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**HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH REGULATION
ANALYSIS**

BILL #: HB 309
RELATING TO: Advanced Registered Nurse Practitioner Prescribing of Controlled Substances
SPONSOR(S): Representative Green
TIED BILL(S): None.

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

- (1) HEALTH REGULATION YEAS 2 NAYS 9
 - (2) HEALTH & HUMAN SERVICES APPROPRIATIONS
 - (3) COUNCIL FOR HEALTHY COMMUNITIES
 - (4)
 - (5)
-

I. SUMMARY:

This bill redefines the term "practitioner" for purposes of prescribing the controlled substances listed under chapter 893, F.S., to include ARNPs. This change to section 893.02, F.S., will allow ARNPs to prescribe controlled substances to patients while working under general supervision and pursuant to a protocol with an allopathic physician, osteopathic physician, or dentist.

Currently, only allopathic physicians (M.D.s), dentists, veterinarians, osteopathic physicians (D.O.s), naturopaths, and podiatric physicians can prescribe controlled substances in Florida. Each practitioner must be licensed in Florida and must hold a valid federal controlled substance registry number (D.E.A. registration).

Florida law schedules certain drugs as controlled substances based on the drug's potential for abuse and whether it has an accepted medical use in treatment in the United States. Practitioners may prescribe drugs listed on Schedules II-V of section 893.03, F.S.

Florida's approximately 8,500 ARNPs are currently allowed to prescribe drugs other than controlled substances. ARNPs are licensed and regulated by the Florida Board of Nursing.

The effective date of this bill is July 1, 2002.

Prior to the unfavorable vote on the bill, the Committee on Health Regulation adopted six amendments. The amendments are explained in the Amendments section of this analysis.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

- | | | | |
|-----------------------------------|------------------------------|-----------------------------|---|
| 1. <u>Less Government</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" 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 type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" 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:

B. PRESENT SITUATION:

Florida Controlled Substance Provisions—Chapter 893, F.S.

Currently, only allopathic physicians (M.D.s), dentists, veterinarians, osteopathic physicians (D.O.s), naturopaths, and podiatric physicians can prescribe controlled substances in Florida. Each practitioner must be licensed in Florida and must hold a valid federal controlled substance registry number (D.E.A. registration). Practitioners may prescribe drugs listed on Schedules II-V of section 893.03, F.S.

Florida law schedules certain drugs as controlled substances based on the drug's potential for abuse and whether it has an accepted medical use in treatment in the United States. There are 5 schedules:

- C Schedule I drugs have a high potential for abuse and no currently accepted medical use in treatment in the United States. These drugs may not be prescribed in Florida.
- C Schedule II drugs have a high potential for abuse and have a currently accepted but severely restricted medical use in treatment in the United States. The abuse of such drugs may lead to severe psychological or physical dependence.
- C Schedule III drugs have a potential for abuse less than those drugs listed in Schedules I or II and have a currently accepted medical use in the United States. Abuse of these drugs may lead to moderate or low physical dependence or high psychological dependence, or in the case of anabolic steroids, may lead to physical damage.
- C Schedule IV drugs have a low potential for abuse relative to the substances in Schedule III and have a currently accepted medical use in treatment in the United States. Abuse of such drugs may lead to limited physical or psychological dependence relative to the drugs in Schedule III.
- C Schedule V drugs have a low potential for abuse relative to the substances in Schedule IV and have a currently accepted medical use in treatment in the United States. Abuse of such drug may lead to limited physical or psychological dependence relative to the drugs in Schedule IV.

Licensure and Regulation of Advanced Registered Nurse Practitioners—Chapter 464, F.S.

Advanced registered nurse practitioners (ARNPs) are licensed in Florida pursuant to s. 464.012, F.S. They are regulated by the Florida Board of Nursing. ARNPs are first licensed as registered nurses (RNs) and then can become certified as an ARNP to practice advanced or specialized nursing.

Pursuant to s. 464.003(6), F.S., an ARNP means “any person licensed in this state to practice professional nursing and certified in advanced or specialized nursing practice.”

A registered nurse (RN) is defined in s. 464.003(4), F.S., as “any person licensed in this state to practice professional nursing.”

The “practice of professional nursing” is defined in s. 464.003(3)(a), F.S., as:

“...the performance of those acts requiring substantial specialized knowledge, judgment, and nursing skill based upon applied principles of psychological, biological, physical, and social sciences which shall include, but not be limited to:

1. The observation, assessment, nursing diagnosis, planning, intervention, and evaluation of care; health teaching and counseling of the ill, injured, or infirm; and the promotion of wellness, maintenance of health, and prevention of illness of others.
2. The administration of medications and treatments as prescribed or authorized by a duly licensed practitioner authorized by the laws of this state to prescribe such medications and treatments.
3. The supervision and teaching of other personnel in the theory and performance of any of the above acts.”

“Advanced or specialized nursing practice” is defined in s. 464.003, F.S., as:

“...in addition to the practice of professional nursing, the performance of advanced-level nursing acts approved by the board which, by virtue of postbasic specialized education, training, and experience, are proper to be performed by an advanced registered nurse practitioner. Within the context of advanced or specialized nursing practice, the advanced registered nurse practitioner may perform acts of nursing diagnosis and nursing treatment of alterations of the health status. The advanced registered nurse practitioner may also perform acts of medical diagnosis and treatment, prescription, and operation which are identified and approved by a joint committee composed of three members appointed by the Board of Nursing, two of whom shall be advanced registered nurse practitioners; three members appointed by the Board of Medicine, two of whom shall have had work experience with advanced registered nurse practitioners; and the secretary of the department or the secretary's designee. Each committee member appointed by a board shall be appointed to a term of 4 years unless a shorter term is required to establish or maintain staggered terms. The Board of Nursing shall adopt rules authorizing the performance of any such acts approved by the joint committee. Unless otherwise specified by the joint committee, such acts shall be performed under the general supervision of a practitioner licensed under chapter 458, chapter 459, or chapter 466 within the framework of standing protocols which identify the medical acts to be performed

and the conditions for their performance. The department may, by rule, require that a copy of the protocol be filed with the department along with the notice required by s. 458.348.”

The term “nursing diagnosis” is defined in s. 464.003(3)(d), F.S., as “the observation and evaluation of physical or mental conditions, behaviors, signs and symptoms of illness, and reactions to treatment and the determination as to whether such conditions, signs, symptoms, and reactions represent a deviation from normal.”

The term “nursing treatment” is defined in s. 464.003(3)(e), F.S., as “the establishment and implementation of a nursing regimen for the care and comfort of individuals, the prevention of illness, and the education, restoration, and maintenance of health.”

All ARNPs must meet the requirement of s. 464.012(1), F.S., in order to become licensed as an ARNP in Florida. Specifically, that subsection states:

(1) Any nurse desiring to be certified as an advanced registered nurse practitioner shall apply to the department and submit proof that he or she holds a current license to practice professional nursing and that he or she meets one or more of the following requirements as determined by the board:

(a) Satisfactory completion of a formal postbasic educational program of at least one academic year, the primary purpose of which is to prepare nurses for advanced or specialized practice.

(b) Certification by an appropriate specialty board. Such certification shall be required for initial state certification and any recertification as a registered nurse anesthetist or nurse midwife. The board may by rule provide for provisional state certification of graduate nurse anesthetists and nurse midwives for a period of time determined to be appropriate for preparing for and passing the national certification examination.

(c) Graduation from a program leading to a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills. For applicants graduating on or after October 1, 1998, graduation from a master's degree program shall be required for initial certification as a nurse practitioner under paragraph (4)(c). For applicants graduating on or after October 1, 2001, graduation from a master's degree program shall be required for initial certification as a registered nurse anesthetist under paragraph (4)(a).

ARNPs work under protocol with a licensed doctor or dentist. Subsection 464.012(3), F.S., provides:

(3) An advanced registered nurse practitioner shall perform those functions authorized in this section within the framework of an established protocol. A practitioner currently licensed under chapter 458, chapter 459, or chapter 466 shall maintain supervision for directing the specific course of medical treatment. Within the established framework, an advanced registered nurse practitioner may:

(a) Monitor and alter drug therapies.

(b) Initiate appropriate therapies for certain conditions.

(c) Perform additional functions as may be determined by rule in accordance with s. 464.003(3)(c).

(d) Order diagnostic tests and physical and occupational therapy.

ARNPs are divided into three main types: nurse practitioners, nurse anesthetists, and nurse midwives. The Board of Nursing has rulemaking authority to provide for appropriate requirements for ARNPs in each of these categories, pursuant to s. 464.012(2), F.S.

Subsection 464.012(4)(c), F.S., permits a nurse practitioner to perform any or all of the following acts within the framework of established protocol:

1. Manage selected medical problems.
2. Order physical and occupational therapy.
3. Initiate, monitor, or alter therapies for certain uncomplicated acute illnesses.
4. Monitor and manage patients with stable chronic diseases.
5. Establish behavioral problems and diagnosis and make treatment recommendations.

Subsection 464.012(4)(a), F.S., permits a certified registered nurse anesthetist, "to the extent authorized by established protocol approved by the medical staff of the facility in which the anesthetic service is performed," to perform any or all of the following:

1. Determine the health status of the patient as it relates to the risk factors and to the anesthetic management of the patient through the performance of the general functions.
2. Based on history, physical assessment, and supplemental laboratory results, determine, with the consent of the responsible physician, the appropriate type of anesthesia within the framework of the protocol.
3. Order under the protocol preanesthetic medication.
4. Perform under the protocol procedures commonly used to render the patient insensible to pain during the performance of surgical, obstetrical, therapeutic, or diagnostic clinical procedures. These procedures include ordering and administering regional, spinal, and general anesthesia; inhalation agents and techniques; intravenous agents and techniques; and techniques of hypnosis.
5. Order or perform monitoring procedures indicated as pertinent to the anesthetic health care management of the patient.
6. Support life functions during anesthesia health care, including induction and intubation procedures, the use of appropriate mechanical supportive devices, and the management of fluid, electrolyte, and blood component balances.
7. Recognize and take appropriate corrective action for abnormal patient responses to anesthesia, adjunctive medication, or other forms of therapy.

8. Recognize and treat a cardiac arrhythmia while the patient is under anesthetic care.
9. Participate in management of the patient while in the postanesthesia recovery area, including ordering the administration of fluids and drugs.
10. Place special peripheral and central venous and arterial lines for blood sampling and monitoring as appropriate.

Subsection 464.012(4)(b), F.S., permits a certified nurse midwife "...to the extent authorized by an established protocol which has been approved by the medical staff of the health care facility in which the midwifery services are performed, or approved by the nurse midwife's physician backup when the delivery is performed in a patient's home," to perform any or all of the following:

1. Perform superficial minor surgical procedures.
2. Manage the patient during labor and delivery to include amniotomy, episiotomy, and repair.
3. Order, initiate, and perform appropriate anesthetic procedures.
4. Perform postpartum examination.
5. Order appropriate medications.
6. Provide family-planning services and well-woman care.
7. Manage the medical care of the normal obstetrical patient and the initial care of a newborn patient.

C. EFFECT OF PROPOSED CHANGES:

This bill expands the scope of practice of advanced registered nurse practitioners (ARNPs). It redefines the term "practitioner" for purposes of prescribing the controlled substances listed under chapter 893, F.S., to include ARNPs. This change to section 893.02, F.S., will allow ARNPs to prescribe controlled substances to patients while working under general supervision and pursuant to a protocol with an allopathic physician, osteopathic physician, or dentist.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Amends the definition of "practitioner" in s. 893.02(19), F.S., to allow ARNPs to prescribe controlled substances.

Section 2. Provides an effective date of July 1, 2002.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

See Fiscal Comments.

2. Expenditures:

See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

The Florida Attorney General will notify the United States Drug Enforcement Administration (DEA) that ARNPs are authorized to prescribe controlled substances. The DEA will then issue a federal controlled substance registry number (DEA#) to qualified persons.

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

A. APPLICABILITY OF THE MANDATES PROVISION:

The bill does not require a city or county 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:

None.

B. RULE-MAKING AUTHORITY:

None.

C. OTHER COMMENTS:

According to the Department of Health, 37 states currently allow ARNPs to prescribe controlled substances.

The Board of Nursing supports the ability of ARNPs to prescribe controlled substances under protocols with a supervising physician. A recommendation was made by the Joint Committee (members of the Boards of Nursing and Medicine and the Secretary of Health's designee,) that any ARNP seeking controlled substance prescribing privileges must have a master's degree and complete a post-graduate comprehensive pharmacology course.

The Florida Nurses Association (FNA) supports this bill. The FNA argues that ARNPs and physicians have worked in collaboration in Florida since the mid-1970s and that ARNPs have been authorized to prescribe other drugs since 1988 under the general supervision of and under protocol with a licensed physician. The FNA asserts that there have been very few complaints regarding the competency of nurse prescribing during these last twelve to thirteen years.

The Board of Medicine has historically opposed the expansion of prescriptive authority of ARNPs, since the Board of Medicine has not found there to be compelling evidence of an 'access to care' issue for patients that would warrant such expansion for high-risk controlled medications. The Board of Medicine representatives of the Joint Committee agree with the Board of Nursing in that if legislation were to be passed to expand ARNP prescriptive authority, that consideration should be given to establishing specific pharmacological training requirements as a prerequisite for this expanded prescriptive authority.

The Florida Medical Association (FMA) provided the following statement regarding its opposition to allowing ARNPs to prescribe controlled substances:

"The FMA believes it is not in the public's best interest to allow ARNPs the ability to prescribe Controlled Substances. The care of a patient whose symptoms require prescribing Controlled Substances must be closely supervised by a physician. Granting authority for ARNPs to prescribe Controlled Substances could potentially harm patients and mask underlying conditions. For example, drugs could be prescribed in inappropriate amounts, in combinations that could lead to harmful interactions, and the growing concern of Controlled Substances being diverted for abuse. Inherent within the right to prescribe Controlled Substances is the need to correctly diagnose the patient. The practitioner must be able to make the appropriate diagnosis and suggest proper treatment options. Controlled Substances can easily mask an underlying condition and MDs and DOs are the only properly educated and trained health care providers who can determine the cause of their patient's condition. ARNPs do not have the required training and medical education necessary to support an expansion of their scope of practice. The training programs vary significantly and can include very little clinical education. There are ARNPs who hold licenses in Florida who do not even hold a bachelor's degree. In contrast, the standards for the training of MDs and DOs are clearly defined and uniform. MDs and DOs have not only substantial pharmacological courses during school but have experience in proper prescriptive practices through their internship and residency programs. Many ARNPs (CRNAs for instance) simply do not have the need within their practice

setting to prescribe. Granting prescriptive authority without a demonstrated need will lead to abuses of the system by practitioners and patients. It is imperative for the safety and welfare of patients and the general public that this type of legislation not be passed into law. Prescribing Controlled Substances must be a privilege obtained through training and education, not legislation.”

Concerns have been raised in the law enforcement community about the ongoing problem with drug abuse and drug misuse. Expanding the pool of persons authorized to prescribe controlled substances may exacerbate the current drug abuse problem.

Florida Department of Law Enforcement Commissioner Tim Moore stated in an October 29, 2001, news release entitled *Mid-Year Report Indicates Rise in Some Drug Related Deaths in Florida*, that “...the rising abuse of pharmaceutical drugs such as Oxycodone and Hydrocodone should be monitored closely and investigated by the law enforcement community.”

The Legislature should consider strengthening the penalties for all practitioners who prescribe controlled substances outside the course of the professional practice of their profession and for inappropriate prescribing. The law currently provides for a maximum penalty of \$10,000 but does not set a minimum penalty. Section 456.072, F.S., could be amended to set a penalty of \$10,000 per inappropriate prescription in the same manner as there is a set penalty of \$10,000 per incident of fraud. Similarly, the Legislature could consider setting a minimum period of suspension or revocation for a practitioner who inappropriately prescribes controlled substances. Enhancement of the penalties may serve as a disincentive for practitioners to participate in trafficking of controlled substances. In addition, practitioners found to be abusing controlled substances could be prohibited in statute from prescribing controlled substances for a designated period. Moreover, to reduce the incidence of illegal drug use, the Legislature could consider other deterrents, including the use of tamper-proof prescription pads.

Additionally, the Legislature could consider requiring continuing education courses on appropriate prescribing of controlled substances. Such a course could educate prescribers on making appropriate medication choices for their patients as well as recognizing drug abuse.

Furthermore, the Legislature could consider an “active practice” requirement for ARNPs similar to that required of allopathic physicians. Under s. 458.319, F.S., only physicians who have actively practiced medicine or who have been on the active teaching faculty of an accredited medical school for at least 2 years of the immediately preceding 4 years can renew an active license. Any physician who has not met this requirement must pass a clinical competency examination prior to renewing an active license. There is no such active practice requirement for ARNPs.

It should be noted that there appears to be no statutory prohibition on ARNPs or physician assistants (PAs) employing physicians who serve as their supervising physician. In order to prohibit coercion, duress, or other problems, the Legislature could consider prohibiting a physician from supervising or entering into a protocol with an ARNP or PA who is the physician’s employer.

Moreover, there is no statutory requirement that an ARNP be supervised by a physician working in the same specialty as the ARNP. For instance, a certified registered nurse anesthetist (CRNA) need not enter into a protocol or supervisory relationship with a physician anesthesiologist. A certified nurse midwife (CNM) need not enter into a protocol or supervisory relationship with an obstetrician. The ARNP can work under protocol and under the general supervision of any licensed allopathic or osteopathic physician, or dentist.

There has been a lot of discussion recently about a shortage of nurses willing to work in Florida and across the country. Several studies and surveys have been done to gauge the number of vacant

nursing positions and to determine what can be done to alleviate this shortage. The Florida Hospital Association has provided information showing that approximately 21% of Florida's licensed RNs are not currently employed in the nursing field.

Furthermore, it has been alleged that some ARNPs are working based on their RN license rather than their ARNP certification since there are more jobs presently available for RNs. There does not appear to be a significant need for additional ARNPs in the current health care workforce. However, in order to address the nursing shortage through the training of new nurses, there is a need to increase nursing faculty at the nursing schools.

It is not clear what impact this bill will have on the nursing shortage in Florida. The Florida Nurses Association (FNA) has argued that allowing ARNPs to prescribe controlled substances will enhance the practice of advanced nursing, thereby making advanced nursing a more attractive profession for nurses. The FNA believes that this bill will lengthen the career path for nurses, allow ARNPs to practice to the full extent of their training, and eliminate the current prohibition which they find to be demeaning to nurses. Thus, by making the advanced nursing profession more attractive, new students will enter nursing school and the nursing shortage will be relieved. However, since an ARNP must first be a registered nurse (RN), all new ARNPs are effectively coming out of the already reduced pool of licensed RNs. Encouraging more RNs to become ARNPs may further reduce the number of RNs working as RNs.

The most recent Florida study of this issue occurred more than four years ago. In 1996, the Legislature established a task force appointed by the then-Director of the Agency for Health Care Administration (AHCA) to study the prescribing of controlled substances by ARNPs. The task force presented its report to the House Health Standards and Quality Assurance Subcommittee on January 5, 1998. The task force noted the differences in course content between ARNP and physician educational programs, including the differences in pharmacology contact hours. The task force also reviewed malpractice claims histories and malpractice insurance costs. This task force recommended that ARNPs be allowed to apply for authority to prescribe controlled substances in Florida under protocol, conditioned upon the applicant's satisfaction of course requirements including the prescribing of controlled substances, and conditioned upon documented experience in successfully prescribing non-controlled substances.

There is a Minority Report included in the Addenda from the physician members of the task force representing the Florida Medical Association (FMA). The Minority Report identifies some concerns of the physicians which were not included by AHCA in the task force report, including a recommendation that ARNPs must be supervised by a physician in the same medical specialty in which the ARNP is working. Additionally, there is a position statement included in the Addenda written on behalf of the nurses on the task force representing the Florida Nurses Association (FNA) which sets forth the reasons why the FNA supports ARNP prescribing of controlled substances.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

On December 4, 2001, prior to the *unfavorable* vote on the bill, the Committee on Health Regulation adopted the following six amendments:

Amendment 1, as amended, prohibits an ARNP from employing their supervising physician.

Amendment 2 requires the ARNP to notify the supervising physician within 24 hours of writing a prescription for a controlled substance. The supervising physician is then responsible for ensuring the appropriateness of the prescription and must take immediate action to correct any inappropriate prescribing, including notifying the patient and the Department of Health.

Amendment 3 requires ARNPs to provide evidence of the active practice of advanced nursing for at least 2 of the immediately preceding 4 years in order to renew an active license to practice as an ARNP. The amendment defines “actively practiced advanced nursing” and “clinical nursing.”

Amendment 4 requires all health care practitioners who are authorized to prescribe controlled substances to complete a continuing education course on appropriate prescribing of controlled substances as a condition of licensure renewal. The amendment also sets the penalty for inappropriate prescribing at \$10,000 per prescription and includes a minimum suspension of the practitioner’s license for a minimum of one year. It also provides grounds for discipline in the Nurse Practice Act consistent with those in the Medical Practice Act relating to prescribing.

Amendment 5 removes dentists from the list of persons who can supervise ARNPs when the ARNP writes a prescription for a controlled substance.

Amendment 6 requires ARNPs to apply for controlled substance prescriptive authority. In order for the Board of Nursing to approve the ARNP to prescribe controlled substances, the ARNP must provide evidence of the completion of the board-required pharmacology and appropriate prescribing instructional courses and must provide evidence of the successful prescription of non-controlled substances for a period of at least 2 years.

VII. SIGNATURES:

COMMITTEE ON HEALTH REGULATION:

Prepared by:

Staff Director:

Wendy Smith Hansen

Lucretia Shaw Collins