

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 811 Specialty Nursing
SPONSOR(S): Green
TIED BILLS: None. **IDEN./SIM. BILLS:** SB 2072 (i)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Standards (Sub)		Mitchell	Collins
2) Health Care			
3) Health Appropriations (Sub)			
4) Appropriations			
5)			

SUMMARY ANALYSIS

HB 811 provides a definition of Clinical Nurse Specialist (CNS) to mean nurses with advanced degrees and expertise in specialized areas of nursing care. It provides for state certification and title protection for clinical nurse specialists who are already certified nationally.

The bill also provides for registration of Advanced Registered Nurse Practitioners (ARNPs) to prescribe medicinal drugs and to prescribe controlled substances. It establishes requirements for protocols with the supervising physician, continuing education, and fees for registration. Additional requirements for prescribing controlled substances include possession of a valid mid-level federal Drug Enforcement Administration registration and continuing education. The bill provides for disciplinary sanctions and criminal penalties. It redefines the term "practitioner" under the "Florida Comprehensive Drug Abuse Prevention and Control Act" to include ARNPs who hold federal controlled substance registry numbers and are registered with the state to prescribe controlled substances.

The provisions for Clinical Nurse Specialists (CNS) will establish that a person can not present themselves as a clinical nurse specialist unless they have the required training and certification to do so. Currently the only specialized nursing licensure certification in Florida is the Advanced Registered Nurse Practitioner. CNSs are licensed in 23 states, but not in Florida. A CNS is prepared at master's level by several nursing programs in Florida, but since there is no title protection, any nurse can use the CNS title.

The provisions for ARNPs will assist their patients in receiving their medication. As the number and use of ARNPs has increased in primary care, patients are not able to receive prescriptions for all of their drugs from one practitioner, requiring some patients to have second appointments, delays in treatment, and increased expense for consultations. Currently, ARNPs may prescribe drugs, but not controlled substances, under a protocol with a physician. Advanced registered nurse practitioners are not included on the list of practitioners able to prescribe controlled substances under the Florida Comprehensive Drug Abuse Prevention and Control Act. As a result, ARNPs are not authorized by state statute to be able to obtain a federal Drug Enforcement Administration (DEA) number required by pharmacies to fill their patients' prescriptions. Some insurance companies require pharmacies, when submitting claims for prescriptions, to include a DEA number as an identifier for each prescription submitted, regardless of whether or not it is for a controlled substance.

The effective date of the bill is July 1, 2004. The Department of Health is concerned that the effective date does not allow time for implementation of rules and procedures.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h0811.hc.doc
DATE: March 3, 2004

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

- | | | | |
|--------------------------------------|---|-----------------------------|---|
| 1. Reduce government? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 2. Lower taxes? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 3. Expand individual freedom? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 4. Increase personal responsibility? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 5. Empower families? | 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. EFFECT OF PROPOSED CHANGES:

HB 811 provides a definition of Clinical Nurse Specialist (CNS) to mean nurses with advanced degrees and expertise in specialized areas of nursing care. It provides for state certification and title protection for CNSs who are already certified nationally. The Department of Health estimates that 2,065 nurses would apply for CNS certification, based on data from comparable states and the National Council of State Boards of Nursing.

The bill also provides for registration of Advanced Registered Nurse Practitioners (ARNPs) to prescribe medicinal drugs and to prescribe controlled substances. It establishes requirements for protocols with the supervising physician, continuing education, and fees for registration. Additional requirements for prescribing controlled substances include possession of a valid mid-level federal Drug Enforcement Administration registration and continuing education. The bill provides for disciplinary sanctions and criminal penalties. It redefines the term "practitioner" under the "Florida Comprehensive Drug Abuse Prevention and Control Act" to include ARNPs who hold federal controlled substance registry numbers and are registered with the state to prescribe controlled substances. According to the Department of Health, the number of ARNPs in Florida is 9,386. The department estimates that 80% will apply for the medicinal drug registration and of those 50% will apply for the controlled substance registration.

The bill requires ARNP who prescribes medicinal drugs to: register with the Board of Nursing; complete at least 16 hours of continuing education in pharmacology biennially; and submit a copy of the protocol between the ARNP and the supervising physician with renewal or sooner. The bill requires general supervision by the physician, and requires the nurse to maintain medical records for each prescription. The Board of Nursing is required to review new applications and documents related to continuing education and protocols, and establish a registration process for prescribing medicinal drugs. The bill provides for the board to adopt rules.

The bill establishes similar requirements for an ARNP who prescribes medicinal drugs and controlled substances, with the additional requirements of possessing a mid-level practitioner registration from the Federal Drug Enforcement Administration; completing a course in legal and clinical aspects of prescribing controlled substances; and incorporating schedules of controlled substances authorized in the protocol. The bill excludes certified registered nurse anesthetists from these requirements.

The provisions for Clinical Nurse Specialists (CNSs) will establish that a person can not present themselves as a CNS unless they have the required training and certification to do so. Currently the only specialized nursing licensure certification is the ARNP. CNSs are licensed in 23 states, but not in Florida. A CNS is prepared at master's level by several nursing programs in Florida, but since there is no title protection, any nurse can use the CNS title.

The provisions for Advanced Registered Nurse Practitioners (ARNPs) will assist their patients in receiving their medication. As the number and use of advanced registered nurse practitioners has increased in primary care, patients are not able to receive prescriptions for all of their drugs from one practitioner, requiring some patients to have second appointments, delays in treatment, and increased expense for consultations.

Currently, ARNPs may prescribe drugs, but not controlled substances, upon licensure and establishment of a protocol with a physician. ARNPs are not included on the list of practitioners able to prescribe controlled substances under the Florida Comprehensive Drug Abuse Prevention and Control Act. As a result, ARNPs are not authorized by state statute to be able to obtain a federal Drug Enforcement Administration (DEA) number required by pharmacies to fill their patients' prescriptions. Some insurance companies require pharmacies, when submitting claims for prescriptions, to include a DEA number as an identifier for each prescription submitted, regardless of whether or not it is for a controlled substance.

The effective date of the bill is July 1, 2004.

CURRENT SITUATION

Clinical Nurse Specialists

Clinical Nurse Specialists (CNSs) are licensed registered nurses who have graduate preparation (Master's or Doctorate) in nursing as a Clinical Nurse Specialist. According to the National Association of Clinical Nurse Specialists, they are trained to be expert clinicians in a specialized area of nursing practice. They can provide direct care, expert consultation to nursing staffs, and implement improvements in health care delivery systems. Their specialty may be identified in terms of:

- A Population (e.g. pediatrics, geriatrics, women's health);
- A Setting (e.g. critical care, emergency room);
- A Disease or Medical Subspecialty (e.g. diabetes, oncology);
- A Type of Care (e.g. psychiatric, rehabilitation); or
- A Type of Problem (e.g. pain, wounds, stress).

According to the National Association of Clinical Nurse Specialists, an estimated 69,017 RNs have the education and credentials to practice as a clinical nurse specialist (CNS). Approximately 14,643 are qualified to work as a nurse practitioner and a CNS.

Currently CNSs can obtain certification by examination in some specialties, but many specialty areas have not certification exam available. The American Nurses Credentialing Center (ANCC) offers the APRN – BC credential to individuals who successfully complete clinical nurse specialist exams in:

- Child/Adolescent Psychiatric Mental Health Nursing
- Adult Psychiatric Mental Health Nursing
- Medical Surgical Nursing
- Gerontological nursing
- Community Health Nursing
- Home Health Nursing
- Pediatric Nursing

In addition, the Oncology Nursing Certification Corporation offers the Advanced Oncology Certified Nurse (AOCN) certification; the Rehabilitation Nursing Certification Board offers the Certified Rehabilitation Registered Nurse – Advanced (CRRN-A) certification; and the American Association of Critical Care Nurses Certification Corporation offers the Critical Care Nurse Specialist (CCNS) certification.

Regulation of Health Care Professions in Florida

The criteria for regulation of health professions is set forth in various sections of chapter 456, F.S. Specific health care professions are regulated by separate Practice Acts in Florida Statutes. These acts establish the profession's scope of practice, grounds for disciplinary actions, and other licensure functions.

Section 464.003, F.S., defines three types of licensed nurse: Licensed Practical Nurse; Registered Nurse; and Advanced Registered Nurse Practitioner.

Certification of Advanced Registered Nurse Practitioners

Section 464.012, F.S., provides for certification of Advanced Registered Nurse Practitioners that have met one or more of the following requirements:

- Completed a post basic education program that prepares nurses for advanced or specialized practice;
- Are certified by a specialty board, such as a registered nurse anesthetist or nurse midwife; or
- Have graduated with a master degree in a nursing clinical specialty area.

Three General Types of Professional Regulation: Licensure, Certification, and Registration

The three primary forms of regulation used to grant individuals the right or privilege to perform certain activities are licensure, certification, and registration. Although these terms are often used interchangeably, the literature on professional regulation makes the following distinctions:

- **Licensure** is the most restrictive mechanism and entails the creation of a monopoly on the regulated activity of a profession through enactment of profession-specific Practice Acts. Licensed practitioners gain an exclusive right to deliver services, and the profession enjoys protection of its title.
- **Certification** is less restrictive than licensure. It is achieved through the use of title protection acts that give a designated "recognition" to individuals who meet qualifications set by a regulatory agency. Non-certified individuals may still offer services, but they are prohibited from using the term "certified" or the designated title. Certification is also used in the context of licensure, as in the American Medical Association's scheme of specialty boards which certify physicians specializing in different practice areas. In this context, certification denotes that a licensed practitioner has met certain professional standards.
- **Registration** is the least restrictive regulatory mechanism and is achieved through registration requirement acts. Registration requires an individual to file his or her name and address with a designated agency. Unlike licensure, registration does not require complex or onerous pre-entry screening requirements, nor is a registration regime exclusionary. It does little more than provide a roster of practitioners.

Authorization of Advanced Registered Nurse Practitioners to Prescribe Medications

Advanced Registered Nurse Practitioners are authorized to prescribe prescription medications, excluding controlled substances, under standards of a protocol agreement with a physician, as provided by s. 464.003(3)(c), F.S., and Rule 64B9-4.010, Florida Administrative Code.

All medications that the supervising physician has agreed for the ARNP to prescribe must be listed in the protocol. The writing of the protocols and approval of the collaborative practice physician gives the ARNP prescriptive privileges. Nurse practitioners have their own prescription pads.

A nurse practitioner can not write prescriptions for controlled substances. Federal law requires that anyone prescribing controlled substances have a DEA license number. All prescriptions for controlled substances must be written and signed by a licensed physician.

Controlled Substances and the DEA Registration Number

Federal regulation, Title 21, section 1306.5, CFR requires prescriptions for controlled substances to indicate the federal registration number, which is the Drug Enforcement Administration (DEA) number that is issued to physicians, veterinarians, dentists, and podiatrists authorized to prescribe controlled substances.

The federal Controlled Substances Act (CSA), Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 regulates the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illegal production of controlled substances. It places all substances regulated under existing federal law, in one of five schedules based on the substance's medicinal value, harmfulness, and potential for abuse or addiction. Schedule I is reserved for the most dangerous drugs that have no recognized medical use, while Schedule V is the classification used for the least dangerous drugs.

Through the registration of all those authorized by the DEA to handle controlled substances the Controlled Substances Act creates a closed distribution system for controlled substances. All individuals and firms that are registered are required to maintain complete and accurate inventories and records of all transactions involving controlled substances, as well as security for the storage of controlled substances.

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. It classifies controlled substances into five schedules based on federal law in order to regulate the manufacture, distribution, preparation, and dispensing of the substances.

- Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in the United States.
- Schedule II drugs have a high potential for abuse and a severely restricted medical use. Cocaine and morphine are examples of Schedule II drugs.
- Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use. Substances listed in Schedule III include anabolic steroids, codeine, and derivatives of barbituric acid.
- Schedule IV and Schedule V substances have a low potential for abuse, compared to substances in Schedules I, II, and III, and currently have accepted medical use. Substances in Schedule IV include phenobarbital, librium, and valium. Substances in Schedule V include certain stimulants and narcotic compounds.

Section 893.04 (1)(c)2., F.S., prohibits pharmacists from filling prescriptions for controlled substances without a DEA number indicated on the prescription.

Inability of ARNPs to Obtain DEA Registration Numbers

Because ARNPs cannot prescribe controlled substances by statute or rule, they cannot obtain a DEA number. Nurse Practitioners in Florida cannot receive a DEA number because there is no statutory authority for these practitioners to prescribe controlled substances.

The Drug Enforcement Agency does issue Mid-Level Practitioner DEA numbers to ARNPs in other states where these practitioners are authorized to prescribe controlled substances. For Nurse Practitioners that includes 44 states and the District of Columbia.

Pharmacist Use of Physician DEA Registration Numbers for Prescriptions by ARNPs for Non-Controlled Medications

It has become common procedure for pharmacies to use the federal DEA number as a unique identifier for pharmacy companies billing for reimbursement from insurance companies and managed care companies.

Because ARNPs can not obtain DEA numbers, Florida pharmacists use the DEA number of the physician who supervises the ARNP to bill insurers and managed care companies for prescriptions written by ARNPs.

Pharmacy rules require that all the information necessary to properly label the prescription container be included on the prescription. The pharmacist is required to put the prescriber's name on the medication label [Rule 64B16-28.402(1)(b)].

By using the DEA number to bill insurers the pharmacist labels the prescription with the name of the physician rather than the name of the ARNP who actually wrote the prescription. This practice is a violation of the rules of the Florida Board of Pharmacy that requires that the name of the actual prescribing practitioner be on each prescription label.

Medicaid Use of Practitioner License Number Instead of DEA Registration Number

According to the Department of Health, when the Medicaid program used DEA numbers as identifiers for claims a number of years ago, the same problems occurred with regard to ARNP prescriptions. Medicaid converted to a system that utilizes the practitioner's license number rather than a DEA number and the program is working.

C. SECTION DIRECTORY:

Section 1. Amends s. 464.003, F.S., to define the scope of practice of a clinical nurse specialist.

Section 2. Creates s. 464.0115, F.S., to establish certification criteria for clinical nurse specialists, fees for application and renewal, and rulemaking authority.

Section 3. Creates s. 464.0125, F.S., to establish registration requirements for an advanced registered nurse practitioner who prescribes medicinal drugs and who prescribe controlled substances.

Section 4. Amends s. 464.015, F.S., to provide title protection for "Clinical Nurse Specialist" and the abbreviation "C.N.S."

Section 5. Amends s. 464.016, F.S., to prohibit CNS practice without an active license or certification and the use of the title unless the person is duly licensed or certified.

Section 6. Amends s. 893.02, F.S., to include advanced registered nurse practitioners in the list of practitioners authorized to prescribe controlled substances.

Section 7. Amends s. 458.348, F.S., to make technical changes.

Section 8. Amends s. 464.012, F.S., to make technical changes.

Section 9. Reenacts s. 921.0022, F.S., to incorporate changes in s. 464.016, F.S., by reference.

Section 10. Provides an effective date of July 1, 2004.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The Department of Health estimates the following revenue:

<u>Estimated Revenue</u>	<u>1st Year</u>	<u>2nd Year</u>
CNS Certification	\$51,625	\$5,000
ARNP Registration to prescribe medicinal drugs	\$562,500	\$15,000
ARNP Renewal to prescribe controlled substances	\$62,500	\$125,000
Total Estimated Revenue	\$676,625	\$145,000

*See Fiscal Comments below.

2. Expenditures:

The Department of Health estimates the following expenditures

<u>Estimated Expenditures</u>	<u>1st Year</u>	<u>2nd Year</u> <u>(Annualized/Recurring)</u>
Salaries		
2-Nurse Consultants, PG 077	\$80,057	\$106,743
1-RSII, PG 17	\$28,345	\$37,794
1-RSI, PG 15	\$25,861	\$34,482
Other Personal Services	\$0	\$0
Expense		
Non-recurring expense for 3 FTEs	\$9,183	
Non-recurring expense for 1 FTE	\$2,603	\$0
Recurring expense for 2 Nurse Consultant w/ limited travel	\$21,682	\$21,682
Recurring expense for 1 RSII	\$6,854	\$6,854
Recurring expense for 1 RSI	\$5,416	\$5,416
Operating Capital Outlay		
Standard OCO pkg for 3 FTEs	\$4,500	
Standard OCO pkg for 1 FTE	\$2,000	
Total Estimated Expenditures	\$186,501	\$212,971

*See Fiscal Comments below.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

According to DOH, the creation of a registration for prescribing privileges for ARNPs, will fiscally impact all advanced registered nurses with an additional \$75 fee at the time of application and another \$25 on renewal.

According to DOH, the ability to prescribe controlled substances provided by the bill will enable ARNPs to provide a wider scope of services, especially in underserved and underfunded clinics that can not afford a physician to be present.

The impact of provisions for CNSs will be on employers who will have to revise job descriptions for Clinical Nurse Specialists to conform to the certification requirements. According to DOH, some CNS employees currently using this title may need additional education and/or certification to meet requirements or may not qualify for the title at all.

D. FISCAL COMMENTS:

The Department of Health (DOH) expects 2,065 nurses will apply for Clinical Nurse Specialist certification. This is based on data from comparable states and the National Council of State Boards of Nursing. The number of advanced registered nurse practitioners in Florida is 9,386. DOH expects that 80% will apply for the medicinal drug registration and of those 50% will apply for the controlled substances registration. According to DOH, the Division of Medical Quality Assurance will require 1 additional FTE for the Clinical Nurse Specialist portion of this bill and 3 additional FTEs for the prescribing portion.

DOH estimates revenues based on the following:

- 2,065 CNS applicants in year 1 and 200 in year 2 at \$25;
- 7,500 ARNPs will register to prescribe medicinal drugs in year 1 and 200 in year 2 at \$75; and
- 2,500 ARNPs will renew to prescribe controlled drugs in year 1 and 5,000 in year 2 at \$25.

According to DOH, after the first year, revenue from CNSs will not be sufficient to recover costs of administration in subsequent years. According to DOH, the impact of processing the applications for clinical nurse specialist will be similar to that of an advanced registered nurse practitioner. The bill allows only a \$25 application fee and \$10 renewal fee for CNSs, while for ARNPs it is \$75 and \$50. According to DOH, the average Clinical Nurse Specialist application fee for 13 states polled was \$104 and the renewal average was \$69. The net result of the fee structure established in the bill is that ARNPs will be subsidizing the regulatory costs for CNSs.

DOH is also concerned that revenue from renewals of ARNPs will not be sufficient to recover costs of administration after the first year.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides for rulemaking authority.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The Department of Health has expressed concern that it will have to create forms and establish initial licensure and renewal procedures for implementation of the two classes of advanced registered nurse practitioners as well as the clinical nurse specialists. According to DOH, application processing personnel as well as nursing staff will be required to process applications and to evaluate protocols and credentials of advanced registered nurse practitioners for compliance with these standards. The Board of Nursing will have to create rules to implement provisions of the bill.

The department is also concerned that the effective date does not allow time for implementation of rules and procedures.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES