

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 Health Policy

BILL: CS/SB 478

INTRODUCER: Health Policy Committee and Senators Bean and Joyner

SUBJECT: Telehealth Services

DATE: February 18, 2015

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	Fav\CS
2.			AHS	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 478 creates s. 456.4501, F.S., relating to the provision of telehealth services. The bill defines telehealth services and telehealth provider. CS/SB 478 establishes that the standard of care for a telehealth service is the same as the standard of care for a health professional providing in-person services. A telehealth provider is not required to research the patient's medical history or conduct a physical examination if the telehealth provider conducts an evaluation sufficient to diagnose and treat the patient. Additionally, a telehealth provider must document health care services in the patient's medical record under the same standard as for in-person care.

The bill specifies that a non-physician telehealth provider who is using telehealth and acting within the relevant scope of practice is not practicing medicine without a license.

The bill prohibits a telehealth provider from prescribing lenses, spectacles, eyeglasses, contact lenses, or other optical lenses based solely on the use of computer controlled device through telehealth.

Additionally, controlled substances may not be prescribed through telehealth for chronic non-malignant pain. However, this provision does not preclude a physician from using telehealth to order a controlled substance for an inpatient in a hospital or for a hospice patient.

II. Present Situation:

Telemedicine utilizes various advances in communications 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 include:¹

- 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 include home tele health, 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.

The federal Centers for Medicare and Medicaid Services (CMS) defines telehealth as:

*The use of telecommunications and information technology to provide access to health assessment, diagnosis, intervention, consultation, supervision and information across distance. Telehealth includes such technologies such as telephones, facsimile machines, electronic mail systems, and remote patient monitoring devices which are used to collect and transmit data for monitoring and interpretation.*³

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 had focused on standards for the prescribing of medicine via the Internet. On March 12, 2014, the Board of Medicine's new Telemedicine Rule, 64B8-9.0141, became effective for Florida licensed physicians. The new rule defined telemedicine, established standards of care, prohibited the

¹ American Telemedicine Association, *What is Telemedicine?* <http://www.americantelemed.org/about-telemedicine/what-is-telemedicine#.VN5LgU0cSpp> (last visited Feb. 10, 2015).

² Anita Majerowicz and Susan Tracy, "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 Feb. 10, 2015).

³ Department of Health and Human Services, Centers for Medicare and Medicaid Services, *Telemedicine*, <http://www.medicare.gov/medicaid-chip-program-information/by-topics/delivery-systems/telemedicine.html> (last visited Feb. 17, 2015).

prescription of controlled substances, permitted the establishment of a doctor-patient-relationship via telemedicine, and exempted emergency medical services.⁴

An emergency rule followed shortly after the initial rule's implementation to address concerns that the prohibition on physicians ordering controlled substances may also preclude physicians from prescribing controlled substances via telemedicine for hospitalized patients. The board said it was never their intention through its new rule to prohibit physicians from this practice.⁵ The emergency rule went into effect on April 30, 2014, and was later incorporated during the regular rulemaking process.

Subsequent changes have also been made to the Telemedicine Rules to clarify medical record requirements and the relationship between consulting or cross-coverage physicians.

Telemedicine in Other States

As of February 2015, at least 23 states and the District of Columbia have mandated that private insurance plans cover telemedicine services at reimbursement rates equal to an in-person consultation.⁶ Such laws require insurance companies and health plans to reimburse providers the same amount for the same visit regardless of whether the visit was conducted face to face or via electronic communications.

Forty-six state Medicaid programs also reimburse for some form of telemedicine via live video according to a state survey completed in September 2014.⁷ A smaller number of states offer reimbursement for other types of telemedicine services such as store-and-forward activities,⁸ facility fees for hosting either the telemedicine provider, patient, or both; and remote patient monitoring.⁹

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.¹⁰ As a

⁴ Rule 64B15-14.0081, F.A.C., also went into effect March 12, 2014 for osteopathic physicians.

⁵ Florida Board of Medicine, *Latest News - Emergency Rule Related to Telemedicine*, <http://flboardofmedicine.gov/latest-news/emergency-rule-related-to-telemedicine/> (last visited Feb. 10, 2015).

⁶ American Telemedicine Association, *2015 State Telemedicine Legislation Tracking (as of 2/6/2015)*, <http://www.americantelemed.org/docs/default-source/policy/2015-ata-state-legislation-matrixEF9F3AD41F02.pdf?sfvrsn=18> (last visited Feb. 10, 2015).

⁷ Center for Connected Health Policy, *Telehealth Medicaid & State Policy*, <http://cchpca.org/telehealth-medicare-state-policy> (last visited Feb 10, 2015).

⁸ Store and forward technology refers to the electronic transmission of medical information and data such as digital images, documents and pre-recorded images for review by a physician or specialist at a later date, not simultaneously with the patient.

⁹ *Supra*, Note 7.

¹⁰ Futurity, *In Rural ERs, Kids Get Better Care with Telemedicine*, <http://www.futurity.org/in-rural-ers-kids-get-better-care-with-telemedicine/> (last visited Feb. 10, 2015).

Futurity article notes, “while 21 percent of children in the United States live in rural areas, only 3 percent of pediatric critical-care medicine specialists practice in such areas.”¹¹

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 rates 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. Federal regulation, 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.¹² However, the Ryan Haight Online Pharmacy Consumer Protection Act,¹³ 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 substances 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.¹⁴ The federal regulatory definition of telemedicine under the DEA includes, but is not limited to, the following elements:

- The patient and 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 substances 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.¹⁵

¹¹ Id.

¹² 21 CFR §829(e)(2).

¹³ Ryan Haight Online Consumer Protection Act of 2008, Public Law 110-425 (H.R. 6353).

¹⁴ Id., at sec. 3(j).

¹⁵ 21 CFR §802(54).

Medicare Coverage

Specific telehealth services delivered at designated sites are covered under Medicare. Regulations of federal CMS require both a distant site (location of physician delivering the service via telecommunications) and an originating site (location of the patient).

To qualify for Medicare reimbursement, the Medicare beneficiary must be located at an originating site that meets one of three qualifications. These three qualifications are:

- A rural Health Professional Shortage Area either outside of a Metropolitan Statistical Area (HPSA) or in a rural census tract;
- A county outside of a MSA; or
- Participation in a federal telemedicine demonstration project approved by the Secretary of Health and Human Services as of December 31, 2000.¹⁶

Additionally, federal requirements provide that an originating site must be one of the following location types as further defined in federal law and regulation:

- The offices of physicians or practitioners;
- Hospitals;
- Critical access hospitals (CAH);
- Rural health clinics;
- Federally qualified health centers;
- Hospital-based or CAH-based renal dialysis centers (including satellites);
- Skilled nursing facilities; and,
- Community mental health centers.¹⁷

Distant site practitioners are limited, subject also to state law, under Medicare to:

- Physicians;
- Nurse practitioners;
- Physician assistants;
- Nurse-midwives;
- Clinical nurse specialists;
- Certified registered nurse anesthetists;
- Clinical psychologists and clinical social workers (limited CPT codes); and,
- Registered dietitians and nutrition professionals.

For 2015, Medicare added four new services under telehealth:

- Annual wellness visits;
- Psychoanalysis;
- Psychotherapy; and,

¹⁶ Department of Health and Human Services, Centers for Medicare and Medicaid Services, *Telehealth Services- Rural Health Fact Sheet* (Dec. 2014), <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/TelehealthSrvcsfctsht.pdf> (last visited Feb. 10, 2015).

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

- Prolonged evaluation and management services.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 2015, the originating fee for telehealth is 80 percent of the lesser of the actual charge or \$24.83.²⁰

Telemedicine Services in Florida

University of Miami

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.²¹ Today, UM has several initiatives in the area of telehealth, including:

- Tele-dermatology;
- Tele-trauma;
- Humanitarian and disaster response relief;
- School telehealth services; and
- Acute tele-neurology or telestroke.

While some of 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 hospital patients and conducting training exercises.

Florida Medicaid Program

Florida’s Medicaid program reimburses only physicians for telemedicine services where there is two-way, real-time interactive communication between the patient and the physician at the distant site.²² Equipment is also required to meet specific technical safeguards under 45 CFR 164.312, where applicable, which require implementation of procedures for protection of health information, including unique user identifications, automatic log-offs, encryption, authentication of users, and transmission security. Telemedicine services must also comply with all other state and federal laws regarding patient privacy.

¹⁸ Department of Health and Human Services, Centers for Medicare and Medicaid Services, *MLN Matters - News Flash #MM9034* (Dec. 24, 2014), <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9034.pdf> (last visited Feb. 10, 2015).

¹⁹ See 42 U.S.C. s. 1395(m)(m)(2)(A).

²⁰ *Supra*, Note 18.

²¹ University of Miami, Miller School of Medicine, *UM Telehealth - Our History*, <http://telehealth.med.miami.edu/about-us/our-history> (last visited Feb. 10, 2015).

²² Agency for Health Care Administration, *Practitioner Services Handbook - Telemedicine Services (April 2014)* p.136, http://portal.flmmis.com/FLPublic/Portals/0/StaticContent/Public/HANDBOOKS/Practitioner%20Services%20Handbook_Adoption.pdf (last visited Feb. 10, 2015).

For Medicaid, the distant or hub site is site where the consulting physician delivering the telemedicine service is located. The spoke site is the location of the Medicaid recipient at the time the service occurs. The spoke site does not receive any reimbursement unless the provider located at the spoke site performs a separate service for the Medicaid recipient on the same day as the telemedicine consultation. The telemedicine referral consultation requires the presence of the referring practitioner and the Medicaid recipient.²³

Under fee for services Medicaid, reimbursement for telemedicine services are limited to certain services and settings. The following minimum services are currently covered:²⁴

- Behavioral Health
 - Telepsychiatry services for psychiatric medication management by practitioners licensed under ch. 458 or 459, F.S.
 - Telebehavioral health services for a provision of individual and family behavioral health therapy services by qualified practitioners licensed under ch. 490 or 491, F.S.
- Dental Services
 - Provided using video conferencing between a registered dental hygienist employed by and under contract with a Medicaid-enrolled group provider and supervising dentist.
 - Services provided include oral prophylaxis, topical fluoride application and oral hygiene instructions.
- Physician Services
 - Services provided using audio and video equipment that allow for two-way, real-time, interactive communication between the physician and patient.
 - Consultation services provided via telemedicine.
 - Physicians actively licensed in Florida may also interpret diagnostic testing results through telecommunications and information technology.
 - Synchronous emergency services provided under parts III and IV of ch. 409, F.S., using an all-inclusive rate.

Medicaid does not reimburse for the following telemedicine services:

- Telephone conversations;
- Video cell phone conversations;
- E-mail messages;
- Facsimile transmission;
- Telecommunication with recipient at a location other than the spoke; and,
- “Store and forward” consultations which are transmitted after the recipient or physician is no longer available.²⁵

Medicaid also does not reimburse providers for the costs of any equipment related to telemedicine services.

²³ *Supra*, Note 21 at 137.

²⁴ Agency for Health Care Administration, *Senate Bill 478 Analysis* (Feb. 4, 2015) p. 3, (on file with the Senate Committee on Health Policy).

²⁵ *Id.*

Coverage of telemedicine services under Medicaid includes specific documentation requirements. The clinical record must include the following information:

- A brief explanation of why the services were not provided face-to-face;
- Documentation of telemedicine service provided including the results of the assessment; and,
- A signed statement from the recipient (parent or guardian, if a child), indicating their choice to receive services through telemedicine. This statement may be for a set period of treatment or a one-time visit.²⁶

Under Medicaid Managed Care Assistance (MMA), the model contract executed by the plans provides a telemedicine coverage option and permits the plan to use telemedicine for behavioral health, dental services, and physician services.²⁷ The plan may use telemedicine for other services if approved by the Agency for Health Care Administration. The contract's model Attachment includes a check-off for the inclusion specifically for behavioral health care and dental services under telemedicine.²⁸

Most of the same reimbursement guidelines, technology requirements and privacy provisions apply under the MMA contract as were applicable under the Medicaid fee-for-service and general Medicaid Provider Handbook.²⁹

Child Protection Teams

The Child Protection Team (CPT) program under the Children's Medical Services 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.³⁰ 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.³¹

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.³² Twenty four hub sites throughout the state facilitate these child abuse assessments and with the evaluation of suspected cases of child abuse. The University of Florida

²⁶ Id.

²⁷ Agency for Health Care Administration, *2012-2015 Medicaid Health Plan Model Agreement Attachment II - Exhibit II-A*, http://ahca.myflorida.com/medicaid/statewide_mc/pdf/mma/Attachment_II_Exhibit_II-A_MMA_Model_2014-01-31.pdf, p. 63-64 (Last visited Feb. 10, 2015).

²⁸ Agency for Health Care Administration, *2012-2015 Medicaid Health Plan Model Contract Attachment I - Scope of Services (PSN Model)*, http://ahca.myflorida.com/mchq/managed_health_care/MHMO/docs/contract/1215_Contract/2012-2015/Jan2013/2012-15_HP-ContractAtt-I-FFS-JAN-2013-CLEAN.pdf p. 6, (Last visited Feb. 10, 2015).

²⁹ *Supra*, Note 25.

³⁰ Florida Department of Health, *Child Protection Teams*, http://www.floridahealth.gov/AlternateSites/CMS-Kids/families/child_protection_safety/child_protection_teams.html (Last visited Feb. 10, 2015).

³¹ Florida Department of Health, *Children Protection Team - Telemedicine Network* http://www.floridahealth.gov/AlternateSites/CMS-Kids/families/child_protection_safety/documents/cpt_telemedicine_fact_sheet.pdf (Last visited Feb. 10, 2015)

³² Id.

Child Abuse Protection Team, for example, serves a 12 county area and for the first 6 months of 2012 provided over 250 telemedicine examinations with medical community partners.³³

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 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.³⁴

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:

CS/SB 478 creates s. 456.4501, F.S., relating to the provision of telehealth services and designates by chapter which health care practitioners may provide such services. The telehealth provision covers all health care practitioners as defined under s. 456.001, F.S.,³⁵ with the exception of naturopaths and nursing home administrators. The definition of a telehealth provider also includes radiological personnel and an emergency medical technician or a paramedic certified under part III of ch. 401, F.S.

The bill defines telehealth as the "use of synchronous or asynchronous telecommunications to perform services that include, but are not limited to:

³³ Sunshine Arnold and Debra Esernio-Jensen, *Telemedicine: Reducing Trauma in Evaluating Abuse*, pp. 105-107, <http://cdn.intechopen.com/pdfs-wm/41847.pdf> (Last visited Feb. 14, 2015).

³⁴ Public Law 111-5, s. 3002(b)(2)(C)(iii) and s. 3011(a)(4).

³⁵ The definition of a "health care practitioner" includes 26 different disciplines: Acupuncture, medical practice, osteopathic medicine, chiropractic medicine, podiatry, naturopathy, optometry, nursing, pharmacy, dentistry, midwifery, speech-language-pathology-audiology, nursing home administration, occupational therapy, respiratory therapy, dietetics and nutrition practice, athletic trainers, orthotics, prosthetics, and pedorthotics, electrolysis, massage, clinical laboratory personnel, medical physicists, dispensing of optical devices and hearing aids, physical therapy, psychological services, and clinical, counseling, and psychotherapy.

- Patient assessment;
- Diagnosis;
- Consultation;
- Treatment;
- Monitoring;
- Transfer of medical data; and,
- Provision of patient and professional health related education.

CS/SB 478 specifically excludes from the definition of telehealth audio-only transmissions, email messages, or facsimile transmissions. The term also does not include consultations between a telehealth provider located in this state and a provider lawfully licensed in another state when the Florida licensed provider maintains responsibility for the patient in this state.

A telehealth provider is prohibited from solely using telehealth to prescribe lenses, spectacles, eyeglasses, contact lenses, or other optical devices or prescribe based solely on the use of a computer-controlled device such as an autorefractor.

Controlled substances may not be prescribed through telehealth for chronic non-malignant pain.³⁶ However, a physician may use telehealth to order a controlled substance for an inpatient admitted to a hospital facility licensed under ch. 395, F.S., or a hospice patient under ch. 400, F.S.

CS/SB 478 provides other practice standards for practicing via telehealth. The standards of care for services delivered via telehealth must be comparable to in-person health care services with a patient evaluation sufficient to diagnose and treat. The telehealth provider must maintain record-keeping that is also comparable to in-person health care services.

The bill clarifies that a non-physician practicing via telehealth within the applicable scope of practice for a telehealth provider is not deemed to be practicing medicine.

The effective date of the bill is July 1, 2015.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

³⁶ “Chronic non-malignant pain” is defined as pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.

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.

Patients in Florida may have greater access and more convenient access to health care services.

C. Government Sector Impact:

To the same extent that privately funded health care facilities may demand the expanded use of health care technology, publicly funded facilities and providers may see an equivalent increase in demand from health care practitioners for new equipment and maintenance needs of any existing equipment.

Patients located in more rural areas or areas with physician workforce shortages that rely on county health departments, federally qualified health centers or rural health clinics may see an increased benefit in the use and availability of telehealth technology.

VI. Technical Deficiencies:

None.

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 CS/SB 478 does not define “in person” for purposes of this legislation either, there are other usages of this phrase in statute.

VIII. Statutes Affected:

This bill creates section 456.4501 of the Florida Statutes.

IX. Additional Information:**A. Committee Substitute – Statement of Changes:**

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

CS by Health Policy on February 17, 2015:

The committee substitute:

- Changes the subject of and references in the bill to telehealth rather than telemedicine.
- Specifies the practitioners who may be telehealth providers.
- Prohibits a telehealth provider from using telehealth to prescribe lenses, spectacles, eyeglasses, contact lenses, or other optical devices or prescribe based solely on a computer controlled device.
- Provides practice standards for practicing via telehealth.
- Deletes:
 - The Medicaid provision for coverage parity;
 - Rulemaking authority for the boards and the department, there is no practice board; and
 - Protection clause for the delivery of emergency medical services.

B. Amendments:

None.