HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 699 CS Health Care
SPONSOR(S): Negron
TIED BILLS: **IDEN./SIM. BILLS:** SB 1216

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee	7 Y, 4 N, w/CS	Bell	Mitchell
2) Health Care General Committee			
3) Health & Families Council			
4)			
5)			

SUMMARY ANALYSIS

HB 699 w/ CS amends ss. 458.331 & 459.015, F.S., to give the Allopathic (MD) and Osteopathic (DO) Medical Boards more oversight of standards involving the supervision of licensed health care practitioners.

The bill allows the Medical Boards to craft rules related to standards of practice and standards of care for supervision of physician assistants, paramedics, emergency medical technicians, advanced registered nurse practitioners, anesthesiologist assistants, and persons performing electrolysis or laser electrology who are not under direct on-sight supervision of the supervising physician. The Medical Boards may vary the rules based on specialty of the physician, type of licensed health care practitioner under supervision, and the practice setting.

The rules may include:

- The percentage of time the supervising physician spends directly supervising the licensed health care practitioners;
- Standards for adequate supervision, including the standards for review of medical records and the allowable distance of the licensed health care practitioners from the supervising physician; and
- The number of each type of licensed health care practitioner which a supervising physician may supervise.

Currently, general guidelines determining supervision of the professions above are provided for by statute and administrative code.

The bill provides that the rules developed by the Medical Boards will take precedent over all other statutorily defined health care practitioner supervision provisions in chapters 458 and 459, F.S.

The bill includes a list of facilities in which the rules, promulgated by the Board of Medicine, would not apply.

The full impacts of the bill, fiscal and otherwise, are difficult to determine because the bill allows the Board of Medicine to promulgate rules. Without knowing the specific rules to be promulgated, it is impossible to determine the impact.

Concerns have been raised that rulemaking authority provided in the bill may not meet the standards of ch. 120, F.S., the Administrative Procedures Act. Section 120.536, F.S., requires that an agency may only adopt rules that implement or interpret the specific powers and duties granted by the enabling statute. Agencies do not have the power to adopt a rule only because it is reasonably related to the purpose of the enabling legislation. The bill grants rulemaking authority to the Board of Medicine but specifies that the rules “may include,” the standards in the bill.

The effective date of the bill is upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – The bill expands regulatory control by the Board of Medicine. It provides that the Board of Medicine may establish by rule standards of practice and standards of care, including delegation to other personnel, for particular practice settings. The rules may include: time of direct supervision, standards for adequate supervision, distance limitations, and the number of practitioners that physicians can supervise.

B. EFFECT OF PROPOSED CHANGES:

HB 699 w/ CS amends ss. 458.331 & 459.015, F.S., to give the Allopathic (MD) and Osteopathic (DO) Medical Boards more oversight of standards involving the supervision of licensed health care practitioners.

The bill allows the Medical Boards to craft rules related to standards of practice and standards of care for supervision of several other professions when they are not under direct on-sight supervision of the supervising physician. The professions that will be affected by the bill are: physician assistants, paramedics, emergency medical technicians, advanced registered nurse practitioners, anesthesiologist assistants, and persons performing electrolysis or electrology using laser or light-based hair removal. The Medical Boards may vary the rules based on specialty of the physician, type of licensed health care practitioner under supervision, and the practice setting.

The rules may include:

- The percentage of time the supervising physician spends directly supervising the licensed health care practitioners;
- Standards for adequate supervision, including the standards for review of medical records and the allowable distance of the licensed health care practitioners from the supervising physician; and
- The number of each type of licensed health care practitioner which a supervising physician may supervise.

The bill specifies that any rule promulgated must apply equally to physician assistants (PAs) and advanced registered nurse practitioners (ARNPs).

The bill provides that the rules developed by the Medical Boards will take precedent over all other statutory defined health care practitioner supervision provisions in chapters 458 and 459, F.S.

The full impact of the bill is indeterminate because the bill gives the Board of Medicine the authority to promulgate more rules in a wide variety of situations. Without knowing the exact rules to be promulgated, it is impossible to guess what potential impacts the rules will have on the health professions referenced in the bill.

The bill lists a number of exemptions to rules promulgated by the Boards of Medicine. The following facilities and health care practitioners are exempt:

- Health care practitioners working in a facility licensed under ch. 395, F.S., which include hospitals, ambulatory surgical centers, and mobile surgical facilities;
- Health care practitioners providing services in conjunction with a college of medicine;
- Health care practitioners providing services in a nursing home licensed under part II of ch. 400, F.S.;
- Assisted living facility licensed under part III of ch. 400, F.S.;

- Retirement community consisting of independent living units and either a licensed nursing home or assisted living facility; and
- Rural health network under s. 381.0406, F.S.

The effective date of the bill is upon becoming law.

PRESENT SITUATION

Overview - the Use of Physician Extenders

ARNPs and physician assistants (PAs) are commonly referred to as "physician extenders" because they extend the ability of a physician to treat, indirectly, more patients. Physician extenders such as nurse practitioners and nurse anesthetists have become prominent health providers. Although they generally work alongside doctors, these physician extenders administer frontline medical care to patients with increasing needs for preventative care or monitoring for people with disabilities, or diseases such as diabetes or congestive heart failure. Physician extenders are more willing to go to rural or inner-city areas, to work beyond traditional office hours[1], and are able to spend additional time with patients on visits.[2] ARNPs and PAs have also taken on increased responsibility in caring for seniors, especially those in nursing homes, due to a severe and growing shortage of geriatricians in the United States.[3] Rising costs of healthcare have further increased the demand for nonphysician providers, who are able to care for patients at the same or lower cost than physicians and whose services are often covered on state and private health plans.[4] Research has shown that many nonphysician providers perform at least as safely as physicians do in these expanded roles[5]; however concerns remain that nonphysicians remain carefully supervised and trained in their scope of practice.[6]

History - Ortiz v. Department of Health, Board of Medicine, 2004[7]

Recently, there has been a court challenge that relates the issue of to the Board of Medicine promulgating rules regarding physician extenders. Specifically, the Board of Medicine promulgated administrative Rule 64B8-9.009(6)(b)1.a., F.A.C., to require a surgeon in an out-patient facility to have a licensed MD or DO anesthesiologist present to supervise the administration of anesthesia by Certified Registered Nurse Anesthetists (CRNAs). Many CRNAs objected to this rule because they felt it was not fiscally prudent for a surgeon's office to employ a physician anesthesiologist to supervise and a CRNA to perform the procedure. The Board of Medicine rule prompted a court challenge in Ortiz v. Department of Health, Board of Medicine, 2004.[8]

The court found that the Board of Medicine's rule requiring a surgeon in an out-patient facility to have a licensed anesthesiologist present to supervise the administration of anesthesia for Level III surgery was an invalid exercise of delegated authority.

As part of the ruling, the court specifically cited s. 458.303, F.S., as limiting the reach of s. 458.331, F.S. Pursuant to s. 458.303(2), F.S., the grant of rulemaking under s. 458.309, F.S., and s. 458.331, F.S., cannot be, "construed to prohibit any service rendered by a registered nurse or a licensed practical nurse, if such service is rendered under the direct supervision and control of a licensed nurse,

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[1] Gearon, C.J. "Medicine's Turf Wars." *US News & World Report.* January 31, 2005. Available online at www.usnews.com/usnews.issue/050131/health/31turf.htm.
[2] "Extend your practice—not your liability." *Medical Economics*. February 18, 2005.
[3] Oliff, L. "Beyond Asking Your Doctor." *Pharmaceutical Executive* 24 no2 102, 104 F 2004.
[4] Hooker, S.H., and McCaig, L.F. "Use of physician assistants and nurse practitioners in primary care, 1995-1999." *Health Affairs*. July/August 2001.
[5] According to Linda Aiken, director of the University of Pennsylvania's Center for Health Outcomes and Policy Research, over 100 studies have examined the care delivered by nurse practitioners and none demonstrated a negative impact of their care on health. Quoted in "Medicine's Turf Wars." *US News & World Report.* January 31, 2005. Available online at www.usnews.com/usnews.issue/050131/health/31turf.htm.
[6] Robert Wise, vice president for standards and survey methods at the Joint Commission on Accreditation of Healthcare Organizations, quoted in Gearon, C.J. "Medicine's Turf Wars." *US News & World Report.* January 31, 2005. Available online at www.usnews.com/usnews.issue/050131/health/31turf.htm.
[7] See *Ortiz*.
[8] See *Ortiz*.

if such service is rendered under the direct supervision and control of a licensed physician who provides specific direction for any service to be performed and gives final approval to all services performed."

Thus, the court found that under ss. 458.331 and 458.303(2), F.S., as long as a licensed physician has direct supervision and control over the registered nurse, the fact that services are provided by that nurse cannot be a ground for discipline of the physician, and no rules can prohibit such services by a registered nurse.

The Board claimed that its rule did not control the actions of CRNAs, but the court found that the rule indirectly limited the practice of CRNAs. Instead of simply prohibiting CRNAs from administering anesthesia under supervision of the surgeon, the Board provided grounds for disciplining the surgeon if he or she supervises the CRNA. Either way, currently, s. 458.303(2), F.S., prevents the use of rulemaking authority for this purpose.

The Ortiz decision noted that both parties agreed that patient safety was not an issue in the proceedings.

SUPERVISION STANDARDS

The health care professionals referenced in the bill are all regulated differently by statute and rule and have varied supervisory relationships with physicians.

Supervision Standards for Advanced Registered Nurse Practitioners

Nurses are regulated in their own practice act. Nurses are licensed and regulated by the Board of Nursing pursuant to part I of chapter 464, F.S. There are approximately 9,500 Advanced Registered Nurse Practitioners (ARNPs) in Florida.

ARNPs practice under a protocol with a supervising physician and are not required to be under direct supervision. There is no limit on the number of ARNPs that a physician may supervise at any one time. ARNPs may practice in locations without the supervising physician on premises.[9] A 2005 Florida Board of Nursing study determined that 90% of nursing protocols have one physician supervising one or two ARNPS. The study also concluded that less that 2% of nurse protocols have one physician supervising four or more ARNPs. Almost all, 99%, of the ARNPs and supervising physicians are located within the same metropolitan area (roughly a 50-mile radius of an urban center).[10]

ARNPs perform medical acts of diagnosis, treatment, and operation pursuant to a protocol between the ARNP and a Florida-licensed medical doctor, osteopathic physician, or dentist. The degree and method of supervision is determined by the ARNP and the supervisor, must be appropriate for prudent health care providers under similar circumstances, and must be specifically identified in a written protocol. Unless these rules set a different level of supervision for a particular act, general supervision is required.[11] The number of ARNPs to be supervised must be limited to insure that an acceptable standard of medical care is rendered in consideration of: risk to patient, educational preparation, specialty, and experience of parties to the protocol, complexity and risk of the procedures, practice setting, and availability of the supervisor.

Supervision Standards for Anesthesiologist Assistants (a form of specialty nursing)

Anesthesiologist Assistants or Certified Registered Nurse Anesthesiologists (CRNAs) are a specialized form of Advanced Registered Nurse Practitioner that requires a masters degree. CRNAs are licensed under part I of the Nurse Practice Act, chapter 464, F.S. Every CRNA must enter into a supervisory relationship with a physician or dentist; and must file a written protocol describing the relationship based on criteria set forth in chapters 458, 459, and 466, F.S. The supervising physician must only delegate tasks and procedures to the CRNA which are within the supervising physician's scope of

[9] Rule 64B8-35, Florida Administrative Code.
[10] Florida Board of Nursing, Study of ARNP Protocols, November 1, 2005.
[11] The written protocol signed by all parties represents the mutual agreement of the supervising physician and the ARNP and must include information defined by Rule 64B9-4, Florida Administrative Code, and s. 458.348(2), F.S.

practice, and the CRNAs can work in any setting that is within the scope of practice of the supervisor's practice. CRNAS personally administer 65% of all anesthetics given to patients each year in the United States.[12]

Under facility licensure requirements of s. 395.0191, F.S., CRNAs working in ambulatory surgery centers or hospitals must be supervised by a physician or a dentist.

Supervision Standards for Paramedics & Emergency Medical Technicians

Paramedics and emergency medical technicians are regulated under ch. 401, F.S., Medical Transportation and Services. They are also referenced in s. 458.348, F.S. There are approximately 18,000 paramedics and 28,000 emergency medical technicians (EMTs) in Florida. Each paramedic and EMT employed within an Emergency Medical Services (EMS) system must operate under the direct supervision of a physician medical director, or indirectly by standing orders and/or protocols.[13] Each EMS agency employs or contracts with a physician medical director to provide this medical oversight and quality assurance. The larger EMS providers in Florida have over 1,000 EMTs and paramedics on staff, all of them working under one medical director.

Medical directors must supervise and assume direct responsibility for the medical performance of the EMTs and paramedics, and must perform duties including advising, consulting, training, counseling, and overseeing of services. This includes appropriate quality assurance but does not include administrative or managerial functions. Each medical director is required to establish a quality assurance committee to provide reviews of all EMTs and paramedics operating under the director's supervision.[14]

The Emergency Medical Services Advisory Council was created for the purpose of acting as the advisory body to the EMS program. The Council's role includes:

- Identify and make recommendations to the Department of Health (DOH) concerning the appropriateness of suggested changes to statute and administrative rules; and
- To provide technical support to DOH in the areas of EMS and trauma systems design, technology, drugs and dosages, medical protocols, training requirements, and other aspects of procedure.[15]

The Division of Emergency Medical Operations has noted that limiting the number of allied health practitioners that can practice under the authority of a single physician could potentially significantly impact the daily operations of an EMS service. According to the Division, while the implementation of the bill alone would not directly impact the EMS community, the rule language required by the bill may have a tremendous impact on the way EMS is designed and operated statewide.

Supervision Standards for Physician Assistants

Physician assistants (PAs) are regulated under ss. 458.347 & 459.022, F.S. There are approximately 3,000 licensed PAs in Florida. PAs may practice under the direct or indirect supervision of an MD or DO. A physician may supervise up to four PAs at any one time and the supervising physician must be

[12] American Association of Nurse Anesthetists, 2006.
[13] Chapter 64E-2, Florida Administrative Code.
[14] Section 401.265, F.S
[15] Section 401.245, F.S. The council has up to 15 members, and representatives include physicians, EMS administrators, paramedics, EMTs, emergency nurse, hospital administrators, air ambulance service representatives, educators, and laypersons who are in no way connected with emergency medical services and one of whom is a representative of the elderly. Ex officio members of the advisory council from state agencies include, but are not limited to, representatives from the Department of Education, the Department of Management Services, the State Fire Marshal, the Department of Highway Safety and Motor Vehicles, the Department of Transportation, and the Department of Community Affairs.

qualified in the medical treatment areas delegated to a PA.[16] The "primary supervising physician" assumes responsibility and legal liability for the services rendered by the PAs at all times. "Direct supervision" entails the physical presence of the supervising physician on the premises so that he or she is immediately available to the PA when needed. "Indirect supervision" requires reasonable proximity between the supervising physician and the PA and requires the ability to communicate by telecommunications.[17]

There is a Council on Physician Assistants that reports to the Board of Medicine. The Council's duties include:

- Recommendation of the licensure of PAs to the Department of Health (DOH); and
- Development of rules regulating the use of PAs by physicians (proposed rules submitted by the council must be approved by both medical and osteopathic boards).

The council is comprised of five members including three physicians appointed by the chairperson of the Board of Medicine, one physician appointed by the chairperson of the Board of Osteopathic Medicine, and a PA appointed by the secretary of the department or his or her designee. At least two of the members appointed to the council must be physicians who supervise PAs in their practice.[18]

Disciplinary Procedures

Disciplinary procedures for health professions vary in practice and procedures. Nurses (ARNPs and CRNAs) are disciplined directly under Chapter 464, F.S., the Nurse Practice Act, whereas, emergency personnel and PAs are disciplined by a mixed member council. The commonality is that all of the health professions have at least one peer that is included in disciplinary and regulatory proceedings.

Disciplinary Actions for Nursing

Currently RNs and LPNs may be directly disciplined under s. 464.018, F.S. One of the disciplinary criteria is, "failing to meet minimal standards of acceptable and prevailing nursing practice, including engaging in acts for which the licensee is not qualified by training or experience." Nurses can also be disciplined for violating any of the Nurse Practice Act (chapter 464), the Health Professions and Occupations: General Provisions (chapter 456, F.S.), or rules adopted by the Board of Nursing.

Disciplinary Actions for Doctors

Section 458.331(1)(v), F.S., provides ground for discipline of MDs who practice beyond the scope permitted by law or perform any procedure that he or she is not competent to perform. This section also provides that the Board of Medicine may establish rules for standards of practice and standards of care for particular practice settings including delegating to other professions.

Joint Committee of the Boards of Nursing and Medicine

In s. 464.003, F.S, the Legislature created a joint committee of the Boards of Nursing and Medicine to develop rules concerning protocols and supervision of ARNPs and other advanced specialty nurses. According to the Department of Health, HB 699 makes possible rulemaking by the Board of Medicine which may restrict the practice of nursing through threatened discipline of physicians who supervise nurses. DOH asserts that this rulemaking authority may some rulemaking authority rom the Joint Committee of the Board of Nursing and Medicine.

BACKGROUND

Scope of Practice Authority

Each year, the Florida Legislature hears bills and amendments to change the scope of practice and standards of existing professions. The legal authority to provide and be reimbursed for health care

[16] Sections 458.347 and 459.022, F.S.
[17] Rules for Medical Practice, Chapter 64B8-30, Florida Administrative Code; Rules for Osteopathic Medicine, Chapter 64B15-6, Florida Administrative Code.
[18] Sections 458.347 and 459.022, F.S.

services is tied to state statutes generally referred to as practice acts, which establish professional "scopes of practice." These practice acts often differ from state to state and are a source of "turf battles" which clog the legislative agendas. Legislators must decide whether new or unregulated disciplines and occupations should be regulated and whether professions should be granted expanded practice authority. Many of the proposed changes brought to the Legislature come from professions that want to gain direct, third-party reimbursement for their services. Such changes often generate heated "turf" battles among professions and other health care interests and have potential effects on patient safety and the cost of health care.

According to the Department of Health, some physicians have raised concerns that physician extenders may economically impact sole practitioners or small practices who may not be able to compete with a practitioner who has several physician extenders located throughout a city or county.

Specialized Nursing Practice

Specialization in nursing dates from the early part of the twentieth century. Many specialty nursing programs require a master's degree and require additional state certification and licensure. Some of the primary nurse specialties are[19]:

- Critical Care;
- Nurse Anesthetists;
- Nurse Midwives;
- Public Health Nursing; and
- Nursing Education.

There have been some concerns raised that HB 699 may limit the practice of specialty nursing if a nurse is working under a physician that does not share their specialty.

C. SECTION DIRECTORY:

Section 1. – Amends s. 458.331, F.S., to direct the Board of Medicine to promulgate rules regarding the standards of practice and standards of care for physicians who supervise licensed health care practitioners who are not under direct, onsite supervision and provides exemptions.

Section 2. - Amends s. 459.051, F.S., to direct the Board of Osteopathic Medicine to promulgate rules regarding the standards of practice and standards of care for physicians who supervise licensed health care practitioners who are not under direct, onsite supervision and provides exemptions.

Section 3. – Provides that the bill shall take effect upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

[19] Nursing Health Care. 1992 May; 13(5):254-9

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The direct economic impact on the private sector is indeterminate because the bill allows the Board of Medicine to develop rules regarding supervision standards of health professionals. The impact cannot be determined until the Board of Medicine promulgates the rules.

D. FISCAL COMMENTS:

HB 699 w/ CS may result in an increase in health care costs in certain markets. The bill allows the Board of Medicine to promulgate stronger physician supervision rules. When promulgated, the rules may decrease the financial advantage of hiring a nurse or physician assistant to perform certain tasks and result in more direct physician care. Patient care received from a nurse or physician assistant is usually less expensive than care received by a physician.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides the necessary rulemaking authority for the Department of Health to carry out the provisions in the bill.

Concerns have been raised that rulemaking authority provided in the bill may not meet the standards of ch. 120, the Administrative Procedures Act. Section 120.536, F.S., requires that an agency may only adopt rules that implement or interpret the specific powers and duties granted by the enabling statute. Agencies do not have the power to adopt a rule only because it is reasonably related to the purpose of the enabling legislation. The bill grants rulemaking authority to the Board of Medicine but specifies that the rules “may include,” the standards in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On March 8, 2006 the Health Care Regulation Committee adopted five amendments and reported the bill favorably.

Amendment 1: Inserted a list of facilities and practitioners who are exempt from the rules promulgated as a result of the bill.
Amendment 2 & 3: Specified that rural health networks are exempt from the rules promulgated as a result of the bill.

Amendment 4 & 5: Specified that the rules promulgated as a result of the bill would apply equally to physician assistants and advanced registered nurse practitioners.

The analysis is drafted to the committee substitute.