition of telemedicine in April 2009 as required under the Haight Act.¹³ The federal regulatory definition of telemedicine under the DEA includes, but is not limited to, the following elements:

- The patient and the practitioner are located in separate locations;
- Patient and practitioner communicate via a telecommunications system;
- The practitioner must meet other registration requirements for the dispensing of controlled substance via the Internet; and,
- Certain practitioners (Department of Veterans Affairs' employees, for example) or practitioners in certain situations (public health emergencies) may be exempted from registration requirements.¹⁴

⁹ *In Rural ERs, Kids Get Better Care with Telemedicine*, <http://www.futurity.org/in-rural-ers-kids-get-better-care-with-telemedicine> (last visited Jan. 28, 2014).

¹⁰ *Id.*

¹¹ 21 CFR §829(e)(2).

¹² Ryan Haight Online Consumer Protection Act of 2008, Public Law 110-425 (H.R. 6353).

¹³ *Id.*, at sec. 3(j).

¹⁴ 21 CFR §802(54).

Medicare Coverage

Specific telehealth services delivered at designated sites are covered under Medicare. The federal Centers for Medicare and Medicaid Services' regulations require both a distant site (location of physician delivering the service via telecommunications) and a separate originating site (location of the patient) under their definition of telehealth. Asynchronous "store and forward" activities are only reimbursed under Medicare in federal demonstration projects.¹⁵

To qualify for Medicare reimbursement, the originating site must meet one of these qualifications:

- Located in a federally defined rural county;
- Designated rural health professional shortage area;¹⁶ or,
- Identified as a participant in a federal telemedicine demonstration project as of December 21, 2000.¹⁷

Federal requirements provide additional qualifications for an originating site once one of the initial elements above has been satisfied. 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; and,
- A community mental health center.¹⁸

Reimbursement for the distant site is established as "an amount equal to the amount that such physician or practitioner would have been paid under this title had such service been furnished without the use of a telecommunications system."¹⁹

Federal law also provides for a facility fee for the originating site that started and remained at \$20 through December 31, 2002, and then, by law, is subsequently increased each year by the percentage increase in the Medicare Economic Index or MEI. For calendar year 2014, the originating fee was 80 percent of the lesser of the actual charge or \$24.63.²⁰

¹⁵ Only two states have a federal demonstration project that meets these qualifications, Hawaii and Alaska.

¹⁶The 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).

¹⁷ See 42 U.S.C. sec. 1395(m)(m)(4)(C)(i).

¹⁸ See 42 U.S.C. sec. 1395(m)(m)(4)(C)(ii).

¹⁹ See 42 U.S.C. sec. 1395(m)(m)(2)(A).

²⁰ Department of Health and Human Services, Centers for Medicare and Medicaid Services, *MLN Matters - News Flash #MM8533(December 20, 2013)*, <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8533.pdf> (last visited: Jan 28, 2014).

Telehealth services covered under Medicare include professional consultations, office visits, and office psychiatry services within certain health care procedure codes.²¹ Practitioners eligible to bill for telehealth services include physicians, nurse practitioners, physician assistants, nurse midwives, clinical nurse specialists, clinical psychologists, clinical social workers, and registered dietitians or nutrition specialists who are licensed to provide the service under state law.²²

Telemedicine Services in Florida

The University of Miami (UM) initiated telehealth services in 1973 and claims the first telehealth service in Florida, the first use of nurse practitioners in telemedicine in the nation, and the first telemedicine program in correctional facilities.²³ Today, UM has several initiatives in the areas of tele-dermatology, tele-trauma, humanitarian and disaster response relief telehealth, school telehealth services, and acute teleneurology or telestroke.²⁴ While some of the UM's activities reach their local community, others reach outside of Florida including providing Haiti earthquake relief and teledermatology to cruise line employees. Telehealth communications are also used for monitoring patients in the hospital and conducting training exercises.

The UM also utilizes telemedicine to research the effectiveness of telemedicine in different trauma situations with the United States military. The research utilizes a robot which is operated from a control station using a joystick. The control station is on a laptop that allows the provider to operate the robot from any location with a wireless connection.²⁵ Lessons learned from this research are intended to provide assistance to deployed surgeons on the battlefield treating injured soldiers.

The UM along with other designated trauma centers participate in the Florida Emergency Trauma Telemedicine Network (FETTN). Coordinated by the DOH, the FETTN, facilitates the treatment of trauma patients between trauma centers and community or rural hospitals.²⁶ The FETTN allows for multiple interface options and currently 7 out of 25 trauma centers are part of the network.²⁷ In 2011-2012, 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.²⁸

²¹ See 42 U.S.C. sec. (m)(m)(4)(F) for statutory authority and visit <http://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/> for additional federal guidance.

²² Department of Health and Human Services, Centers for Medicare and Medicaid Services, *Telehealth Services - Rural Health Fact Sheet Series*, December 2012, <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/telehealthsrvcfsht.pdf> (last visited Jan. 27, 2014).

²³ University of Miami, Miller School of Medicine, *UM Telehealth - Our History*, <http://telehealth.med.miami.edu/about-us/our-history> (last visited Jan. 31, 2014).

²⁴ University of Miami, Miller School of Medicine, *UM Telehealth*, <http://telehealth.med.miami.edu/featured/teledermatology> (last visited Jan. 28, 2014).

²⁵ University of Miami, Miller School of Medicine, *UM Telehealth - Teletrauma*, <http://telehealth.med.miami.edu/featured/teletrauma> (last visited Jan. 31, 2014).

²⁶ Florida Department of Health, *2014 Agency Legislative Bill Analysis of SB 70*, p.2, on file with the Senate Health Policy Committee (August 26, 2013).

²⁷ *Id.*, at 3.

²⁸ Florida Department of Health, *Long Range Program Plan* (September 28, 2012), on file with the Senate Health Policy Committee.

According to the DOH, the trauma centers and their satellites as well as the rural hospitals that currently participate in the FETTN are not reimbursed for the consultation and treatment services provided within the telemedicine network.

Florida Medicaid Program

Florida's Medicaid program reimburses for a limited number of telemedicine services by designated practitioners.²⁹ 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.

Telemedicine is currently covered by Medicaid for the following services and settings:³⁰

- Behavioral Health
 - Tele-psychiatry services for psychiatric medication management by practitioners licensed under chapter 458 or chapter 459, F.S.
 - Tele-behavioral health services for individual and family behavioral health therapy services by qualified practitioners licensed under chapter 490 or chapter 491, F.S.
- Dental Services
 - Video conferencing between a registered dental hygienist employed by and under contract with a Medicaid-enrolled group provider and under the supervision of a supervising dentist.
 - Services include oral prophylaxis, topical fluoride, and oral hygiene instructions.
- Physician Services
 - Services provided using audio and video equipment that allow for two-way, real time interactive communication between physician and patient.
 - State plan waiver specifically authorizes reimbursement for specialty physician services for Children's Medical Services Network.
 - Physicians may bill for consultation services only provided via telemedicine.

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.³¹

Medicaid requires the following specific clinical records documentation to qualify for reimbursement as a telemedicine service:³²

- A brief explanation of why services were not provided face-to-face;
- Documentation of telemedicine services, including results of assessment; and,
- A signed statement from the patient (or parent or guardian, if a child), indicating their choice to receive services through telemedicine.

²⁹ Agency for Health Care Administration, *Highlights of Practitioner Services Coverage and Limitations Handbook Presentation*, Bureau of Medicaid Services, Summer 2013, p.30.

³⁰ Agency for Health Care Administration, *2014 Legislative Bill Analysis of SB 70*, November 7, 2013, p. 3, on file with the Senate Health Policy Committee.

³¹ Agency for Health Care Administration, *supra*, note 29, at 34.

³² *Id.* at p. 36.

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.³³

Since 2006, the Children's Medical Services Network (CMS Network) has been authorized to provide specified telemedicine services under Florida's 1915(b) Medicaid Managed Care waiver. Authorized services include physician office visits (evaluation and management services) and consultation services already covered by the Medicaid state plan in select rural counties. Currently, the CMS Network provides telemedicine services in 57 of Florida's 67 counties.³⁴

The CMS Network works with the University of Florida's (UF) pediatric endocrinology staff to provide telehealth services for enrollees with diabetes and other endocrinology diseases in the Daytona Beach service area.³⁵ Additional partnerships with the Institute for Child Health Policy at UF include referring children with special health care needs to community health centers for consults via telehealth for nutritional, neurological, and orthopedics in Southeast Florida.³⁶

Child Protection Teams

The Child Protection Team (CPT) program under Children's Medical Services utilizes a telemedicine network to perform child assessments. 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.³⁷ The CPT patient is seen at a remote site and a registered nurse assists with the medical exam. A physician or Advanced Registered Nurse Practitioner (ARNP) 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 telemedicine technology.³⁸

Other Department of Health Initiatives

The DOH utilizes tele-radiology through the Tuberculosis (TB) Physician's Network.³⁹ 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 DOH. This service is not currently reimbursed by Medicaid.

³³ See Chapter 2013-150, L.O.F., sec. 1.

³⁴ Florida Department of Health, *supra*, note 28, at 2.

³⁵ 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: Jan. 31, 2014).

³⁶ *Id.*

³⁷ Florida Department of Health, *Child Protection Teams*, http://www.floridahealth.gov/AlternateSites/CMS-Kids/families/child_protection_safety/child_protection_teams.html (last visited Jan. 7, 2014).

³⁸ Florida Department of Health, *supra* note 35, at 21.

³⁹ Florida Department of Health, *supra* note 26, at 2.

Compliance with Health Insurance Portability and Accountability Act (HIPAA)

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects personal health information (PHI). Privacy rules were initially issued in 2000 by the Department of Health and Human Services and later modified in 2002. These rules address the use and disclosure of an individual's health information as well as create standards for privacy rights. Additional privacy and security measures were adopted in 2009 with the Health Information Technology for Economic Clinical Health (HITECH) Act.

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

- Health plans;
- Health care providers;
- Health care clearinghouses; and,
- Business Associates.

While not a covered entity as an individual, the patient still maintains his or her privacy and confidentiality rights regardless of the method in which the medical service is delivered. The HITECH Act specifically identified telemedicine as an area for review and consideration and funding was provided, in part, to strengthen infrastructure and tools to promote telemedicine.⁴⁰

Under the provisions of HIPAA and the HITECH Act, a health care provider or other covered entity participating in telemedicine is required to meet the same technical and physical HIPAA and HITECH requirements as would be required for a physical office visit. These requirements include ensuring that that the equipment and technology is HIPAA compliant.

III. Effect of Proposed Changes:

Section 1 designates ss. 456.4501-456.4506, F.S., as the "Florida Telemedicine Act."

Section 2 creates s. 456.4502, F.S., and provides definitions for the terms used in the Florida Telemedicine Act, including:

- Act
- Advanced Communications Technology
- Distant Site
- Encounter
- Health Care Provider
- In Person
- Originating Site
- Patient Presenter
- Store and forward
- Telehealth
- Telemedicine
- Telemedicine provider

⁴⁰ Public Law 111-5, sec. 3002(b)(2)(C)(iii) and sec. 3011(a)(4).

Section 3 creates s. 456.4503, F.S., and establishes requirements for an out-of-state physician who provides telemedicine across state lines to a patient physically located in Florida. In order to practice telemedicine, the out-of-state physician must:

- Have a Florida license to practice medicine under chapter 458, F.S., or chapter 459, F.S., or,
- Hold an active, unrestricted license to practice allopathic or osteopathic medicine in the distant site and that state's licensure requirements must meet or exceed this state's requirements;
- Maintain professional liability coverage that includes telemedicine that is consistent with s. 458.320, F.S.;
- Have one of the following:
 - Privileges or be on the medical staff of an out-of-state hospital that is affiliated with a Florida hospital licensed under chapter 395, F.S.; or,
 - Affiliation with an out-of-state health insurer or health plan that is also authorized to conduct business in Florida under chapter 627, F.S., or chapter 641, F.S.; and,
- Practice in a state that authorizes Florida-licensed physicians to provide telemedicine services to patients in that state without having to be licensed in that state.

An out-of-state physician who provides telemedicine services to a patient in Florida is subject to disciplinary action by the Florida Board of Medicine, the Board of Osteopathic Medicine, or a regulatory entity that has jurisdiction over the hospital, insurer, or health plan affiliated with the physician. The physician and the hospital, insurer, or health plan of the affiliated physician must agree to make available any pertinent records upon the request of the applicable board, the DOH, or any other federal or state regulatory authority. Failure to comply with a records request may result in revocation of the out-of-state practitioner's license or a fine, as established by the appropriate board or the DOH, as applicable.

Licensure is not required for consultations between an out-of-state practitioner and an in-state practitioner where the physician licensed in this state retains ultimate responsibility for the diagnosis, treatment, and care of the patient. Physician consultations via telemedicine that occur on an emergency basis are also exempt from licensure.

A health care provider or patient presenter using telemedicine technology at the direction and supervision of a physician may not be interpreted as practicing medicine without a license. Providers, however, are required to be trained and knowledgeable about the equipment being used. Failure to acquire appropriate training and knowledge is grounds for disciplinary action. Upon license renewal, a physician practicing telemedicine must identify himself or herself as a telemedicine provider on the physician's practitioner profile and submit proof of the successful completion of a course and subsequent examination, on the standards of practice in telemedicine. The act requires that the board-approved course consist of at least 2 web-based contact hours and the first course must be offered by July 1, 2014.

Venue for any civil or administrative action initiated by a telemedicine recipient or the appropriate regulatory board shall be based on the location of the patient or shall be in Leon County.

The regulatory boards, or the DOH if there is no board, may adopt rules to implement this act and are directed to repeal any rules that prohibit the practice of telemedicine. The boards may

also adopt rules regarding patient presenters but may not require the use of a presenter, if special skills and training are not needed for the patient to participate in the encounter.

Section 4 creates s. 456.4504, F.S., to specify standards for the delivery of telemedicine services. The standard of care for the delivery of telemedicine services shall be the same as if the services were delivered in person.

The bill references the standard of care in s. 766.102, F.S. That section of law addresses medical negligence and provides:

The prevailing professional standard of care for a given health care provider shall be that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar health care providers.

The telemedicine provider is responsible for the quality of the telemedicine equipment and technology and its safe use. Telemedicine equipment must be able to provide the same information, at a minimum, that would have been obtained in an in-person encounter. The equipment and technology must enable the telemedicine provider to meet or exceed the prevailing standard of care for the practitioner's profession.

The telemedicine provider is not required to conduct a patient history or physical exam before the telemedicine encounter as long as the telemedicine evaluation meets the prevailing standard of care for the services provided.

The act prohibits prescribing a legend drug based solely on an electronic questionnaire without a visual examination. Additionally, a practitioner may not prescribe a controlled substance through the use of telemedicine for chronic non-malignant pain.

Medical record-keeping requirements must be of the same manner as an in-person encounter under federal and state law. All records generated must conform to confidentiality and record-keeping laws of this state, regardless of the patient's location. Telemedicine technology must be encrypted and include a record-keeping program to verify each interaction.

If a third party vendor is used by a telemedicine provider, a business associate agreement is required. The act requires that the third party vendor comply with the HITECH Act.

Section 5 creates s. 456.4505, F.S., to provide standards for the provision of telemedicine services to diagnose or treat the human eye and its appendages. Automated equipment may be utilized for telemedicine services to diagnose or treat the human eye if the following requirements are met:

- The automated equipment is approved by the United States Food and Drug Administration for the intended use;
- The automated equipment is designed and operated to accommodate any requirements of the federal ADA Amendments Act of 2008;
- The automated equipment and accompanying technology gathers and transmits information in compliance with HIPAA;

- The procedures for which the automated equipment is used has a recognized Current Procedural Terminology (CPT) code approved by the Centers for Medicare and Medicaid Services;
- The physical location of the automated equipment prominently displays the name and location of the individual that will read and interpret the information and data;
- The diagnostic information and data gathered by the automated equipment will be read and interpreted by an optometrist licensed under chapter 463 or a physician skilled in diseases of the human eye and licensed under chapter 458 or chapter 459; and,
- The owner or lessee of the automated equipment maintains liability insurance in amounts adequate to cover claims by individuals diagnosed or treated based on information and data generated by the automated equipment.

A prescription for spectacles or contact lenses may not be made based on telemedicine services or based solely on the refractive error of the human eye generated by a computer controlled device.

Section 6 creates s. 456.4506, F.S., to establish a requirement for the AHCA to reimburse for telemedicine services under Medicaid. Telemedicine services are to be reimbursed in the same manner and in an equivalent amount to Medicaid services provided in-person under parts III (Medicaid) and IV (Medicaid Managed Care) of chapter 409, F.S. An exception to this requirement is provided if the AHCA determines a service that is delivered through telemedicine is not cost effective or does not meet the clinical needs of recipients. If, after implementation, the AHCA documents this determination, then coverage for that particular service may be discontinued.

Before receipt of a telemedicine service, a Medicaid recipient or legal representative of the recipient must provide informed consent for telemedicine services. The recipient must be provided the opportunity to receive the same service through an in-person encounter.

Under this section, the reimbursement amount for Medicaid services delivered via telemedicine shall be negotiated between the parties; however, both the originating site and distant site should receive compensation based on the services rendered.

The AHCA is also required to submit a usage and cost report on telemedicine services in the Medicaid program. The report is due to the President of the Senate, Speaker of the House of Representatives, and the minority leaders by January 1, 2017.

This section relating to telemedicine services under the Medicaid program sunsets on June 30, 2017.

Section 7 provides an effective date of October 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Telemedicine services are currently available in Florida. These services are being performed by more than physicians licensed under chapters 458, F.S., and 459, F.S. With the definition of “telemedicine provider” being limited to these providers, existing health care practitioners would no longer be able to provide telemedicine services as defined under this act.

Health care technology companies that provide the equipment for these services may see an increase in demand from health care practitioners for new equipment and maintenance needs of any existing equipment.

C. Government Sector Impact:

For SB 70, which had a similar provision for telemedicine coverage of Medicaid services, the AHCA provided an indeterminate fiscal impact because the rulemaking in SB 70 had been delegated to the DOH and both costs and savings would be associated with the bill’s provisions. The expected savings were based on possible efficiencies, improvements in disease management, and improved patient outcomes that resulted from telemedicine services.⁴¹

An increase in the services covered by telemedicine could also lead to an indeterminate increase in utilization and costs. SB 1646 broadens the number of services available through telemedicine.⁴²

The DOH stated in its analysis of SB 70 that a potential increase in Medicaid reimbursement funds for consultation and treatment under Medicaid could be achieved

⁴¹ Agency for Health Care Administration, *supra*, note 30, at 7.

⁴² *Id.*, p. 8.

for the TB project. According to the DOH, the estimated revenue impact to the state would be \$103,190.⁴³

The bill's limitation on telemedicine services to physicians only could impact existing services being delivered by other state agencies and departments, such as the behavioral health services at the Department of Children and Families which can be performed by non-physician health care practitioners and certain health care services for Medicaid enrollees. There could be a negative fiscal impact to the state if the state could no longer use telemedicine to provide these services and had to require in-person encounters.

VI. Technical Deficiencies:

The word "certified" is used to describe a type of physician on line 195. It is unclear what certification is being referenced.

The act does not take effect until October 1, 2014, yet the telemedicine course is required to be offered by July 1, 2014 (line 181).

VII. Related Issues:

The definition of a "telemedicine provider" limits providers to physicians under chapters 458 and 459, F.S. However, under s. 456.4505, F.S., the act permits an optometrist licensed under chapter 463, F.S., or a physician skilled in diseases of the human eye and licensed under chapter 458 or chapter 459, F.S., to review information and data generated from automated equipment via telemedicine. This provision permitting a non-physician to provide telemedicine services conflicts with the other provisions of the act that limit participation to only physicians.

There are numerous other sections of state law that refer to "in person" or "face to face" requirements for certain medical services or health care related activities. While SB 1646 defines "in person" for purposes of the Florida Telemedicine Act, there are other usages of this phrase in statute.

VIII. Statutes Affected:

This bill creates the following sections of the Florida Statutes: 456.4501, 456.4502, 456.4503, 456.4504, 456.4505, and 456.4506

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

⁴³ Florida Department of Health, *supra* note 26, at 5.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
