

STORAGE NAME: h1953s1.go

DATE: April 2, 2000

**HOUSE OF REPRESENTATIVES
AS REVISED BY THE COMMITTEE ON
GOVERNMENTAL OPERATIONS
ANALYSIS**

BILL #: CS/HB 1953 (PCB HCL 00-08)

RELATING TO: Telehealth

SPONSOR(S): Committee on Health Care Licensing & Regulation, Committee on Health Care Licensing & Regulation and Representatives Fasano and Kyle

TIED BILL(S): None

ORIGINATING COMMITTEE(S)/COMMITTEE(S) OF REFERENCE:

- (1) HEALTH CARE LICENSING & REGULATION YEAS 10 NAYS 2
 - (2) GOVERNMENTAL OPERATIONS
 - (3)
 - (4)
 - (5)
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I. SUMMARY:

In 1999, the Florida Legislature created the Task Force on Telehealth. This bill incorporates the recommendations made by the Task Force in its report dated January 1, 2000 relating to civil, administrative, and criminal law. This bill does not attempt to address the related issues of technology, reimbursement, and access because many of those issues will be resolved in the private sector without government involvement as telehealth becomes firmly established. Other issues such as reimbursement through government programs will need in-depth study to determine the costs and benefits and may be addressed in future years.

Specifically, this bill creates a new section in ch. 455, Part II, F.S., providing for the regulation of any health care service regulated under Florida law that is delivered or provided to a patient through telecommunications. This bill requires a Florida telehealth license for the provision of telehealth services by out-of-state practitioners to patients located in Florida. As with current law, episodic consultative services between out-of-state practitioners and Florida licensed practitioners may be provided without requiring the out-of-state practitioner to obtain a Florida license. In addition, only practitioners licensed in Florida may order out-of-state electronic communications, diagnostic-imaging or treatment services for patients in Florida. This bill also includes requirements for the advertisement of telehealth services and provides for prosecution of unlicensed activity and other crimes. Finally, the bill amends Florida's medical negligence statute to clarify that if an injury or death results from telehealth services provided to a Florida patient, the action for recovery of damages may be brought in Florida regardless of the location of the practitioner.

The Department of Health expects the fiscal impact of this bill to be minimal and believes that the workload can be absorbed within existing resources. While this bill establishes the telehealth license and clarifies the civil, administrative, and criminal laws governing the practice of telehealth in Florida, there is no immediate incentive for out-of-state practitioners to apply for a Florida telehealth license since the requirements are almost identical to full licensure. Any workload growth resulting from this bill can be considered in future legislative budget requests.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

- | | | | |
|-----------------------------------|-----------------------------------------|----------------------------------------|-----------------------------------------|
| 1. <u>Less Government</u> | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. <u>Lower Taxes</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 3. <u>Individual Freedom</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 4. <u>Personal Responsibility</u> | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 5. <u>Family Empowerment</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |

For any principle that received a "no" above, please explain:

This bill does not support less government because it creates new responsibilities and rulemaking authority for the implementation of telehealth licensing regulations.

B. PRESENT SITUATION:

The development of telecommunications has greatly expanded the opportunity to address issues relating to access to health care. The opportunity to receive health care through video transmissions, Internet communications, and other telecommunications can alleviate the necessity and burden of traveling great distances for specialized services. However, with the benefits of increased access to care, there are also concerns about protection of patient safety from incompetent, unscrupulous or fraudulent persons.

The Florida Legislature has found a compelling state interest in protecting the health, safety and welfare of the public from incompetent, impaired, or unscrupulous practitioners. Such protection is afforded through required licensure of health care practitioners. Florida licensure regulation of health care practitioners is based on Chapter 455, Part II, F.S., and individual practice acts for 37 different professions. These laws provide requirements for obtaining a license, including education and training, examination, review of past work history, and other requirements. The laws also require compliance with standards of care and provide for discipline against practitioners who are found to be incompetent, impaired, fraudulent, or otherwise unscrupulous.

Telehealth is a generic term that characterizes the delivery of health care by a health care practitioner through telecommunications, rather than the traditional face-to-face delivery system. Telehealth falls into two major categories of services. The first category is the access to specialized services from experts located in regional, national, or international centers of excellence. Florida practitioners can access consultation services from regional, national, or international experts through telecommunications that include sharing of medical information and may even include a video presentation of a patient. The Florida Department of Health, Division of Children's Medical Services, is an example of how technology has improved the health care available to Florida's most vulnerable children.

The second major category of telehealth services is the rapidly growing Internet-based telehealth services. Websites are proliferating, offering medical information, prescriptions, and other treatment services via e-mail communication. This category poses the most

significant danger to Floridians as the range of expertise varies tremendously from site to site. Some websites provide excellent general information to patients and practitioners, much like a traditional library reference center. Others provide patient chat rooms similar to traditional patient support groups. These informational sites are usually in compliance with federal and state laws. However, other websites pose a serious danger to the public by offering potent drugs without examination, requiring a patient's full medical history, and the possibility of incorrectly addressing drug interactions and other contraindications. There have been many news reports exposing the ease of obtaining drugs such as the hair loss medication, Propecia, and the erectile dysfunction medication, Viagra. Dispensing these drugs without a prescription is a violation of federal and state law.

Florida law does not explicitly address the practice of health care through a telecommunications delivery system. Because Florida law is not explicit, arguments are made that the "silence" of the law could be either permissive or restrictive. In practicality, practitioners are unclear what the "rules" are regarding telehealth, whether and under what conditions or restrictions they may provide telehealth services to Floridians. Clarification and confirmation of federal and state law in this regard would be helpful to patients, practitioners, and regulators.

Generally, Florida's health care licensure laws are based on two primary licensure methods: examination or endorsement. Licensure by examination requires the passage of a state or national exam as a condition of licensure. Licensure by endorsement applies to a person who has already passed the required examination or its equivalent, and is licensed in another state. However, endorsement does not simply accept the other state license and "reciprocate" by granting a Florida license. Licensure by endorsement requires independent review by the Florida regulatory board, or the department when there is no board, of the required credentials for licensure, e.g., education and training, work history, etc.

Florida's Administrative Procedures Act provides authority in s. 120.542, F.S., for agencies, including regulatory boards, to grant variances or waivers to requirements of rules established by the agency or board. Agencies and boards may not grant variances or waivers to statutory requirements. The authority to grant waivers and variances was established to allow for reasonable exceptions to unreasonable or unfair consequences of a rule, or unintended results. Specifically, the applicant for the variance or waiver must demonstrate that the purpose of the statute underlying the rule has been achieved by other means and the application of the rule would create a substantial hardship on the applicant or would violate principles of fairness. A person unfairly affected by a rule must petition for a waiver or variance and the regulatory agency considers petitions on a case-by-case basis.

National legislation has been proposed to regulate interstate telehealth services. State laws regarding the regulation of telehealth vary from state to state and from profession to profession. The Federation of State Medical Boards and the National Association of State Boards of Nursing have proposed models for "reciprocal" licensure between participating states. These models have different features but are similar in establishing an agreement between participating states who determine that their licensure requirements are comparable and therefore are willing to allow a practitioner who is licensed in one state to practice in the reciprocating state without obtaining a separate license from the reciprocating state. Florida law does not authorize the Board of Medicine, Board of Osteopathic Medicine, or the Board of Nursing to enter into such a reciprocating agreement.

The Florida Pharmacy Act provides for the licensure of pharmacists, the permitting of community and institutional pharmacies, and in s. 465.0156, F.S., for the registration of nonresident pharmacies. Nonresident pharmacies are pharmacies located outside Florida that deliver dispensed drugs into Florida. Nonresident pharmacies are sometimes referred to as "mail order pharmacies." Section 465.0156, F.S., requires the nonresident pharmacy to apply to the Florida Board of Pharmacy, maintain a valid license from the state in which the pharmacy is physically located, pay a registration fee and biennial renewal fees to the Florida Board of Pharmacy, provide pharmacy services at a high level of protection and competence, be subject to discipline in Florida like any other Florida pharmacy, and provide information about the corporate officers and pharmacist manager responsible for dispensing drugs to Floridians.

The Florida Pharmacy Act also provides in s. 465.003(14), F.S., that a pharmacist may fill a prescription from a physician licensed in another state but only if the prescription is for the treatment of a chronic or recurrent illness. This provision allows for the continuance of drug therapy treatment of tourists or visitors to Florida by their regular physician located and licensed in the patient's home state.

Chapter 766, F.S., addresses medical malpractice and related matters. Section 766.102, F.S., provides standards for actions brought in Florida courts for recovery of damages based on the death or personal injury of a person resulting from the negligence of a health care provider. The definition of "health care provider," s. 766.101(1)(b), F.S., includes allopathic, osteopathic, podiatric, and chiropractic physicians, optometrists, dentists, pharmacists, hospitals, and ambulatory surgery centers -- all licensed under Florida law.

Section 175 of HB 2125 (ch. 99-397, Laws of Florida), passed by the Florida Legislature in 1999, created a Task Force on Telehealth within the Department of Health. The legislation required the Task Force to examine issues relating to the utilization of telecommunication technology, the regulation of telehealth practice, and the impact on access and quality of health care. In the January 1, 2000 report to the Legislature, the Task Force reported its finding that the delivery of health care services through telecommunications can enhance the delivery of care to persons in rural and under served areas, as well as providing access to centers of excellence throughout the country. Additionally, the Task Force determined that Floridians must be afforded protection for safe and quality health care delivered through telecommunications, comparable to protections for traditional health care service delivery. The Task Force on Telehealth formed five workgroups to study the legal implications, the licensure alternatives, the available technology, the impact on access to care, and current reimbursement for services. The Task Force identified many barriers and benefits of telehealth and made over 40 recommendations relating to telehealth laws, licensure, technology, access, and reimbursement.

C. EFFECT OF PROPOSED CHANGES:

This bill addresses the legal and licensure recommendations from the Telehealth Task Force. It sets forth the intent and compelling state interest in protecting the public from unsafe and unscrupulous health care practitioners. It states that the delivery of all health care services, including telehealth services, to the people of Florida should be regulated through the licensure of health care practitioners. The purpose of licensure is to hold practitioners accountable for providing quality services.

This bill establishes a procedure to obtain a Florida telehealth license. The requirements to obtain a telehealth license are incorporated by reference as being identical to the

requirements set forth in each practice act for the applicable profession. The requirements for a telehealth license include profiling, credentialing, informed consent, financial responsibility and malpractice insurance in the same manner as currently required for each profession. This bill does not modify existing licensure requirements for out-of-state pharmacies that register with Florida as a nonresident pharmacy and comply with the requirements of s. 465.0156, F.S.

All other laws and rules regulating health care practitioners in Florida must be followed by persons obtaining a Florida telehealth license. Any violation of law by the telehealth practitioner may result in criminal, administrative, and civil penalties in the same manner as currently applicable to the traditional health care provider under Florida law. Florida licensees who chose to practice telehealth on patients located outside of Florida are not able to evade Florida requirements under this bill. They will still be subject to Florida's criminal, administrative, and civil laws. This bill provides that the venue for any action involving a Florida patient or a Florida practitioner may be Florida.

This bill establishes requirements for advertising telehealth services to Floridians. The purpose of such requirement is to educate and inform patients of the necessity and value of licensure, as well as providing information to patients on how to file a complaint against the practitioner if necessary. It provides for prosecution of criminal activity in Florida, including the unlicensed practice of a health care professional.

Lastly, this bill provides an exemption from licensure for consultative services to ensure that Floridians and Florida's health care practitioners have access to the best health care experts around the country and throughout the world. This provision allows episodic consultations with out-of-state practitioners so long as a Florida licensee is involved and remains primarily responsible for the diagnosis, treatment, and care of the Florida patient.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Creates s. 455.5641, F.S., to provide legislative findings and intent necessitating licensure of health care practitioners. Establishes a Florida telehealth license with requirements equal to the requirements for full licensure. Requires license number and disclaimer on advertisements of telehealth services. Clarifies applicability of criminal laws and administrative laws to telehealth providers. Provides exemption for episodic consultative services. Excludes from telehealth licensure nonresident pharmacies that are registered pursuant to s. 465.0156, F.S. Provides rulemaking authority to the applicable board or department when there is no board.

Section 2. Creates s. 766.102(7), F.S., to clarify that an action for recovery of damages in a medical negligence case may be brought in Florida regardless of the location of the provider alleged to have caused the injury through telehealth if the patient is located in this state at the time of injury.

Section 3. Provides an effective date of July 1, 2000.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

See fiscal comments section.

2. Expenditures:

See fiscal comments section.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

See fiscal comments section.

D. FISCAL COMMENTS:

The Department of Health expects the fiscal impact of this bill to be minimal and believes that the workload can be absorbed within existing resources. There is no immediate incentive for out-of-state practitioners to apply for a Florida telehealth license since the requirements are almost identical to full licensure. Any workload growth resulting from this bill can be considered in future legislative budget requests.

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

The bill does not require counties or municipalities to expend funds or to take any action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This bill does not reduce the authority that municipalities or counties have to raise revenues in the aggregate.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of state tax shared with counties or municipalities.

V. COMMENTS:

A. CONSTITUTIONAL ISSUES:

The Internet is currently believed to connect more than 159 countries and over 109 million users.¹ Through a connection to the Internet, individuals can have “live” interaction although they may be thousands of miles apart.² There have been previous attempts by federal and state governments to direct legislation at the Internet. Some of these attempts have failed on constitutional grounds relating to the First Amendment and the right to free speech as well as the commerce clause preemption of state regulation of issues affecting interstate commerce.³

The 1999 legislation that created the Task Force on Telehealth directed the Task Force to study the potential preemption of state regulation by the Commerce Clause of the United States Constitution. The Task Force concluded in its study that there is no present federal law regulating telehealth which would preempt state regulation, but that, because telehealth involved the use of federally regulated interstate telephone lines, any state imposed restrictions on telehealth must have a clear and rational basis in order to withstand possible constitutional challenge.

The Task Force recommended that Florida reestablish its “local concern” in protecting the health, safety, and welfare of its citizens and visitors in order to establish a compelling state interest in regulating health care provided by persons in any jurisdiction to persons located in Florida. This bill attempts to establish, in statute, a local concern and compelling state interest by providing findings, intent, and purpose, and by clearly stating that no other less restrictive means is available to protect Floridians.

The laws regarding telehealth that have been held unconstitutional by the courts are distinguishable from this bill. This bill restricts the delivery of health care services when provided via telecommunications, including over the Internet, to those persons who meet minimum competency standards as determined through the licensure process. This bill is no different than the existing laws that limit the provision of health care services via traditional face-to-face encounters and written documentation to only those persons who meet minimum competency standards as determined through the licensure process.

First Amendment protection extends to “expressive conduct” as well as “pure speech.”⁴ Laws that may silence speakers whose message would be entitled to constitutional protection are deemed to have a “chilling effect” and hold disfavor with the courts.⁵ If this bill restricts expressive conduct protected by the First Amendment, it may be viewed by the courts as a content-based limitation. Content-based restrictions of speech are disfavored

¹See ACLU v. Johnson, 194 F.3d 1149, 1153 (10th Cir. 1999).

²Reno v. ACLU, 521 U.S. 844, 851 (1997).

³See, e.g., Reno, Johnson.

⁴Tinker v. Des Moines School District, 393 U.S. 503 (1969); Stromberg v. California, 283 U.S. 359 (1931).

⁵ See Reno v. ACLU, 521 U.S. at 874.

by the courts and justify a burden on protected speech only if they serve a compelling state interest and are narrowly drawn to further that interest.⁶

Opponents could argue that this bill infringes on an individual's expressive conduct. However, this bill does not limit all speech, it only limits who can provide medical diagnosis and treatment recommendations through advanced electronic communication means. This follows existing laws that limit medical diagnosis and treatment recommendations when provided through traditional communication means such as face-to-face meeting or through written letters sent via the postal system. This bill also makes conduct that is currently illegal if it occurs "in person" a crime if the same conduct occurs "live" over the Internet or on the telephone. Furthermore, this bill will provide civil remedies for medical negligence that occurs through advanced technology in the same manner that remedies are currently provided for face-to-face negligence.

The existing laws have not been challenged as unconstitutional based on the first amendment, therefore this bill should not be held unconstitutional based on first amendment grounds. Furthermore, the language of this bill sets forth the compelling state interest in protecting the health, safety, and welfare of Floridians and Florida visitors. Moreover, this bill is drafted narrowly and states that there is a local interest in protecting Floridians from harm.

This bill does require that all advertisements for telehealth services contain the practitioner's license number and a disclaimer that Florida law requires health care practitioners to be licensed in Florida if providing health care services to Floridians. The advertisement must also include information which informs the reader how and where to file a complaint. This disclaimer is intended for educational purposes as well as informing patients how to file a complaint against the license of the practitioner in order to hold him or her accountable for their actions. There are other similar laws in Florida requiring license numbers and disclaimers to be placed in advertisements for health care practitioners. As long as the law requires a disclaimer to be added rather than prohibiting the content of the advertisement, the laws have been upheld.

The state has never been successfully challenged regarding its ability to regulate the conduct of those persons providing, attempting to provide or offering to provide health care services to Floridians without a license. The bill does not make criminal "on-line" activity that is otherwise protected and legal if performed "off-line." Arguably, the bill protects the Internet and other telecommunication services against providing a venue for otherwise illegal activity.

This bill also addresses the issue of jurisdiction, venue, and sufficient contacts. It overcomes constitutional arguments with regard to long-arm jurisdiction by establishing a licensure requirement. The license gives Florida jurisdiction over the health care practitioner who is doing business in Florida via advanced technology in the same manner as it provides jurisdiction over persons providing health care services using traditional methods of communication.

⁶See Reno, 521 U.S. at 874.

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B. RULE-MAKING AUTHORITY:

This bill provides rulemaking authority to the regulatory boards and the Department of Health when there is no board to promulgate rules necessary to implement this bill.

C. OTHER COMMENTS:

None.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

On March 23, 2000, the Committee on Health Care Licensing and Regulation adopted one amendment to clarify that consultative services may be provided so long as they are "episodic" instead of continuous. This amendment closes a perceived loophole in the original language. The bill was reported favorably as a committee substitute.

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE LICENSING & REGULATION:

Prepared by:

Staff Director:

Wendy Smith Hansen

Lucretia Shaw Collins

AS REVISED BY THE COMMITTEE ON GOVERNMENTAL OPERATIONS:

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