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Committee on Health Regulation

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## **AUTHORIZATION FOR ADVANCED REGISTERED NURSE PRACTITIONERS TO PRESCRIBE CONTROLLED SUBSTANCES**

### **Issue Description**

Advanced registered nurse practitioners (ARNPs) are registered nurses who, by virtue of advanced educational preparation at the graduate level, are authorized to perform certain functions that historically have been within the practice of medicine. Prescribing drugs is one of the medical functions that ARNPs are authorized to perform. In Florida, ARNPs' authority to prescribe does not include controlled substances. Controlled substances are drugs or substances whose general availability is restricted by federal and state laws because of their potential for abuse or addiction, including narcotics, depressants, stimulants, and hallucinogenic drugs. Advanced practice nurses in 47 states currently have the authority to prescribe controlled substances.

Proponents of giving ARNPs the authority to prescribe controlled substances argue that such authority will increase access to needed health care services in areas of the state where there are underserved populations and shortages of physicians; increase convenience for patients and physicians; and improve the quality of patient care. The proponents argue that ARNPs have the education to safely and effectively prescribe controlled substances and that the evidence from the 47 states where advanced practice nurses currently prescribe controlled substances supports this claim.

Opponents of giving ARNPs the authority to prescribe controlled substances argue that ARNPs do not have adequate training to make the appropriate diagnosis and suggest proper treatment options relative to controlled substances. They argue that increasing the number of persons prescribing controlled substances will lead to further opportunities for abuse of prescription drugs and diversion of prescription drugs from legal distribution systems. Opponents also assert that there is no indication that patients who need controlled substances have problems getting these drugs.

### **Background**

#### **Advanced Practice Nursing**

The term "advanced practice nurse" or "APN" refers generically to a group of licensed registered nurses who have advanced clinical training and who serve as primary care providers in a broad range of acute care and outpatient settings. The titles given to APNs vary from state to state. In Florida, the generic licensure title is "advanced registered nurse practitioner." Within the titles of APN, there are four general categories: nurse practitioner, nurse midwife, registered nurse anesthetist, and clinical nurse specialist. Within these categories there may be subspecialties based on the APN's training, the patients to be served, or the conditions to be treated by the APN.

Nursing education and practice have evolved in recent years to meet the needs of the health care delivery system. The profession of advanced practice nursing is a relatively new one which began in the 1960s in response to a nationwide physician shortage. The requirements to be recognized as an APN have been enhanced significantly since that time. States independently regulate the practice of nursing, and there is considerable variation among the states as to APNs' scope of practice and the limitations placed on their practice.

Education for APNs includes advanced studies and intensive clinical experience tailored to the APN's area of practice. In addition to nursing, an APN may perform medical acts of diagnosis, treatment, prescription, and operation under specified circumstances. APNs usually practice in collaboration with physicians and other health care practitioners. The

required level of physician involvement in an APN's practice varies from state to state, although few states require direct supervision.

### ***Florida's Laws and Regulations***

Florida initially authorized advanced practice nursing in 1975.<sup>1</sup> Advanced practice nursing is regulated by the Board of Nursing under part I of chapter 464, F.S. Florida certifies ARNPs in the following categories: nurse practitioner, certified registered nurse anesthetist, and certified nurse midwife.<sup>2</sup> Clinical nurse specialists are APNs whose nursing specialty is recognized separately under Florida law.<sup>3</sup>

Florida Registered Nurses and Advanced Registered Nurse Practitioners with Active Licenses as of September 12, 2008*	
Total Active RNs	202,137
RNs with no additional qualification	202,115
RNs with a Clinical Nurse Specialist qualification	22
Total Active RNs with an ARNP rank**	13,206
RN/ARNPs with an Nurse Practitioner qualification	9,112
RN/ARNPs with a Certified Registered Nurse Anesthetist qualification	3,469
RN/ARNPs with a Certified Nurse Midwife qualification	620
RN/ARNPs with a Clinical Nurse Specialist qualification	5

\* Strategic Planning Services Unit, Division of Medical Quality Assurance, Florida Department of Health

\*\* Includes RN/ARNPs with active licenses who are not Florida residents

In order to be certified as an ARNP, a nurse must hold a current license to practice professional nursing and submit proof to the Board of Nursing that he or she meets one or more of the following requirements as determined by the board: satisfactory completion of a formal postbasic educational program of specialized or advanced nursing practice; certification by an appropriate specialty board; or completion of a master's degree program in the appropriate clinical nursing specialty. A nurse who holds a current license to practice professional nursing, has a master's degree in a clinical nursing specialty, and holds current certification in a clinical nursing specialty from a nationally recognized certifying body may be certified as a clinical nurse specialist.

Under s. 464.003(3)(d), F.S., the Board of Nursing is required to adopt rules authorizing ARNPs to perform acts of medical diagnosis and treatment, prescription, and operation. Under Rule 64B9-4.009, F.A.C., ARNPs may monitor and alter drug therapies, initiate appropriate therapies for certain conditions, and order diagnostic tests and physical and occupational therapy. The rule further elaborates that the scope of practice of ARNPs includes functions which the ARNP has been educated to perform, according to established protocols and consistent with the practice setting. Although ARNPs may prescribe medications in accordance with a protocol, they are not authorized to prescribe controlled substances. ARNPs may perform medical acts under the general supervision of a medical physician, osteopathic physician, or dentist within the framework of standing protocols that identify the medical acts to be performed and the conditions for their performance. The Board of Nursing and the Board of Medicine have adopted identical administrative rules setting forth the standards for the protocols.<sup>4</sup>

### **Prescribing and Prescription Drugs**

A prescription is an order, usually written in a specified format, by a licensed health care practitioner for the preparation and administration of a drug. Not all drugs require a prescription, such as over-the-counter drugs. Prescription drugs are drugs that are approved by the U.S. Food and Drug Administration that require the signature of a licensed prescribing health care practitioner to dispense. The following health care practitioners are authorized in Florida to prescribe drugs

<sup>1</sup> See section 2, ch. 75-273, Laws of Florida, and s. 5, ch. 76-204, Laws of Florida.

<sup>2</sup> Section 464.012, F.S.

<sup>3</sup> Section 464.0115, F.S.

<sup>4</sup> See Rules 64B-4.010 and 64B-35.002, F.A.C.

within the scope of their practice: medical physicians, osteopathic physicians, podiatric physicians, naturopathic physicians, certified optometrists, physician assistants, ARNPs, and dentists. Veterinarians are also authorized to prescribe drugs for animals. Clinical nurse specialists do not have authority to prescribe in Florida.

Prescription drugs are used by licensed health care practitioners in treating the sickness or injury for which the drugs are prescribed. Advances in pharmaceutical therapies have transformed health care over the last several decades. Many diseases are prevented, cured, or managed effectively with prescription drugs. Prescription drugs often replace other forms of treatment, such as surgery. However, there are also risks associated with prescription drugs and they can be dangerous if used improperly.

### ***Prescribing in the ARNP's practice***

ARNPs independently manage common medical problems and may initiate, monitor, alter or order drug therapies as a nursing function, although these acts are medical acts of prescription.<sup>5</sup> Any drug therapy that an ARNP prescribes, initiates, monitors, alters or orders must be within the ARNP's scope of practice, knowledge, and training, and must be authorized by the supervising physician or dentist. The ARNP's prescribing authority must be outlined in a protocol and the protocol must state that it excludes prescribing controlled substances. The protocol must be reviewed annually by the ARNP and supervising physician or dentist. Nurse midwives and nurse anesthetists administer and *order* controlled substances in facilities as a part of their scope of practice.

Studies conducted during the mid-1980s found that APNs prescribe less frequently than physicians and limit their prescribing to well-known and "relatively simple drugs."<sup>6</sup> In Florida, ARNPs are authorized to manage drug therapies that may involve prescription medications that are potentially more dangerous than controlled substances, such as cardiac medications and medications used with cancer treatment. Currently, ARNPs are managing their patient's health care without the authority to prescribe controlled substances. If the ARNP believes her or his patient needs a controlled substance, or if the patient has already been prescribed a controlled substance, the ARNP, within his or her specialized knowledge and training, must still manage the patient's health care. Without authority to prescribe controlled substances, the ARNP must collaborate with or refer the patient for direct evaluation by a physician or dentist, who must then independently determine the need for the drug therapy.

### **Controlled Substances**

Controlled substances are drugs or chemicals, including illegal drugs and prescription medications that are strictly regulated or outlawed because of their potential for abuse or addiction. They include drugs classified as narcotics, stimulants, depressants, hallucinogens, and cannabis. The prescribing of controlled substances is a privilege that is separate from the regulation of the practice of the prescribing practitioner.

The Drug Enforcement Administration (DEA) within the U.S. Department of Justice regulates controlled substances that are classified under the federal Controlled Substances Act.<sup>7</sup> A health care practitioner must register with and obtain a registration number from the DEA to prescribe a controlled substance. The DEA registration provides a tracking system to discourage unauthorized prescribing of controlled substances. A DEA registrant must also comply with applicable state law for prescribing controlled substances. If state law does not authorize a practitioner to prescribe controlled substances, the DEA may not issue a DEA registration number.

Federal regulations provide a classification of "mid-level practitioner" for practitioners other than physicians, dentists, veterinarians, or podiatrists, who are authorized under state law to prescribe controlled substances in the course of professional practice.<sup>8</sup> Examples of mid-level practitioners include, but are not limited to, nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, physician assistants, optometrists, and psychologists.

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<sup>5</sup> See Section 464.012(3), F.S., and Rule 64B9-4.009, F.A.C.

<sup>6</sup> "Nurse Practitioners, Physician Assistants, and Certified Nurse-Midwives: A Policy Analysis" U.S. Congress Office of Technology Assessment, (December 1986).

<sup>7</sup> See Title 21 CFR, 1300 generally and 21 CFR 1308.11 to 1308.15.

<sup>8</sup> See 21 CFR 1300.01(b)(28).

In Florida, ch. 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. The chapter classifies controlled substances into five schedules 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 severely restricted medical use. Cocaine and morphine are 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 controlled substances have a low potential for abuse, compared to substances in Schedules I, II, and III, and currently have accepted medical uses. Substances in Schedule IV include phenobarbital, librium, and valium. Substances in Schedule V include certain stimulants and narcotic compounds.

Chapter 893, F.S., defines “practitioner” to mean a licensed medical physician, dentist, veterinarian, osteopathic physician, naturopathic physician, or podiatrist, if the practitioner holds a valid federal controlled substance registry number. The definition does not include any mid-level practitioners, so mid-level practitioners are unable to register with the DEA to prescribe controlled substances.

### **Prescribing of Controlled Substances Task Force**

The 1996 Florida Legislature required the director of the Agency for Health Care Administration to appoint a task force to evaluate the prohibition on the prescription of controlled substances by ARNPs,<sup>9</sup> including the medical necessity of the prohibition and the potential for harm if the prohibition was relaxed or removed in hospital or office settings. The law also required the task force to study the educational and clinical training of ARNPs and the potential liability exposure of physicians, pharmacists, and hospitals if ARNPs were allowed to prescribe controlled substances. The task force issued a report in December 1997 recommending changes to Florida law to allow ARNPs to prescribe controlled substances after completion of certain approved course and experience requirements.<sup>10</sup>

### **Physician Assistants**

Physician assistants, like APNs, are designated by the federal DEA as “mid-level practitioners” for the prescribing of controlled substances. In 46 states, physician assistants have prescribing authority for controlled substances, with some specified restrictions. Physician assistants are trained to work under the supervision and control of medical physicians and osteopathic physicians. In Florida, for purposes of the regulation of physician assistants, “supervision” is defined in ss. 458.347 and 459.022, F.S., to mean responsible supervision and control. Except for cases of emergency, supervision requires the easy availability or physical presence of the licensed physician for consultation and direction of the actions of the physician assistant. “Easy availability” is defined to include the ability to communicate by way of telecommunication.

A Florida-licensed physician may delegate to a physician assistant the authority to prescribe any medication used in the supervisory physician’s practice unless the medication is a controlled substance. The physician assistant must meet requirements specified in s. 458.347, F.S., before the physician assistant may prescribe.

## **Findings**

### **Educational Preparation to Prescribe**

The requirements of private advanced practice nursing specialty organizations for certification of individual practitioners and the requirements of private accrediting bodies for approval of nursing educational programs are similar for the various nursing specialties. To gain entry into advanced nursing practice, professional nurses must complete a formal course of education in an accredited nursing program at the graduate level.<sup>11</sup> In addition, most states

<sup>9</sup> Ch. 96-274, Laws of Florida.

<sup>10</sup> “Prescribing of Controlled Substances by Advanced Registered Nurse Practitioners” Prescribing of Controlled Substances Task Force, December 1997.

<sup>11</sup> See “Consensus Model for APRN Regulation: Licensure, Accreditation, Certification & Education” July 7, 2008, APRN Consensus Work Group and the APRN Advisory Committee of the National Council of State Boards of Nursing.

require APN applicants to be certified by a recognized national organization. These requirements ensure that applicants for licensure as an APN have the necessary knowledge and skills to practice, including prescribing, in a specialty area at the advanced nursing level.

### ***Accredited Nursing Programs***

Accreditation is a private, nongovernmental review of the quality of educational programs. Advanced practice nursing programs are accredited by the National League of Nursing Accreditation Commission (NLNAC) and the Commission on Collegiate Nursing Education (CCNE). Both are nationally-recognized accrediting organizations that accredit a broad array of nursing programs.<sup>12</sup> As a condition of accreditation by these organizations, graduate degree nursing programs must include in each degree program and specialty area curricula that incorporate separate graduate level courses in health/physical assessment, physiology/pathophysiology, and pharmacology. Subject matter from these courses may also be integrated into specialty or subspecialty courses. Accreditation also requires advanced nursing programs to provide a minimum of 500 hours of supervised clinical experience. A minimum of 500 hours of supervised clinical experience is also required for APNs to receive national certification.<sup>13</sup>

Accreditation by the NLNAC or the CCNE ensures that the graduates of these accredited nursing degree programs have obtained the core curricula needed to enable them to sit for their nursing specialty examinations. The accreditation requirements for nurse anesthesia and nurse midwife education programs have comparable standards which prepare graduates to sit for national certification examinations.<sup>14</sup>

The Florida Board of Nursing has adopted Rule 64B9-4.003, F.A.C., to establish guidelines for advanced nursing programs. The guidelines require the curriculum of an advanced nursing program to be at least 1 academic year in length and include theory in the biological, behavioral, nursing, and medical sciences relevant to the area of advanced practice, in addition to clinical experience with a qualified preceptor. The program must include: theory and directed clinical experience in comprehensive physical and biopsychosocial assessment; interpretation of laboratory findings; pharmacotherapeutics, to include the initiation, selection, and modification of selected medications; initiation and modification of selected therapies; management of selected diseases and illnesses; and differential diagnosis related to specialty problems. The program must provide a minimum of 500 hours of supervised clinical experience in the performance of the specialized diagnostic procedures that are essential to practice in that specialty area.

### ***Certification***

Certification is a method of documenting that a professional has the knowledge, skills, and experience required to practice a profession. The evolution of advanced nursing practice has led to certification of nursing specialties by national organizations. The majority of certification organizations require nurses to obtain, at a minimum, a master's degree in professional nursing from an accredited program in order to be eligible to sit for their advanced nursing certification examinations. Only those individuals who meet the qualifications may use certain designated titles awarded by national certification programs. Certification in advanced nursing practice is also mandated by Medicare<sup>15</sup> and many insurers for purposes of third-party billing.

The Florida Board of Nursing has adopted Rule 64B9-4.002, F.A.C., to establish requirements for state certification as an ARNP. Applicants for ARNP certification are required to submit proof of national certification from an approved nursing specialty board. The rule specifies which specialty boards are approved. As of October 1, 2008, there were 13,410 Florida-licensed ARNPs and about 9,012 of this number held nursing specialty board certification.<sup>16</sup> Since

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<sup>12</sup> In addition to the NLNAC and the CCNE, various advanced nursing specialty entities accredit advanced nursing programs.

<sup>13</sup> See "The Essentials of Master's Education for Advanced Practice Nursing," 1994, American Association of Colleges of Nursing at < <http://www.aacn.nche.edu/Education/mastessn.htm> > (Last visited on October 10, 2008).

<sup>14</sup> See "Standards for Accreditation of Nurse Anesthesia Educational Programs (Jan. 2006)," by the Council on Accreditation of Nurse Anesthesia Educational Programs; and "Core Competencies for Nurse Midwifery Practice (including 2007 Revision)," and "Standards for Nurse Midwifery Practice" by the American College of Nurse Midwifery.

<sup>15</sup> See 42 CFR 410.75.

<sup>16</sup> Source: Florida Department of Health.

national certification is now required for ARNP applicants in Florida, the percentage of Florida ARNPs with national certification will increase in the future.

### Access to Needed Health Care/Controlled Substances

Nationally, there is a shortage of health professionals who provide primary care. As of June 30, 2008, there were 5,987 areas within the U.S. designated as health professional shortage areas (HPSAs) for primary care with 63 million people living in these areas.<sup>17</sup> According to the federal government, it would take 16,261 health professionals to meet the need for primary care providers in these designated areas (a population to health professional ratio of 2,000:1).<sup>18</sup>

A number of rural counties in Florida have been designated by the federal government as HPSAs for primary care.<sup>19</sup> An HPSA is defined as a geographic area with less than 2.86 primary care physicians per 10,000 population. HPSAs are redesignated every 4 years. Shortages of physicians in a geographic area can prevent the delivery of timely and appropriate health care services for routine medical conditions.

Advanced Registered Nurse Practitioners (ARNPs) with Active Licenses as of October 13, 2008, and Primary Care Physician FTEs in Health Professional Shortage Areas*					
County	Number of ARNPs	Primary Care Physician FTE	County	Number of ARNPs	Primary Care Physician FTE
Dixie	1	7.94	Lafayette	2	2.0
Franklin	5	2.0	Liberty	1	0.6
Gadsden	31	10.0	Madison	10	6.0
Gilchrist	4	5.65	Okeechobee	11	9.0
Glades	0	7.0	Sumter	25	9.3
Hamilton	3	0.8	Suwannee	16	7.8
Hardee	2	3.0	Wakulla	18	4.0
Hendry	17	7.0	Washington	15	4.8
Jefferson	2	4.2			

\*Source: Florida Department of Health

A total of 163 ARNPs who hold active Florida licenses have primary addresses in Florida rural counties that have been designated as HPSAs for primary care.<sup>20</sup>

Recent nursing workforce studies present demographic trends that suggest a need for new strategies to increase the number of APNs in Florida.<sup>21</sup> Statewide, the potential ARNP workforce (ARNPs with an active license, eligibility to practice, and a Florida address) is showing a slight increase of 566 ARNPs in 2008 for a total of 11,094.<sup>22</sup> The number of ARNPs in the workforce grew more slowly in rural panhandle counties and rural and urban southeastern counties relative to the central and northern counties.

A recent survey of medical school graduates showed that only 2 percent were choosing to work in primary care, in part, due to high educational debt and low salaries relative to more lucrative medical specialties.<sup>23</sup> The decline in the salary of family medicine physicians is also well-documented.

<sup>17</sup> Source: U.S. Bureau of Health Professions, Health Resources, and Services Administration at <http://www.bhpr.hrsa.gov/shortage/> (Last visited on October 13, 2008).

<sup>18</sup> Id.

<sup>19</sup> Source: Florida Department of Health (May 7, 2008).

<sup>20</sup> Source: Florida Department of Health, Health Professional Shortage Areas - Primary Care (May 2008).

<sup>21</sup> See Workforce Data at the Florida Center for Nursing at <http://www.flcenterfornursing.org/workforce/data.cfm> (Last visited on October 10, 2008).

<sup>22</sup> Source: Florida Center for Nursing.

<sup>23</sup> See Hauer, K. et al. "Factors Associated With Medical Students' Career Choices Regarding Internal Medicine," *JAMA*. 2008;300(10):1154-1164.

## Prescription Drug Abuse/Diversion

In 2006 and 2007 over 3.5 billion prescriptions were dispensed each year in the U.S.<sup>24</sup> About 13 percent of all prescriptions dispensed in the U.S. during 2006 and 2007 were for controlled substances.<sup>25</sup> An estimated 6.3 percent of all refilled prescriptions in 2007 were for controlled substances.<sup>26</sup>

Prescription drug abuse is a significant problem in the U.S. and has been increasing recently.<sup>27</sup> By definition, controlled substances have a high potential for abuse. Prescribing health care practitioners who have access to controlled substances may abuse those drugs themselves or may prescribe to patients who abuse controlled substances. The diversion of controlled substances from legitimate sources into illicit street drug traffic is a major problem. Patients may obtain legitimate prescriptions and then fraudulently sell the drugs for a profit.

The federal government and state governments have adopted laws aimed at preventing drug diversion, drug abuse, and inappropriate prescribing. Over 30 states have implemented prescription monitoring programs to track the prescribing and dispensing of controlled substances, which could potentially address the issue of prescription drug diversion. There is significant variability in the information tracked in state prescription monitoring systems.<sup>28</sup> Florida has not implemented a prescription monitoring program.

Florida has imposed significant restraints on the prescribing of controlled substances by: limiting to 30 days any prescription for a Schedule III drug; requiring a patient to present identification to a dispensing pharmacist to obtain Schedules II-IV drugs; and requiring a prescription for a Schedule II drug to be in writing, with an exception for emergencies. Florida also does not permit mid-level practitioners to prescribe controlled substances.

National data on discipline, or other disposition, for chemical impairment of APNs and other prescribing health care professionals is difficult to analyze due to the variability of state regulation of APNs and other health care professionals. A recent survey of state boards of nursing found that APNs experience a low incidence of discipline related to chemical impairment, exceeding scope of practice, unprofessional conduct, and safety or abuse of patients.<sup>29</sup>

In Florida, a prescribing practitioner who engages in inappropriate prescribing may be subject to discipline by the appropriate regulatory board. As an alternative to discipline a prescribing practitioner involved with drug diversion/abuse may be referred to a program for impaired professionals. In such cases, the Florida Department of Health currently contracts with the Intervention Project for Nurses (IPN) for licensed nurses and the Professional Resource Network (PRN) for all other licensed professions. According to the department, there are approximately 2,700 participants enrolled in the programs for all types of impairment: 1,600 in the IPN and 1,100 in the PRN. As of September 2008, according to the department, approximately 0.4 percent of ARNPs are being actively monitored for all types of impairment, including chemical impairment, in the IPN.

## Malpractice Liability/Financial Responsibility

Under s. 456.048, F.S., the Florida Board of Nursing requires all ARNPs to document at initial state certification and biennial renewal that the practitioner carries malpractice insurance of at least \$100,000 per claim with a minimum annual aggregate of at least \$300,000 from an insurer or holds an unexpired irrevocable letter of credit in the amount of

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<sup>24</sup> Source: Wolters Kluwer Health Source® Pharmaceutical Audit and PriceCheckPC. Also see, "Top 100 Prescription Drugs of 2006," by Ed Lamb, Pharmacy Times, May 2007 (Reported Data Source: IMS Health).

<sup>25</sup> Id.

<sup>26</sup> Id.

<sup>27</sup> See the testimony of the Director of the National Institute on Drug Abuse in the National Institutes of Health, U.S. Dep't H HS before a subcommittee of the U.S. House of Representatives at: <<http://www.hhs.gov/asl/testify/t060726a.html>> (Last visited on October 17, 2008).

<sup>28</sup> United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control. See "Prescription Drug Monitoring Programs," at <[http://www.deadiversion.usdoj.gov/faq/rx\\_monitor.htm](http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm)> (Last visited on October 10, 2008).

<sup>29</sup> See Hudspeth, R. (April 2, 2007). "Survey of Advanced Practice Registered Nurses Disciplinary Action". *Online Journal of Issues in Nursing*. Vol. 12, No. 2.

\$100,000 per claim with a minimum of \$300,000 in the aggregate, with some exceptions. As a condition of hospital privileges, ARNPs may be required by facilities to carry more coverage.

Medical and osteopathic physicians must also maintain malpractice insurance/financial responsibility in the same amounts as ARNPs. However, physicians also have the option to go “bare” (uninsured) for medical malpractice liability on the condition that the physician gives notice of this fact to his or her patients by posting a sign prominently displayed in the reception area and clearly noticeable to all patients or by providing a written statement to any person to whom medical services are being provided.

Malpractice results when a health professional fails to exercise the appropriate degree of knowledge, training, and skill when treating a patient when compared to reasonably prudent health care professionals with the same level of knowledge, training, and skill. If ARNPs are granted authority to prescribe controlled substances, their exposure to malpractice claims may increase. To establish a malpractice claim against an ARNP or other provider, a plaintiff must establish duty (the presumption that a provider-patient relationship exists), breach (provider failed to meet a standard of care owed to patient), causation (facts that show that the actions of the ARNP or provider caused the plaintiff’s injuries), and injury.

Currently, a supervising physician who consults or who actively provides care may be liable for writing a controlled substance prescription for an ARNP’s patient. If ARNPs are authorized to prescribe controlled substances they would be independently responsible for any negligence that arises from their prescribing activities unless the supervising physician actively conducts an evaluation, treats the patient, or consults with the ARNP over the patient’s care.<sup>30</sup>

### **National Overview of Prescribing of Controlled Substances by APNs**

As of September 2008, all fifty states authorized APNs to prescribe drugs. Forty-seven states authorized APNs to prescribe controlled substances. The states that did not authorize APNs to prescribe controlled substances were Alabama, Florida, and Hawaii. However, rules are being adopted in Hawaii to give APNs the authority to prescribe controlled substances. It is anticipated that those rules will become effective by the end of 2008 or early in 2009. Although almost all states authorize APNs to prescribe controlled substances, there are wide variations among the states with regard to the conditions that are placed on the granting of authority to prescribe and the limitations placed on the prescribing of controlled substances by APNs.

#### ***Limitations on Which Drugs May Be Prescribed***

Of the 47 states that authorize APNs to prescribe controlled substances, 39 authorize the prescribing of controlled substances in Schedules II – V, and 8 states authorize the prescribing of controlled substances in Schedules III – V only. However, many states place further limitations on the drugs that APNs may prescribe. These limitations may be set in one or more of the following ways: establishing the limitations within the terms of agreements between APNs and their supervising/collaborating physicians or dentists; requiring the APN to prescribe within established formularies; requiring the drugs prescribed to be within the APN’s and collaborating physician’s scope of practice; or prohibiting the prescribing of specific drugs by law.

At least half of the states, including Florida, require APNs to prescribe under protocols, standardized procedures, or written agreements with physicians or dentists. These protocols, procedures, or agreements are developed between the APN and the physician or dentist, and specify the drugs that may be prescribed and the conditions under which they may be prescribed.

Ten states restrict the drugs that may be prescribed by APNs through the use of a state-developed formulary. The formulary may specify the drugs that an APN may *not* prescribe (exclusionary formulary) or may specify the drugs that an APN may prescribe (inclusionary formulary). In six of the states with formularies, the formulary is developed by an interdisciplinary team. Practice protocols may impose restrictions beyond those contained in the formulary.

<sup>30</sup> See *Siegel v. Husak*, 943 So.2d 209 (3<sup>rd</sup> DCA) 2006.

At least 21 states require APN prescribing to be within the APN's scope of practice and/or within the scope of practice of the collaborating physician. If an APN's scope of practice is narrow, the range of drugs that could be prescribed would be narrow. A few states prohibit APNs from prescribing specified drugs, such as drugs intended to cause either a miscarriage or fetal death, controlled substances for the purpose of weight reduction or to control obesity, controlled substances for the treatment of chronic or intractable pain, or anabolic steroids for the purpose of human muscle building or enhancing human athletic performance.

### ***Limitations on Which APNs May Prescribe Controlled Substances***

Every state does not authorize every category of APN (nurse practitioner, nurse midwife, nurse anesthetist, and clinical nurse specialist) to prescribe controlled substances. Twenty-one of the 47 states that authorize APNs to prescribe controlled substances authorize all four APN categories to prescribe controlled substances. All 47 states that authorize APNs to prescribe controlled substances authorize nurse practitioners to prescribe controlled substances. Forty-six states authorize nurse midwives to prescribe controlled substances. Thirty-four states authorize one or more clinical nurse specialist categories to prescribe controlled substances. Twenty-eight states authorize nurse anesthetists to prescribe controlled substances, but often limit prescribing by nurse anesthetists to their scope of practice.

### ***Limitations on the Settings in Which or Patients for Whom APNs May Prescribe Controlled Substances***

A few states authorize APNs to prescribe within certain sites or to certain patient groups. In Arizona, certified registered nurse anesthetists may prescribe drugs to be administered by a licensed, certified, or registered health care provider pre-operatively, post-operatively, or as part of a procedure performed in a health care facility, the office of a health care provider, or in an ambulance. Certified registered nurse anesthetists in Washington may select, order, or administer controlled substances that are to be directly administered to patients who require anesthesia for diagnostic, operative, obstetrical, or therapeutic procedures in a hospital, clinic, ambulatory surgical facility, or the office of certain practitioners. In California, a Certified Nurse Midwife may prescribe Schedule II drugs only in the hospital setting and Schedules III – V controlled substances in hospitals, birth centers, home health agencies, physician's offices, clinics, or public or community health services. To use prescriptive authority in Texas, an APN must practice in a qualifying site. Qualifying sites include: sites that serve medically underserved populations; physician primary practice sites; physician alternate practice sites; and facility-based practices in hospitals or long-term-care facilities.

Ohio authorizes an APN to prescribe Schedule II controlled substances only for a patient with a terminal condition, if the nurse's collaborating physician initially prescribed the substance, and only in an amount that does not exceed the amount necessary for the patient's use in a single, 24-hour period. Texas prohibits APNs from prescribing controlled substances to a child less than 2 years of age without physician consultation.

### ***Educational Requirements for Prescriptive Authority***

Forty states, including Florida, require national certification for initial licensure of all APNs. Two additional states require national certification for some categories of APNs. Forty-four states have specific statutory/regulatory requirements for education in pharmacology. In some states the educational requirements are linked to the authorization to prescribe controlled substances, but in other states the pharmacology education requirements are linked to the practice of advanced nursing generally. In some states the educational requirements for national certification would meet the statutory/regulatory requirements for education in pharmacology, but in other states the statutory/regulatory requirements are in addition to what is required for national certification. Twenty-eight states have specific pharmacology continuing education requirements for licensure renewal or renewal of prescriptive authority.

### ***Collaboration/Supervision Requirements***

The degree of oversight by a physician or dentist that is required for an APN to obtain and exercise authority to prescribe controlled substances varies considerably among the states. Ten states do not require a formal collaborative or supervisory relationship between a physician/dentist and an APN for purposes of the APN prescribing controlled substances. In some of these states, however, the APN is required to have a plan for consultation and referral.

Thirty-seven states require a collaborative or supervisory relationship between a physician/dentist and an APN for purposes of the APN prescribing controlled substances. These states require written collaborative practice agreements,

standardized procedures, protocols, or guidelines that define the scope of the prescriptive authority for controlled substances. The level of involvement of the physician/dentist in the APN's prescribing varies among the states.

In California, prescriptive authority for certified nurse midwives and nurse practitioners is contingent upon completion of at least 520 hours of physician supervised experience in the furnishing or ordering of drugs. In Maine, a certified nurse practitioner who qualifies as an advanced practice registered nurse must practice for at least 24 months under the supervision of a licensed physician or be employed by a facility that has a medical director who is a licensed physician before being able to practice independently.

### *Washington State's Experience*

A 2007 study of APNs' response to Washington State's changes in APN authority to prescribe controlled substances indicates that not all APNs will take advantage of expanded authority to prescribe controlled substances.<sup>31</sup> Some APNs in Washington did not want to prescribe controlled substances, while others were comfortable with their existing approaches to providing controlled substances to their patients through physician colleagues.

### **Conclusions**

ARNPs are skilled nursing professionals with advanced clinical training that prepares them to provide primary care services. Giving ARNPs the authority to prescribe controlled substances will enhance the ability of ARNPs to manage their patients' care and reduce delays and costs for patients in obtaining needed medications.

Advanced practice nurses do not appear to be any more susceptible to diversion or inappropriate prescribing than any other prescribing practitioners. If ARNPs may independently prescribe controlled substances for their patients rather than rely on a consultation with a prescribing physician or dentist, any malpractice exposure will be the responsibility of the ARNP.

Although, there are still ARNPs currently in practice who were educated through programs that granted a certificate, today the minimum requirement to practice requires the attainment of a masters degree or higher to obtain certification in the specialty area of practice. The current certification requirements appear to sufficiently protect the public to give qualified ARNPs the authority to prescribe controlled substances.

### **Options and Recommendations**

Senate professional staff recommends that the Legislature consider extending authority to Florida-licensed ARNPs who have attained certification in a nursing specialty from a nationally recognized certifying entity to prescribe controlled substances under protocols and within the scope of practice for their specialty.

This project was limited to ARNPs, but if authority to prescribe controlled substances is extended to ARNPs, the Legislature may be asked to extend this authority to other "mid-level practitioners" who have prescriptive authority, such as physician assistants.

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<sup>31</sup> See Kaplan, Louise and Brown, Marie-Annette "The Transition of Nurse Practitioners to Changes in Prescriptive Authority," *Journal of Nursing Scholarship*, 2007; 39:2, 184-190.