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 Appropriations

BILL:	CS/SB 280
INTRODUCER:	Banking and Insurance Committee and Senator Bean
SUBJECT:	Telehealth
DATE:	February 21, 2018
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	**Fav/CS**
2.	Lloyd	Stovall	HP	**Favorable**
3.	Kidd	Williams	AHS	**Recommend: Favorable**
4.	Kidd	Hansen	AP	**Favorable**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 280 establishes practice standards for telehealth health care services, addresses the prescribing of controlled substances and issuance of a physician certification for medical marijuana through telehealth, and prescribes recordkeeping and patient consent. Telehealth is the delivery of health care services using telecommunication technologies, which allows licensed practitioners in one location to diagnose and treat patients at a different location. The bill will remove regulatory ambiguity regarding the provision of health care services using this technology because it is not currently addressed in Florida Statutes.

The Department of Health indicates it can absorb within existing resources the costs associated with development and dissemination of education materials for telehealth licensees as required in the bill. There is no fiscal impact to the Agency for Health Care Administration.

The bill has an effective date of July 1, 2018.

II. Present Situation:

Health Care Professional Shortage

There is currently a health care provider shortage in the United States (U.S.). Approximately 20 percent of U.S. residents live in rural areas, but only 9 percent of physicians practice in these

areas.[1] As of December 31, 2017,[2] the U.S. Department of Health and Human Services has designated 7,176 Primary Care Health Professional Shortage Areas (HPSA), 5,866 Dental HPSA and 5,042 Mental Health HPSA.[3] An estimated 31,449 practitioners are needed to eliminate the shortage nationwide. Florida is experiencing a health care provider shortage. This is evidenced by the fact that there are 647 federally designated Health Professional Shortage Areas (HPSA) within the state for primary care, dental care, and mental health,[4] and it would take an estimated 2,936 practitioners to eliminate these shortage areas in Florida.

Telehealth

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.[5] Telehealth often collectively defines the telecommunications equipment and technology that are used to collect and transmit the data for a telemedicine consultation or evaluation. Telemedicine may refer to clinical services that are provided remotely via telecommunication technologies. Telemedicine is not a separate medical specialty and does not change what constitutes proper medical treatment and services. There is no consensus among federal programs and health care providers on the definition of either term.

The federal Centers for Medicare & 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 technologies such as telephones, facsimile machines, electronic mail systems, and remote patient monitoring devises, which are used to collect and transmit data for monitoring and interpretation.[6]

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[1] Health Affairs, Health Policy Brief: *Telehealth Parity Laws*, (Aug. 15, 2016) (on file with the Banking and Insurance Committee).

[2] *See* U.S. Department of Health and Human Services, Bureau of Health Workforce, Designated Health Professional Shortage Areas Statistics, *First Quarter of Fiscal Year 2018 Designated HPSA Quarterly Summary* (as of Dec. 31, 2017), available at; https://ersrs.hrsa.gov/ReportServer?/HGDW_Reports/BCD_HPSA/BCD_HPSA_SCR50_Qtr_Smry_HTML&rc:Toolbar=false. (last viewed Jan. 25, 2018).

[3] HPSA designations are used to identify areas and population groups within the U.S. that are experiencing a shortage of health professionals. The primary factor used to determine a HPSA designation is the number of health professionals relative to the population with consideration of high need. Federal regulations stipulate that in order for an area to be considered as having a shortage of providers, an area must have a population-to-provider ratio of a certain threshold. For example, for primary medical care, the population to provider ratio must be at least 3,500 to 1 (3,000 to 1 if there are unusually high needs in the community). *See* https://www.kff.org/other/state-indicator/primary-care-health-professional-shortage-areas-hpsas/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last viewed January 25, 2018).

[4] *Id.*

[5] 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 viewed Jan. 25, 2018).

[6] Department of Health and Human Services, Centers for Medicare and Medicaid Services, *Telemedicine*, available at https://www.medicaid.gov/medicaid/benefits/telemed/index.html (last viewed Jan. 5, 2018).

The federal Medicaid statutes and regulations do not recognize telemedicine as a distinct service, but as an alternative method for the delivery of services. Medicaid defines telemedicine and telehealth separately using telemedicine to define the interactive communication between the provider and patient and telehealth to describe the technologies, such as telephones and information systems.[7]

According to the American Telemedicine Association,[8] telemedicine is a significant and rapidly growing component of health care in the U.S. There are currently about 200 telemedicine networks, with 3,500 service sites in the U.S. Nearly one million Americans are currently using remote cardiac monitors. In 2011, the Veterans Administration delivered over 300,000 remote consultations using telemedicine. Over half of all U.S. hospitals now use some form of telemedicine. Around the world, millions of patients use telemedicine to monitor their vital signs, remain healthy, and out of hospitals and emergency rooms. Consumers and physicians download health and wellness applications for use on their cell phones.

Florida Telehealth Advisory Council

In 2016, legislation[9] was enacted that required the Agency for Health Care Administration (AHCA), with assistance from the Department of Health (DOH) and the Office of Insurance Regulation (OIR), to survey health care practitioners, facilities, and insurers on telehealth utilization and coverage, and submit a report on the survey findings to the Governor, President of the Senate, and Speaker of the House of Representatives by December 31, 2016. The law also created a 15-member Telehealth Advisory Council, and required it to submit a report with recommendations based on the survey findings to the Governor, President of the Senate, and Speaker of the House of Representatives by October 31, 2017.

Summary of the Survey Findings of the Telehealth Advisory Council[10]

The types of health care services provided via telehealth in the state. The most frequent uses of telehealth reported by licensed health care facilities in Florida include neurology (including stroke care), home health/patient monitoring, primary care, behavioral health, and radiology. About 44 percent of home health agencies responding to the AHCA's survey indicated using telehealth to assist with remote patient monitoring.

The extent to which telehealth is used by health care practitioners and health care facilities nationally and in the state. At the national level, an estimated 63 percent of practitioners use some type of telehealth platform to provide services. In contrast, only 6 percent of surveyed practitioners in Florida indicated they use telehealth for the provision of health care services. About 52 percent of hospitals in the U.S. use telehealth, and 45 percent of surveyed Florida hospitals stated they offer care through some form of telehealth. Major factors driving the

[7] *Id.*
[8] *See* https://www.americantelemed.org/about/telehealth-faqs- (last viewed Jan. 5, 2018).
[9] Ch. 2016-240, Laws of Fla. The law designated the Secretary of the Agency for Health Care Administration as the council Chair, and designated the State Surgeon General and Secretary of the Department of Health as a member. The AHCA's Secretary and the Surgeon General appointed 13 council members representing specific stakeholder groups.
[10] *See* Telehealth Advisory Council website available at http://www.ahca.myflorida.com/SCHS/telehealth/ (last viewed Jan. 8, 2018).

adoption of telehealth include advancing technologies, an aging population, health practitioner shortage, and greater acceptance of innovative treatment by patients.

The estimated costs and cost savings to provide health care services. Benefits reported from health care facilities and professionals offering telehealth services include improved convenience for both patients and providers, improved efficiencies, and improved patient care outcomes. Financial barriers are the most frequently reported obstacles among health care facilities and providers during both implementation and ongoing operations of telehealth programs. The American Hospital Association notes that direct return on investment for health care providers is limited; particularly when there is limited coverage and reimbursement by health plans for the services offered by telehealth. Twenty-five Florida health facilities and practitioners identify costs, reimbursement, and inability to determine a Return on Investment (ROI) as challenges in providing telehealth services.

The extent of insurance coverage for providing health care services via telehealth and how such coverage compares to coverage for in-person services. Some public and private payers limit reimbursement for health services offered through telehealth technology by the type of telehealth service offered and/or by the locations where care is provided and received. Approximately 43 percent of Florida health insurers indicate that they cover some form of telehealth services. Companies that offer Medicare Advantage plans were shown as having the largest percentage of plans offering reimbursement to health care providers for service provided through telehealth technologies. Coverage typically is limited to certain delivery types and requires special coding. A majority of health insurers indicate very limited coverage.

As of December 2016, 28 states and the District of Columbia have parity laws, which require private payer coverage and payment for telehealth services to be equitable with coverage and reimbursements for face-to-face health services. The definition of telehealth in each of these states varies, and some state definitions may include limitations on the telehealth modalities encompassed in required coverage and payment models.

Notable differences in the state regulations include whether telehealth services must be reimbursed at the same rate as in-person services; or whether the state only requires that the same services be covered but allow for variable rates of reimbursement. Florida does not currently have any statutory requirements related to private payer parity for telehealth services. Some private payers in the state have voluntarily opted to provide coverage and reimbursement for telehealth services.

According to the survey, 48 states offer some type of live video reimbursement in Medicaid to varying levels of reimbursement and coverage levels.[11] At least 21 states have some reimbursement for remote patient monitoring; 15 states reimburse for store and forward services under their Medicaid program; and 9 state programs reimburse for all three types.[12] Within each

[11] Center for Connect Health Policy, *State Telehealth Laws and Reimbursement Policies: A Comprehensive Scan of the 50 States and District of Columbia (Fall 2017)*, pg. 3, http://www.cchpca.org/sites/default/files/resources/Telehealth%20Laws%20and%20Policies%20Report%20FINAL%20Fall%202017%20PASSWORD.pdf, (last visited Jan. 25, 2018).

[12] *Id.* In their Fall 2017 survey of states, the Center for Connected Health Policy also found that 31 states provide a transmission or facility fee. *See* Center for Connected Health Policy, *50 State Scan of Telehealth Reimbursement Laws and Medicaid Policies-Factsheet* (Fall 2017) (on file with Health Policy Committee).

of these reimbursement models, there are variances in the types of services, specialties, providers, and locations that are covered. The Florida Medicaid fee-for-service rules were updated in June 2016 to expand telehealth payments to a broader array of practitioners. Similar to Medicare, Medicaid coverage in Florida is limited to live video conferencing, and pays the practitioner that provides the diagnosis only. With the vast majority of Florida Medicaid beneficiaries enrolled in managed care, Florida's Medicaid managed care plans are authorized to cover telehealth services with greater flexibility; however, there is no mandate for coverage. Based on survey responses by Florida health plans, coverage for telehealth is greatest for Medicaid managed care and Affordable Care Act Exchange Plans. Florida health care providers indicate very little reimbursement for telehealth services no matter the plan type.

Barriers to using or accessing services through telehealth. The primary issues related to telehealth often cited are financial, interoperability, and licensure. Florida providers and practitioners cited financial issues, such as inadequate reimbursement from payers, insufficient funding capital, and the inability to determine return on investment. An estimated 44 percent of the health plans surveyed noted government regulations and liability as barriers for covering telehealth services. The issue of interstate practice and reimbursement is among the legal issues health plans must consider. For example, health plans must ensure they are reimbursing health providers that are licensed appropriately in the jurisdiction where they are treating patients.[47] Florida facility and practitioner licensees who responded to the survey indicated the top three barriers to implementing telehealth involve finances: inadequate reimbursement from payers, insufficient funding capital, and the inability to determine return on investment.

Summary of the Recommendations of the Telehealth Advisory Council[13]

The report contained the following recommendations:

1. **Create definition of telehealth and replace existing telehealth and telemedicine definitions in Florida statutes and rules.** Telehealth is defined as the mode of providing health care and public health services through synchronous and asynchronous information and communication technology by a Florida licensed health care practitioner, within the scope of his or her practice, who is located at a site other than the site where a recipient (patient or licensed health care practitioner) is located.
2. **Coverage Parity.** A health insurance policy issued, amended, or renewed on or after July 1, 2018, shall provide coverage for services (excluding Medicare plans) provided via telehealth to the same extent the services are covered, if provided in-person. An insurer shall not impose any additional conditions for coverage of services provided via telehealth.[14]
3. **Payment Parity.** For the purpose of health insurance payment (excluding Medicare plans), payment rates for services provided via telehealth shall be equivalent to the rates for comparable services provided via in-person consultation or contact contained in the participation agreement between the insurer and the health care practitioner.[15]

[13] *See* Telehealth Advisory Council, *Expanding Florida's Use and Accessibility of Telehealth* (Oct. 31, 2017), available at http://www.ahca.myflorida.com/SCHS/telehealth/docs/TAC_Report.pdf (last visited January 5, 2018).

[14] According to the report, the intent of this recommendation is to ensure appropriate insurance coverage for the use of telehealth in treating patients. Any legislative language developed should not require insurers to add additional service lines or specialties, mandate a fee-for-service arrangement, inhibit value-based payment programs, or limit health care insurers and practitioners from negotiating contractual coverage terms.

[15] According to the report, the intent of this recommendation is to ensure appropriate insurance reimbursement for the use of telehealth in treating patients. Any legislative language developed should not require insurers to add additional service lines

4. **Medicaid Reimbursement.** The council recommends the AHCA modify the Medicaid telehealth fee-for-service rule to include coverage of store-and-forward and remote patient monitoring modalities in addition to the currently reimbursed live video conferencing modality.
5. **Medicaid Network Adequacy.** The council recommends the AHCA develop a model that would allow Medicaid managed care plans to utilize telehealth for meeting network adequacy.
6. **Interstate Licensure.** In order to ensure the best care for Florida patients and maximize available resources and access to care, the council recommends the following:
    - Maintain the requirement of Florida licensure for health practitioners providing patient care in Florida via telehealth. This recommendation requires no change to current regulations and does not inhibit the use of telehealth to treat patients.
    - The Legislature adopt laws allowing participation in health care practitioner licensure compacts that have licensure requirements that are equivalent to or more stringent than Florida Law.
7. **Standards of Care.** To ensure clarity for Florida licensed health care practitioners and stakeholders regarding the ability to use telehealth as a modality of care, the council recommends the DOH, healthcare regulatory boards and councils continue to educate and raise awareness among licensees that they may use telehealth modalities to serve patients.
8. **Patient-Practitioner Relationships and Continuity of Care**. The council offers the following language for inclusion in Florida statutes: A health care practitioner-patient relationship may be established through telehealth.
9. **Patient Consent.** The council recommends maintaining current consent laws in Florida.
10. **Telehealth and Prescribing.** The council offers the following language:
    Health care practitioners, authorized by law, may prescribe medications via telehealth to treat a patient as is deemed appropriate to meet the standard of care established by his or her respective health care regulatory board or council. The prescribing of controlled substances through telehealth should be limited to the treatment of psychiatric disorders and emergency medical services. This should not prohibit an authorized health care practitioner from ordering a controlled substance for an inpatient at a facility licensed under ch. 395, F.S., or a patient of a hospice licensed under ch. 400, F.S.
11. **Technology and Health Care Facilities/Practitioners.** The council notes that technology-related barriers for practitioners will decrease as technological advances and market forces drive cost reductions. Barriers remain related to interoperability of health care information systems. The council recommends:
    - The AHCA identify existing resources for health information exchange to expand interoperability between telehealth technologies and integration into electronic health record (EHR) platforms.
    - The AHCA continue promotion of existing programs and services available to increase access to technology, access to broadband networks, and improved interoperability.
    - Medical schools, schools of allied health practitioners, and health care associations provide information and educational opportunities related to the utilization to telehealth for serving patients.

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or specialties, mandate fee-for-service arrangements, inhibit value-based payment programs, limit health care insurers and practitioners from negotiating contractual coverage terms, or require insurers to pay for facsimiles or audio only communication.

Florida Board of Medicine

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. On March 12, 2014, the board's new Telemedicine Rule, 64B8-9.0141, became effective for Florida-licensed physicians. The new rule defined telemedicine,[16] established standards of care, prohibited the prescription of controlled substances, permitted the establishment of a doctor-patient relationship via telemedicine, and exempted emergency medical services.[17]

Two months after the initial rule's implementation, the board proposed the development of a rule amendment 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 indicated such a prohibition was not intended.[18] The amended rule took effect July 22, 2014. Additional changes followed to clarify medical record requirements and the relationship between consulting or cross-coverage physicians. On December 18, 2015, the board published another proposed rule change to allow controlled substances to be prescribed through telemedicine for the limited treatment of psychiatric disorders.[19] The proposed rule amendment, Rule 64B8-9.0141-Standards for Telemedicine Practice, became effective March 7, 2016.[20]

On February 3, 2017, the Board of Medicine held a public hearing on a proposed amendment to Rule 64B8-9.0141 to prohibit the ordering of low-THC cannabis or medical cannabis through telemedicine. Additional public hearings were noticed for April and August on the amended rule; however, the rule was eventually withdrawn in August 2017 without being amended.

Florida's Medicaid Program[21]

The Florida Medicaid program is a partnership between the federal and state governments. In Florida, the Agency for Health Care Administration (AHCA) oversees the Medicaid program.[22] The Statewide Medicaid Managed Care (SMMC) program is comprised of the Managed Medical Assistance (MMA) program and the Long-term Care (LTC) managed care program. The AHCA

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[16] The term, "telemedicine," is defined to mean the practice of medicine by a licensed Florida physician or physician assistant where patient care, treatment, or services are provided through the use of medical information exchanged from one site to another via electronic communications. Telemedicine shall not include the provision of health care services only through an audio only telephone, email messages, text messages, facsimile transmission, U.S. Mail or other parcel service, or any combination thereof.

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

[18] Florida Board of Medicine, *Latest News - Emergency Rule Related to Telemedicine*, http://flboardofmedicine.gov/latest-news/emergency-rule-related-to-telemedicine/ (last visited Jan. 14, 2018).

[19] Vol. 41/244, Fla. Admin. Weekly, Dec. 18, 2015, available at https://www.flrules.org/BigDoc/View_Section.asp?Issue=2011&Section=1 (last visited Jan. 14, 2018).

[20] Florida Board of Medicine, Latest News, Feb. 23, 2016, available at http://flboardofmedicine.gov/latest-news/board-revises-floridas-telemedicine-practice-rule/ (last viewed Jan. 7, 2018).

[21] *See* Agency for Health Care Administration, Analysis *of SB 280* (Oct. 9, 2017) (on file with the Senate Banking and Insurance Committee).

[22] Part III of ch. 409, F.S., governs the Medicaid program.

contracts with managed care plans to provide services to eligible enrollees.[23] Under the Managed Medical Assistance (MMA) component of Statewide Medicaid Managed Care, managed care plans may use telemedicine for behavioral health, dental services, and physician services.[24] The AHCA may also approve other telemedicine services provided by the managed care plans if approval is sought by those plans under the MMA component.

Florida Medicaid has adopted a rule on telemedicine, which authorizes services to be delivered via telemedicine. The rule defines telemedicine as the practice of health care delivery by a practitioner who is located at a site other than the site where a recipient is located for the purposes of evaluation, diagnosis, or treatment.[25] Further, telemedicine services must be provided by licensed practitioners operating within their scope of practice and involve the use of interactive telecommunications equipment which includes, at a minimum, audio and video equipment permitting two-way, real time, communication between the enrollee and the practitioner.[26] Additionally, the rule provides that Medicaid reimburse a practitioner rendering services in the fee-for-service delivery system who is providing the evaluation, diagnosis, or treatment recommendation located at a site other than where the recipient is located.

Equipment is also required to meet specific federal technical safeguards, which require implementation of procedures for protection of health information.[27] The safeguards include 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.

Florida Medicaid statutes and the federal Medicaid statutes and regulations consider telemedicine to be a delivery system rather than a distinct service; as such, Florida Medicaid does not have reimbursement rates specific to the telemedicine mode of service. In the fee-for-service system, Florida Medicaid reimburses services delivered via telemedicine at the same rate and in the same manner as if the service were delivered face-to-face.

Medicaid health plans can negotiate rates with providers, so they have the flexibility to pay different rates for services delivered via telemedicine. The managed care plans are required to submit their telemedicine policies and procedures to the AHCA for approval, but are not required to do so prior to use.[28] Telephone conversations, chart review, electronic mail messages, or facsimile transmissions are not reimbursable as telemedicine.

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[23] A managed care plan that is eligible to provide services under the SMMC program must have a contract with the AHCA to provide services under the Medicaid program and must also be a health insurer; an exclusive provider organization or a HMO authorized under chs. 624, 627, or 641, F.S., respectively; a provider service network authorized under s. 409.912(2), F.S., or an accountable care organization authorized under federal law. Section 409.962, F.S.

[24] Agency for Health Care Administration, *2012-2015 Medicaid Health Plan Model Agreement Attachment II - Exhibit II-A,* p. 63-64 http://ahca.myflorida.com/medicaid/statewide_mc/pdf/mma/Attachment_II_Exhibit_II-A_MMA_Model_2014-01-31.pdf , (last visited Jan. 11, 2018).

[25] *See* Rule 59G-1.057, F.A.C.

[26] *Id.*

[27] 45 CFR s. 164.312.

[28] Agency for Health Care Administration, *Statewide Medicaid Managed Care (SMMC) Policy Transmittal (March 11, 2016), http://ahca.myflorida.com/medicaid/statewide_mc/pdf/plan_comm/PT_16-06_Telemedicine_03-11-2016.pdf,* (last visited Jan. 25, 2018).

Regulation of Insurance in Florida

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, health maintenance organizations (HMOs), and other risk-bearing entities.[29] The AHCA regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from the AHCA.[30] As part of the certification process used by the AHCA, an HMO must provide information to demonstrate that the HMO has the ability to provide quality of care consistent with the prevailing standards of care.[31]

Federal Telemedicine Provisions

Federal laws and regulations address telemedicine from several perspectives, including prescriptions for controlled substances, hospital emergency room guidelines, and reimbursement requirements and 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 s. 829 provides:

> 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.[32] However, the Ryan Haight Online Pharmacy Consumer Protection Act,[33] 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.[34] 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

[29] Section 20.121(3)(a), F.S.
[30] Section 641.21(1), F.S.
[31] Section 641.495, F.S.
[32] 21 CFR s. 829(e)(2).
[33] Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Public Law 110-425 (H.R. 6353).
[34] Id., at sec. 3(j).

- Certain practitioners (Department of Veterans Affairs' employees, for example) or practitioners in certain situations (public health emergencies) may be exempted from registration requirements.[35]

Medicare Coverage

Specific services that are covered under Part B of Medicare[36] which are delivered at designated rural sites as a telehealth service are covered under Medicare. Federal CMS regulations 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 (HPSA) that is either outside a metropolitan statistical area (MSA) or in a rural census tract[37];
- A county outside of an MSA; or
- Participation in a federal telemedicine demonstration project approved by the Secretary of Health and Human Services as of December 31, 2000.[38]

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 office of a physician or practitioner;
- A hospital;
- A critical access hospital (CAH);
- A rural health clinic;
- A federally qualified health center;
- A hospital-based or CAH-based renal dialysis center (including satellite offices);
- A skilled nursing facility; or
- A community mental health center.[39]

Under Medicare, distant site practitioners are limited, subject also to state law, to:

- Physicians;
- Nurse practitioners;
- Physician assistants;
- Nurse-midwives;
- Clinical nurse specialists;

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[35] 21 CFR s. 802(54).

[36] Part B of Medicare is the medical insurance portion and covers services such as physician office visits and consultations, mental health services (inpatient and outpatient), and partial hospitalization.

[37] The United States Census Bureau does not define rural, but defines urban leaving all other areas not urban to be considered rural. "Urbanized areas" are those of 50,000 or more people. "Urban clusters" are those of at least 2,500 and less than 50,000 people. *See* Health Resources and Services Administration, *Defining Rural Population, https://www.hrsa.gov/rural-health/about-us/definition/index.html*, (last visited Jan. 25, 2018).

[38] 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 Jan. 7, 2018).

[39] *See* 42 U.S.C. sec. 1395(m)(m)(4)(C)(ii).

- Certified registered nurse anesthetists;
- Clinical psychologists and clinical social workers; and
- Registered dietitians and nutrition professionals.

Medicare added new services under telehealth in 2015:
- Annual wellness visits;
- Psychoanalysis;
- Psychotherapy; and
- Prolonged evaluation and management services.[40]

For 2018, the CMS conducted additional rulemaking to add more telehealth services related to health risk assessments, psychotherapy, and care planning for chronic care management. The proposed rule also sought comment on ways CMS could further expand access to telehealth services within its existing statutory authority.[41] Federal legislation to expand the scope of telehealth to include telestroke services for Medicare beneficiaries has also been under discussion and passed through the House Committee on Energy and Commerce favorably.[42]

Protection of Personal Health Information

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects personal health information (PHI). Initial 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 and 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 of the entities listed above.

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 a medical service is delivered. The HITECH Act specifically identified telemedicine as an area for review and consideration, and funding was provided to, in part, strengthen infrastructure and tools to promote telemedicine.[43]

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[40] Department of Health and Human Services, Centers for Medicare and Medicaid Services, *MLN Matters* (Dec. 24, 2014), http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9034.pdf (last visited Jan. 7, 2018).
[41] Department of Health and Human Services, Centers for Medicare and Medicaid Services, *Fact Sheet: Final Policy, Payment, and Quality Provisions in the Medicare Physician Fee Schedule for Calendar Year 2018 (November 2, 2017), https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-11-02.html* (last visited Jan. 25, 2018).
[42] *See "Furthering Access to Stroke Telemedicine Act of 2017" or the "FAST Act of 2017," H.R. 1148,* 115th Cong. (2017-2018).
[43] Public Law 111-5, s. 3002(b)(2)(C)(iii) and s. 3011(a)(4).

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 are HIPAA compliant.

Department of Veterans Affairs Telehealth Initiative

A draft federal rule proposed in October 2017 would permit a health care provider who met certain requirements set by the Department of Veterans Affairs to provide telehealth services within the scope of his or her practice, and the privileges as granted by the Department of Veterans Affairs, irrespective of state or location within the state where the health care provider or the beneficiary was physically located. The health care provider would be required to:

- Be a licensed, registered, and certified health care provider under 38 U.S.C. 7402(b);
- Be appointed to a specified occupation in the federal Veterans Health Administration;[44]
- Maintain the credentials (license, registration, and certification) required for his or her medical specialty; and
- Not be a Veterans Administration-contracted employee.[45]

Under the draft rule, the health care provider can only practice within the scope of his or her license and would be subject to the limitations of the federal Controlled Substances Act.[46] This federal regulation would also preempt any conflicting state laws relating to the practice of health care when the providers are practicing within the scope of their license.[47]

III. Effect of Proposed Changes:

Section 1 creates s. 456.4501, F.S., which addresses the provision of health care services through telehealth. The section provides definitions of the terms "information and telecommunications technologies," "store and forward," "synchronous," and "telecommunications system," which are terms used in defining the technological means by which telehealth services may be provided.

This section also defines the term, "telehealth," as the mode of providing health care services and public health care services by a Florida licensed practitioner, within the scope of his or her practice, through synchronous and asynchronous information and telecommunication technologies where the practitioner is located at a site other than the site where the recipient, whether a patient or another licensed practitioner, is located.

The section defines "telehealth provider" as a person providing health care services and related services through telehealth, and who is licensed under ch. 457, F.S. (acupuncture); ch. 458, F.S. (medical practice); ch. 459, F.S. (osteopathic medicine); ch. 460, F.S. (chiropractic medicine); ch. 461, F.S. (podiatric medicine); ch. 462, F.S. (naturopathy); ch. 463, F.S. (optometry);

[44] Health care providers listed under this section must meet the individual qualifications for each provider listed and the named providers include physicians, dentists, nurses, directors of a hospital, domiciliary, center, or outpatient clinic, podiatrist, optometrist, pharmacist, psychologist, social worker, marriage and family therapist, licensed mental health counselor, chiropractor, peer specialist, and other designated health care positions as the Secretary shall prescribe.
[45] Authority of Health Care Providers to Practice Telehealth, 82 Fed. Reg. 45756, 45762 (proposed Oct. 2, 2017) (to be codified at 38 CFR 17.417)
[46] *See* 21 U.S.C. 801, et seq.
[47] *Supra,* note 45 at 45762.

ch. 464, F.S. (nursing); ch. 465, F.S. (pharmacy); ch. 466, F.S. (dentistry); ch. 467, F.S. (midwifery); part I (speech-language pathology and audiology), part III (occupational therapy), part IV (radiological personnel), part V (respiratory therapy), part X (dietetics and nutrition practice), part XIII (athletics trainers), or part XIV (orthotics, prosthetics, and pedorthics) of ch. 468, F.S.; ch, 478, F.S. (electrolysis); ch. 480, F.S. (massage practice); parts III (clinical lab personnel) and IV (medical physicists) of ch. 483, F.S.; ch. 484, F.S. (dispensing of optical devices and hearing aids); ch. 486, F.S. (physical therapy); ch. 490, F.S. (psychological services); or ch. 491, F.S. (clinical, counseling, and psychotherapy services); or who is certified under s. 393.17, F.S., (behavior analyst) or part III of ch 401, F.S. (medical transportation services).

The section establishes practice standards for the provision of telehealth services. The standard of care for a telehealth provider is the same as that for an in-person health care provider. However, a telehealth provider is not required to research patient's medical history or conduct a physical examination if a patient evaluation conducted by telehealth is sufficient to diagnose and treat the patient. The bill specifies that the telehealth provider and the patient may be in separate locations and telehealth providers who are not physicians, and who are acting within their relevant scope of practice, are not practicing medicine without a license.

The section specifically provides that telehealth providers who are licensed to prescribe controlled substances listed in Schedule I through V may prescribe those controlled substances through telehealth except to treat chronic nonmalignant pain as defined in s. 458.3265(1)(a), F.S., and s. 459.0137(1)(a), F.S. Telehealth may not be used to issue a physician certification for marijuana pursuant to s. 381.986, F.S. This subsection does not apply when prescribing a controlled substance for an inpatient at a facility licensed under ch. 395, F.S., or a patient of a hospice licensed under ch. 400, F.S.

The Department of Health, in coordination with the relevant boards, must develop and disseminate educational materials for telehealth licensees delineated in s. 456.4501(1)(f), F.S., on using telehealth modalities to treat patients by January 1, 2019.

The section provides that a patient's medical records must be updated by a telehealth provider according to the same standards that apply to an in-person health care provider. Finally, the section provides that while a patient need not specifically consent to be treated via telehealth, the patient must still provide consent for treatment as provided under current law. The patient would retain the right to withhold consent for any particular procedure or treatment to be provided through telehealth.

Section 2 provides that the bill takes effect July 1, 2018.

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:

According to the Telehealth Advisory Council's report,[48] health practitioners indicated the need for a definition of the term, "telehealth" that would clarify the use of technological modalities as an acceptable way to treat patients within their scope of practice. Further, health plans noted the need for clarity in the allowable modes of telehealth for coverage and reimbursement purposes.

These changes may encourage the use of telehealth options, which may result in reduced health care costs; increased patient access to providers, especially in medically underserved areas; improved quality and continuity of care; and faster and more convenient treatment resulting in reduction of lost work time and travel costs for patients. Preventing the unnecessary use of intensive services, such as emergency department visits, improves health outcomes and can reduce overall health care costs.

C. Government Sector Impact:

Department of Health

The Department of Health anticipates additional workload relating to the implementation of the bill. The costs associated with this increased workload and the costs associated with the development and dissemination of educational materials for licensees on using telehealth modalities to treat patients are indeterminate, but Department of Health's current resources and budget authority are adequate to absorb these costs.[49]

Agency for Health Care Administration

To maintain uniform naming conventions and practice standards throughout the state's policies, the AHCA will need to amend the Medicaid state plan, which will require federal approval.

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[48] *See* Telehealth Advisory Council, *Expanding Florida's Use and Accessibility of Telehealth* (Oct. 31, 2017), available at http://www.ahca.myflorida.com/SCHS/telehealth/docs/TAC_Report.pdf (last visited January 5, 2018).
[49] Department of Health, *Analysis of SB 280* (Oct. 12, 2017) (on file with Senate Banking and Insurance Committee).

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 456.4501 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Banking and Insurance on January 16, 2018:
The CS eliminates telehealth provisions relating to the State Group Insurance program, Medicaid, and the Insurance Code and provides a technical change.

B. Amendments:

None.