

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 Appropriations Subcommittee on Health and Human Services

BILL: CS/SB 1646

INTRODUCER: Communications, Energy, and Public Utilities Committee; Health Policy Committee;
and Senator Bean

SUBJECT: Telemedicine

DATE: April 8, 2014

REVISED: 04/11/14 _____

	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>	Fav/CS
2.	<u>Brown</u>	<u>Pigott</u>	<u>AHS</u>	Fav/1 amendment
3.	_____	_____	<u>AP</u>	_____

Please see Section IX. for Additional Information:

AMENDMENTS - Amendments were recommended

I. Summary:

CS/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 or physician assistant licensed under ch. 458 or ch. 459, F.S., an advanced registered nurse practitioner licensed under ch. 464, F.S., or a pharmacist licensed under ch. 465, F.S., who provides telemedicine services or an out-of-state physician who meets the specific requirements for an exemption from Florida licensure.

The standard of care for telemedicine service coincides with health care services provided in-person. A controlled substance may not be prescribed through telemedicine for chronic non-malignant pain.

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 Rules prohibiting telemedicine that are inconsistent with this act must be repealed.

The bill's fiscal impact is indeterminate.

II. Present Situation:

Telemedicine utilizes various advances in communication technology to provide health care 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 involve a primary care or allied health professional providing consultation with a patient or specialist assisting the primary care physician with a diagnosis;
- 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; and
- Medical education that provides continuing medical education credits.

The term telehealth is sometimes used interchangeably with telemedicine. Telehealth, however, generally refers to a wider range of health care services that may or may not include clinical services.² Telehealth often collectively defines the telecommunications equipment and 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 (Board) convened a Telemedicine Workgroup in 2013 to review its rules on telemedicine which had not been amended since 2003. The 2003 rules 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, and some restrict

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).

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).

reimbursement to only rural or low provider access areas.⁵ The breadth of state telemedicine laws varies. While nine states specifically issue a special-telemedicine-only license or certificate, several others allow physicians from contiguous states to practice under certain conditions.⁶

Colorado and Wyoming have used telemedicine in correctional systems to eliminate the need to transport inmates.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, rural hospital emergency rooms received video conference equipment to facilitate the telemedicine consultations. The rural hospital physicians and nurses were linked with pediatric critical care medicine specialists at the University of California, Davis.⁹ Researchers at the university found that parents of children in the project reported significantly higher satisfaction and greater perception of the quality of care 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 prescribing of controlled substances via the Internet without an in-person evaluation. The federal regulation under 21 CFR §829 specifically states:

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

A valid prescription is further defined under the same regulation as one issued by a practitioner who has conducted an in-person evaluation. The in-person evaluation requires that the patient be in the physical presence of the provider without regard to the presence or conduct of other

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).

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.

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

Medicare Coverage

Specific telehealth services delivered at designated sites are covered under Medicare. Regulations of the federal Centers for Medicare and Medicaid Services 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 reimbursed under Medicare only in federal demonstration projects.¹⁵

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

- Be located in a federally defined rural county;
- Be designated rural health professional shortage area;¹⁶ or,
- Be 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 after 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;

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).

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

¹⁶ 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).

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

- 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.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

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 tele-dermatology to cruise line employees. Telehealth communications are also used for monitoring patients in the hospital and conducting training exercises.

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).

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).

UM also utilizes telemedicine to research the effectiveness of telemedicine in different trauma situations with the United States military. The research utilizes a robot that is operated from a control station. 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 who treat injured soldiers on the battlefield.

UM, along with other 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.²⁶ The FETTN allows for multiple interface options, and currently seven of 25 trauma centers are part of the network.²⁷ In Fiscal Year 2011-2012, the seven Level I or Level II 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

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 ch. 458 or ch. 459, F.S.
 - Tele-behavioral health services for individual and family behavioral health therapy services by qualified practitioners licensed under ch. 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.

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

²⁶Florida 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.

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

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

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

- 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.
 - A state plan waiver specifically authorizes reimbursement for specialty physician services for the Children’s Medical Services Network (CMS Network).³¹
 - Physicians may bill for consultation services provided only 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.³²

Medicaid requires the following specific clinical records documentation to qualify for reimbursement as a telemedicine service:³³

- 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 the patient is a child), indicating their choice to receive services through telemedicine.

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.³⁴

Since 2006, the 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.³⁵

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.³⁶ Additional partnerships with the Institute for Child Health Policy

³¹ The Children’s Medical Services program is established within the Department of Health pursuant to ch. 391, F.S. The program is designed to provide children who have chronic health care needs with a family-centered, comprehensive, coordinated, and statewide managed system of care that links community-based health care with multidisciplinary, regional, and tertiary pediatric specialty care.

³² Agency for Health Care Administration, *supra*, note 29, at 34.

³³ *Id.* at p. 36.

³⁴ See Chapter 2013-150, L.O.F., sec. 1.

³⁵ Florida Department of Health, *supra*, note 28, at 2.

³⁶ 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).

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.³⁷

Child Protection Teams

The Child Protection Team (CPT) program under the CMS Network 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.³⁸ 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.³⁹

Other Department of Health Initiatives

The DOH utilizes tele-radiology through the Tuberculosis (TB) Physician's Network.⁴⁰ 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.

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 federal 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

³⁷ Id.

³⁸ 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).

³⁹ Florida Department of Health, *supra* note 35, at 21.

⁴⁰ Florida Department of Health, *supra* note 26, at 2.

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.⁴¹

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 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; and
- Telemedicine provider.

The term “telemedicine provider” means a physician or physician assistant licensed under ch. 458 or ch. 459, F.S., an advanced registered nurse practitioner licensed under ch. 464, F.S., or a pharmacist licensed under ch. 465, F.S., who provides telemedicine services.

Section 3 creates s. 456.4503, F.S., and establishes requirements for providers who provide telemedicine across state lines to a patient physically located in Florida.

The bill provides that an out-of-state physician, physician assistant, advanced registered nurse practitioner, or pharmacist who provides telemedicine across state lines to a patient physically located in Florida must meet the definition of a “telemedicine provider,” which requires the provider to be licensed in Florida. However, the bill provides that an out-of-state physician, physician assistant, advanced registered nurse practitioner, or pharmacist is exempt from the Florida licensure requirement if he or she is consulting with a telemedicine provider who is licensed to practice in Florida and if the telemedicine provider licensed in Florida retains ultimate authority and responsibility for the diagnosis, treatment, and care of the patient located in this state.

⁴¹ Public Law 111-5, sec. 3002(b)(2)(C)(iii) and sec. 3011(a)(4).

The bill provides another exemption to out-of-state physicians. An out-of-state physician is exempt from the Florida licensure requirement if the physician:

- Holds an unrestricted active license to practice allopathic or osteopathic medicine in the distant site and that state's licensure requirements meet or exceed Florida's requirements;
- Maintains professional liability coverage that includes telemedicine that is consistent with s. 458.320, F.S., and appropriate to the physician's scope of practice and location;
- Has one of the following:
 - Privileges at an out-of-state hospital that is affiliated with a Florida hospital licensed under chapter 395, F.S.;
 - A position 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
- Practices in a state that authorizes Florida-licensed physicians to provide telemedicine services to patients in that state without having to be licensed to practice medicine 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, physician assistant, advanced registered nurse practitioner, or pharmacist 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.

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 two 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 is based on the location of the patient or must 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 that:

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 drug⁴² 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;

⁴² Section 465.003(8), F.S., provides that "medicinal drugs" or "drugs" means those substances or preparations commonly known as "prescription" or "legend" drugs which are required by federal or state law to be dispensed only on a prescription, but shall not include patents or proprietary preparations as hereafter defined.

- 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 ch. 463, F.S., or a physician skilled in diseases of the human eye and licensed under ch. 458 or ch. 459, F.S.; 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 ch. 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.

The reimbursement amount for Medicaid services delivered via telemedicine is negotiable 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, the speaker of the House of Representatives, and the legislative minority leaders by January 1, 2017.

Under the bill, s. 456.4506, F.S., sunsets on June 30, 2017.

Section 7 amends s. 409.967(2)(c), F.S., to provide that a managed care plan may not use a telemedicine provider to meet the requirement that the plan maintain a nationwide network of providers in sufficient numbers to meet access standards for specific medical services for all recipients enrolled in the plan, unless the provider is licensed under ch. 458 or ch. 459, F.S.

Sections 8 and 9 amend ss. 627.645(3) and 641.185(1), F.S., to prohibit the denial of a claim for payment under a health insurance policy or a health maintenance organization on the basis of a

medical necessity determination conducted via telemedicine unless the determination is made by a physician licensed under ch. 458 or ch. 459, F.S.

Section 10 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.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Telemedicine services are currently available in Florida. 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:

In its analysis of SB 70,⁴³ which has similar provision for telemedicine coverage of Medicaid services, the Agency for Health Care Administration (AHCA) provided an indeterminate fiscal impact because the rulemaking authorized under SB 70 is delegated to the Department of Health (DOH), and both the costs and savings would be associated with that bill's provisions. The expected savings were based on possible efficiencies, improvements in disease management, and improved patient outcomes that resulted from telemedicine services.⁴⁴

An increase in the services covered by telemedicine could lead to an indeterminate increase in utilization and costs. SB 1646 broadens the number of services available through telemedicine.⁴⁵

⁴³ SB 70 is in the Health Policy Committee as of April 7, 2014.

⁴⁴ Agency for Health Care Administration, *supra*, note 30, at 7.

⁴⁵ *Id.*, p. 8.

VI. Technical Deficiencies:

The terms “emergency services and care” and “emergency medical conditions” are defined in s. 456.4503(6), F.S., but are not used in the bill.⁴⁶ This issue is addressed in amendment barcode 651910, as amended, which was adopted by the Appropriations Subcommittee on Health and Human Services on April 9, 2014.

The act does not take effect until October 1, 2014, yet the telemedicine course is required to be offered by July 1, 2014 (s. 456.4503(8)(b)).⁴⁷

VII. Related Issues:

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.)

CS by Communications, Energy, and Public Utilities on April 1, 2014:

CS/SB 1646 provides that:

- Only a Florida licensed physician can deny a telemedicine encounter claim from Florida.
- Insurance claims for payment for a telemedicine encounter under a health insurance policy or a health maintenance organization may only be denied by a Florida licensed physician.
- Expands definition of telemedicine provider to include physician assistants, advanced registered nurse practitioners, or a pharmacist.
- Modifies other references to telemedicine practitioners in the Florida Telemedicine Act to incorporate these providers and their boards.
- Requires Florida license with exceptions for:
 - Consulting with a Florida licensed provider who holds the ultimate authority.
 - Consulting on an emergency basis.
- Requires that pertinent records be made available upon request of the state or affiliated organization responsible for providers.

⁴⁶ At line 172 and 173 of CS/SB1646.

⁴⁷ At line 194 of CS/SB 1646.

B. Amendments:**Barcode 651910 by Appropriations Subcommittee on Health and Human Services on April 9, 2014 (as amended by barcode 259150):**

The amendment, as amended:

- Deletes the provisions of CS/SB 1646 that exempt certain out-of-state physicians from the requirement that a physician who provides telemedicine across state lines to a patient physically located in Florida have a Florida license to practice medicine;
- Defines “emergency basis” for purposes of the licensing exemption for consultations that occur on an emergency basis via telemedicine; and
- Requires that a telemedicine provider maintain professional liability coverage that includes coverage for telemedicine services in an amount and manner consistent with s. 458.320(1)(b), F.S., or s. 459.0085(1)(b), F.S., or in the amount required by the applicable law in an out-of-state telemedicine provider’s licensing jurisdiction, whichever is greater.