

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

BILL: SB 1324

SPONSOR: Senator Peaden and others

SUBJECT: Health Care

DATE: April 2, 2001

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Thomas	Wilson	HC	Favorable
2.	_____	_____	AHS	_____
3.	_____	_____	AP	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

Senate Bill 1324 authorizes licensed health care practitioners to provide complementary or alternative health care treatment as an option to conventional treatment. The bill provides that health care practitioners utilizing complementary or alternative treatment methods are subject to the same requirements, provisions and liabilities associated with conventional treatment methods. The bill explicitly requires documentation of informed consent communication with the patient. In addition, the bill specifies that it does not modify or change the scope of practice of any Florida health care practitioner or the provisions of the individual practice acts. Finally, the bill revises the Florida Patient's Bill of Rights and Responsibilities to include the right to access complementary or alternative health care treatments.

This bill amends section 381.026, Florida Statutes, and creates section 456.41, Florida Statutes.

II. Present Situation:

The Practice of Medicine

Chapter 458, F.S., governs the regulation of the practice of medicine by the Board of Medicine. Section 458.305, F.S., defines the "practice of medicine" to mean the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition. The Board of Medicine within the Department of Health (DOH) regulates the practice of medical physicians.

Section 458.331, F.S., specifies grounds for which a medical physician may be subject to discipline by the Board of Medicine. A medical physician is subject to discipline for any act in violation of applicable standards of practice, which include gross or repeated malpractice or the

failure to practice medicine with that level of care, skill, and treatment that is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances.¹ A medical physician is also subject to discipline for performing any procedure or prescribing any therapy which, by the prevailing standards of medical practice in the community, would constitute experimentation on a human subject, without first obtaining full, informed, and written consent.²

Chapter 459, F.S., the osteopathic medical practice act, similarly provides for the regulation of osteopathic physicians by the Board of Osteopathic Medicine in DOH. Section 459.003, F.S., defines the “practice of osteopathic medicine” to mean the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition, which practice is based in part upon educational standards and requirements which emphasize the importance of the musculoskeletal structure and manipulative therapy in the maintenance and restoration of health. Chapter 459, F.S., contains provisions relating to the definition of practice and discipline of licensed osteopathic physicians, which are comparable to those in the medical practice act.³

Medical Consent Law

Section 766.103, F.S., the Florida Medical Consent Law, provides immunity from civil damages for physicians treating, examining, or operating on patients without the patient’s informed consent under non-emergency circumstances, subject to two conditions. The first condition is that the physician attempt to obtain consent from the patient or from a person authorized to give consent on behalf of the patient by applying accepted standards of medical practice that would be sufficient to give a reasonable person a general understanding of the procedure, acceptable alternative treatments, and the commonly recognized substantial risks and hazards. The second condition is that the patient could reasonably be anticipated, under all the surrounding circumstances, to have consented to the treatment had he been advised by the physician as required under the first condition.

Alternative and Complementary Treatment Methods

Chapter 456, F.S., establishes general provisions relating to licensure and regulation of all health care practitioners, but does not specifically speak to complementary or alternative modes of treatment. Likewise, the individual practice acts do not specifically address such treatment options. Some treatment methodologies that have historically been considered by traditional health care practitioners as complementary or alternative treatment are specifically authorized, such as, the practice of acupuncture⁴ and the practice of naturopathy.⁵

¹ Section 458.331(1)(t), F.S.

² Section 458.331(1)(u), F.S.

³ See s. 459.015 (1)(x), F.S. An osteopathic physician is subject to discipline for any act in violation of applicable standards of practice, which include gross or repeated malpractice or the failure to practice medicine with that level of care, skill, and treatment that is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances. Under s. 459.015(1)(y), F.S., an osteopathic physician is also subject to discipline for performing any procedure or prescribing any therapy which, by the prevailing standards of medical practice in the community, would constitute experimentation on a human subject, without first obtaining full, informed, and written consent.

⁴ Chapter 457, F.S.

⁵ Chapter 462, F. S.

The State of Florida began licensing naturopaths in the 1920's, but ended the process in 1959. A grandfather clause, enacted in 1985, gave all individuals licensed prior to 1959 an active license. Currently, only seven individuals are practicing naturopathy with a pre-1959 license.

Florida currently defines “naturopathy” and “natureopathy” in chapter 462, F.S. (the definition written in 1927), as:

the use of and practice of psychological, mechanical, and material health sciences to aid in purifying, cleansing, and normalizing human tissues for the preservation or restoration of health, according to the fundamental principles of anatomy, physiology, and applied psychology, as may be required. Naturopathic practice employs, among other agencies, phytotherapy, dietetics, psychotherapy, suggestotherapy, hydrotherapy, zone therapy, biochemistry, external applications, electrotherapy, mechanotherapy, mechanical and electrical appliances, hygiene, first aid, sanitation, and heliotherapy; provided, however, that nothing in this chapter shall be held or construed to authorize any naturopathic physician licensed hereunder to practice materia medica or surgery or chiropractic medicine, nor shall the provisions of this law in any manner apply to or affect the practice of osteopathic medicine, chiropractic medicine, Christian Science, or any other treatment authorized and provided for by law for the cure or prevention of disease and ailments.

Numerous other statutes address other practice acts, to include licensing and regulation provisions for individual health care professions such as:

- chapter 457, F.S., The Practice of Acupuncture
- chapter 458, F.S., The Medical Practice Act
- chapter 459, F.S., The Osteopathic Medicine Practice Act
- chapter 460, F.S., The Chiropractic Medicine Practice Act
- chapter 461, F.S., The Podiatric Medicine Practice Act
- chapter 462, F.S., The Practice of Naturopathy
- chapter 463, F.S., The Optometry Practice Act
- chapter 464, F.S., The Nurse Practice Act and Certified Nursing Assistants
- chapter 465, F.S., The Pharmacy Act
- chapter 466, F.S., The Practice of Dentistry and Dental Hygiene
- chapter 467, F.S., The Midwifery Practice Act
- part I of chapter 468, F.S., The Practice of Speech-Language Pathology and Audiology
- part II of chapter 468, F.S., Nursing Home Administration
- part III of chapter 468, F.S., The Occupational Therapy Practice Act
- part V of chapter 468, F.S., The Respiratory Care Act
- part X of chapter 468, F.S., The Dietetics and Nutrition Practice Act
- part XIII of chapter 468, F.S., Athletic Trainers
- part XIV of chapter 468, F.S., The Practice of Orthotics, Prosthetics and Pedorthics
- chapter 478, F.S., The Electrolysis Practice Act
- chapter 480, F.S., The Massage Practice Act
- part III of chapter 483, F.S., The Practice of Clinical Laboratory Personnel
- part IV of chapter 483, F.S., The Practice of Medical Physicists

- chapter 484, F.S., Dispensing of Optical Devices and Hearing Aids
- chapter 486, F.S., The Physical Therapy Practice Act
- chapter 490, F.S., The Psychological Services Act
- chapter 491, F.S., Clinical, Counseling, and Psychotherapy Services (Clinical Social Workers, Marriage and Family Therapists, and Mental Health Counselors)

The Federation of State Medical Boards is an association of 67 state medical and osteopathic boards throughout the United States, including the Florida Board of Medicine and Florida Board of Osteopathic Medicine. The federation adopted a policy position in 1997 that includes a recommendation that state medical boards review their medical practice acts and pursue legislative support for revisions to strengthen the medical board's ability to regulate physicians engaging in questionable health care practices. This recommendation reflects the concern that there may be substantial direct and indirect harm to patients resulting from unconventional treatments if appropriate safeguards are not provided. Direct harm may result in adverse patient outcomes, while indirect harm may result in delay of appropriate diagnoses and treatment. The federation takes the position that in order to fulfill the responsibility to protect the public from incompetent, unprofessional, improper, unlawful, fraudulent, or deceptive medical practice, it is necessary for state medical boards to have adequate legislative authority to regulate all practices, whether conventional or complementary or alternative, constituting the practice of medicine.

The Florida Board of Medicine has examined issues associated with the practice of complementary or alternative medicine and has affirmed that patients have a right to access alternative modes of treatment. The board affirmed that licensed practitioners must be held accountable to the same standards of care and other medical practice standards as provided in the Medical Practice Act, including critical requirements relating to licensure criteria, informed consent, advertising and promotional claims, and adequate patient assessment and follow-up. The board has determined that Florida's Medical Practice Act contains authority sufficient for the board to be able to hold licensees accountable for safe and appropriate provision of complementary or alternative treatments and procedures.

Section 456.072, F.S., provides grounds for disciplinary actions against licensed health care practitioners, including, but not limited to the following actions:

- making misleading, deceptive, or fraudulent representations related to the practice of the licensee's profession;
- practicing beyond the scope permitted by law or performing responsibilities the licensee knows he or she is not competent to perform;
- failing to perform any statutory or legal obligation placed upon the licensee;
- exercising influence on a patient for the purpose of financial gain; and
- failing to provide patients with information about their patient rights as required in s. 381.026, F.S.

Individual practice acts also contain specific grounds for discipline, as found in s. 458.331, F.S., The Medical Practice Act:

- false, deceptive or misleading advertising;

- failing to keep medical records that justify the course of treatment;
- failure to practice with that level of care, skill, and treatment, which is recognized by a reasonably prudent similar physician as being acceptable;
- performing services which have not been duly authorized by the patient (informed consent); and
- performing any procedure that would constitute experimentation without first obtaining full, informed, and written consent.

Historically, records of disciplinary actions taken against licensed health care practitioners reflect violations of scope of practice and unsafe practice. The current disciplinary data system of DOH does not yield an aggregate analysis of discipline for acts related to the provision of complementary or alternative health care treatments. However, according to DOH, the system may easily be modified to begin tracking pertinent complaints. Anecdotal accounts of individual disciplinary action related to complementary or alternative treatments are reported, but these instances do not reflect widespread reporting of unsafe practice of complementary or alternative treatments. The absence of consumer or patient complaints, however, does not necessarily reflect the absence of patient risk of harm from complementary or alternative treatments from practitioners who do not comply with standards of care for patient assessment, informed consent, and general standards of care.

Patient's Bill of Rights

Section 381.026, F.S., establishes the Florida Patient's Bill of Rights and Responsibilities. The section specifies rights of patients relating to individual dignity, provision of information, financial information and disclosure, access to health care, and experimental research. Under the section, patients have the right to impartial access to medical treatment or accommodations, regardless of race, national origin, religion, physical handicap, or source of payment. Any licensed medical physician, osteopathic physician, or podiatric physician who treats a patient in an office or any hospital or ambulatory surgical center must adopt and make available to the patient, in writing, a statement of the rights and responsibilities of patients.

The bill of rights requires health care providers and health care facilities to provide patients with information, if requested, about state agencies responsible for responding to patient complaints about alleged provider or facility noncompliance with licensure requirements. Health care providers and health care facilities must adopt policies and procedures that ensure inpatients are provided the opportunity, during their hospital stay, to be informed of their rights and how to file a complaint with the facility and the appropriate state regulatory agency. The Agency for Health Care Administration (AHCA) may levy an administrative fine against a health care facility of up to \$5,000 for nonwillful violations of the requirement to make available to patients a summary of their rights, and an administrative fine of up to \$25,000 for intentional and willful violations. The appropriate regulatory board, or DOH if there is no board, may levy an administrative fine against a health care provider of up to \$100 for nonwillful violations of the requirement to make available to patients a summary of their rights, and an administrative fine of up to \$500 for willful violations. In determining the amount of the fine to be levied, AHCA, DOH, or an appropriate regulatory board must consider certain factors, which include the scope and severity of the violation, corrective actions taken, and any previous violation of the requirements of s. 381.0261, F.S.

III. Effect of Proposed Changes:

Section 1. Creates s. 456.41, F.S., to provide for legislative intent that citizens be able to make informed choices for any type of health care they choose, to include complementary or substitute treatment methods. The Legislature intends that health care practitioners be able to offer alternative health care treatments with the same requirements, provisions and liabilities as those associated with prevailing or conventional treatments.

“Complementary or alternative health care treatment” is defined as any treatment designed to provide an effective option to prevailing or conventional methods, and may be provided in addition to or in place of other treatments. “Health care practitioner” is defined as a practitioner defined in s. 456.001(4), F.S.

The bill provides that a health care practitioner who offers a patient complementary or alternative health care treatments must inform the patient of the benefits and risks associated with such treatment in order for the patient to make an informed and prudent decision. The practitioner must inform the patient of the practitioner’s education, experience and credentials in relation to the complementary or alternative treatment. This communication may be oral or written and provided to the patient or the patient’s representative, and must be in the best interests of the patient and in accordance with the practitioner’s license. The health care practitioner must maintain a record of the informed consent to the complementary or alternative treatment.

The section specifically does not modify or change the scope of practice of any licensee, the associated practice acts, or current standards of care.

Section 2. Amends s. 381.026, F.S., the Patient’s Bill of Rights and Responsibilities, to establish the right of a patient to access any mode of treatment that is, in the judgment of the patient and his or her practitioner, in the best interests of the patient, including complementary or alternative health care treatments in accordance with s. 456.41, F.S.

Section 3. Provides that the bill, if enacted, shall take effect upon becoming law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Art. VII, s. 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Art. III, s. 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

The bill may have an indirect impact on health care costs, depending on whether the bill has the effect of encouraging growth in the provision of complementary or alternative treatments. The costs of such treatments are indeterminate and could have either a positive or a negative economic impact on individual consumers.

C. Government Sector Impact:

According to the Department of Health, complaints regarding complementary or alternative health care treatments provided by licensees regulated by the department are not expected to significantly increase current workload sufficiently to necessitate additional resources.

Complaints regarding complementary or alternative health care treatments provided by licensees regulated by the department are not expected to significantly increase the Agency for Health Care Administration's complaint investigation and prosecution workload to the point of requiring additional resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.