

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

BILL: SB 132

SPONSOR: Senator Fasano

SUBJECT: Prescriptions for Medicinal Drugs

DATE: February 9, 2004 REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Munroe</u>	<u>Wilson</u>	<u>HC</u>	<u>Favorable</u>
2.	<u>Peters</u>	<u>Belcher</u>	<u>AHS</u>	<u>Favorable</u>
3.	_____	_____	<u>AP</u>	<u>Withdrawn: Favorable</u>
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

The bill requires a prescription written by a practitioner who is authorized under the laws of Florida to write prescriptions for drugs that are not controlled substances but who is not eligible for a federal drug enforcement administration number to include that practitioner's name and professional license number. The pharmacist or dispensing practitioner must include the practitioner's name on the container of the drug that is dispensed. A pharmacist must be permitted, upon verification by the prescriber, to document any required information.

A prescription written by a Florida-licensed advanced registered nurse practitioner or physician assistant for a drug that is not a controlled substance is presumed, subject to rebuttal, to be valid and within the parameters of the prescriptive authority delegated to the advanced registered nurse practitioner or physician assistant who is prescribing the drug. For purposes of the presumption, the prescriptive authority must be delegated to the advanced registered nurse practitioner by a Florida-licensed medical physician, osteopathic physician, or dentist, and in the case of a physician assistant, the prescriptive authority must be delegated by the physician assistant's supervising physician.

This bill creates s. 456.0392, F.S.

II. Present Situation:

Controlled Substances

Chapter 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 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.

The chapter defines practitioner to mean a licensed medical physician, a licensed dentist, a licensed veterinarian, a licensed osteopathic physician, a licensed naturopathic physician, or a podiatrist, if such practitioner holds a valid federal controlled substance registry number. The chapter provides that every record required by the chapter, including prescription records, be kept and made available for at least two years for inspection and copying by law enforcement officers whose duty it is to enforce the laws of the state relating to controlled substances.¹

Section 893.05, F.S., allows a practitioner, in good faith and in the course of his or her professional practice only to prescribe, administer, dispense, mix, or otherwise prepare a controlled substance, or the practitioner may direct the administration of a controlled substance by a licensed nurse or an intern practitioner under his or her direction and supervision.

Section 893.04, F.S., authorizes a pharmacist, in good faith and in the course of professional practice only to dispense controlled substances upon a written or oral prescription under specified conditions. An oral prescription for controlled substances must be promptly reduced to writing by the pharmacist. The written prescription must be dated and signed by the prescribing practitioner on the day when issued. There must appear on the face of the prescription or written record for the controlled substance: the full name and address of the person for whom, or the owner of the animal for which, the controlled substance is dispensed; the full name and address of the prescribing practitioner and *the prescriber's federal controlled substance registry number must be printed thereon*; if the prescription is for an animal, the species of animal for which the controlled substance is prescribed; the name of the controlled substance prescribed and the strength, quantity, and directions for the use thereof; the number of the prescription, as recorded in the prescription files of the pharmacy in which it is filed; and the initials of the pharmacist filling the prescription and the date filled. Section 893.04(1)(d), F.S., requires the proprietor of the pharmacy in which a prescription for controlled substances is filled to retain the prescription on file for a period of 2 years. The chapter requires the original container in which a controlled substance is dispensed to bear a label with specified information.

Prescribing Authority

In addition to medical physicians, osteopathic physicians, podiatric physicians, and dentists, three other health care professions, advanced registered nurse practitioners, physician assistants, and certified optometrists may currently prescribe medications under specified circumstances. Advanced registered nurse practitioners perform all duties of a registered nurse and advanced

¹ The Second District Court of Appeal upheld a warrantless search and seizure of prescription records pursuant to s. 893.07, F.S. *Gettel v. State* 449 So.2d 413 (2nd DCA 1984).

level nursing in accordance with established protocols, including managing selected medical problems, monitoring and altering drug therapies, initiating appropriate therapies for certain conditions, performing physical examinations, ordering and evaluating diagnostic tests, ordering physical and occupational therapy, and initiating and monitoring therapies for certain uncomplicated acute illnesses.

Chapter 464, F.S., requires the Board of Nursing to adopt rules authorizing advanced registered nurse practitioners to perform acts of medical diagnosis and treatment, prescription, and operation which are identified and approved by a joint committee. Advanced registered nurse practitioners may perform medical acts under the general supervision of a medical physician, osteopathic physician, or dentist within the framework of standing protocols which identify the medical acts to be performed and the conditions for their performance. The Board of Nursing and the Board of Medicine have filed identical administrative rules setting forth standards for the protocols² which establish obligations on medical physicians, osteopathic physicians, and dentists who enter into protocol relationships with advanced registered nurse practitioners. The Board of Osteopathic Medicine and the Board of Dentistry who have regulatory jurisdiction over osteopathic physicians and dentists, respectively, are not required to adopt administrative rules regarding the standards for advanced registered nurse practitioner protocols. Although advanced registered nurse practitioners may prescribe medications in accordance with a protocol, they cannot prescribe controlled substances.

Physician assistants provide health care under the supervision of a physician, including patient evaluation, monitoring, diagnosis, therapy, counseling, and preventative care. Physician assistants may prescribe any medication used in the supervisory physician's practice unless it is listed on a "negative" formulary³ developed by the Council on Physician Assistants. The formulary must include controlled substances as defined ch. 893, F.S., antipsychotics, general anesthetics and radiographic contrast materials, and all parenteral preparations except insulin and epinephrine. The physician assistant may only prescribe medication under the following requirements: the physician assistant clearly identifies himself to the patient; the supervising physician notifies the Department of Health of his or her intent to delegate the authority to prescribe; the physician assistant completes a continuing medical education course of at least 3 classroom hours in prescriptive practice; the physician assistant files evidence of completing a minimum of 3 months of clinical experience in the specialty area of the supervising physician; and the physician assistant files evidence with the Department of Health of having completed a minimum of 10 hours of continuing education in the specialty practice in which the physician assistant has prescriptive authority.

Optometrists provide vision care services, including examining visual efficiency and performance; determine visual, muscular, neurological, or anatomic anomalies of the human eyes; and prescribe and fit lenses, contact lenses, and other methods for the correction of insufficiencies or abnormal eye conditions. A certified optometrist may administer and prescribe topical ocular pharmaceutical agents listed on a formulary developed by a five-member committee. The Board of Optometry has adopted an administrative rule to establish and modify the formulary.

² See Rules 64B-4.010 and 64B-35.002, Florida Administrative Code.

³ See ss. 458.347(4) and 459.022(4), F.S.

Federal Controlled Substances Act

The Controlled Substances Act requires every person who dispenses any controlled substance to obtain from the United States Attorney General a registration number issued in accordance with the rules and regulations adopted by him.⁴ The Attorney General shall register practitioners to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices.⁵ Prescriptions for controlled substances must indicate the federal Drug Enforcement Administration (DEA) number issued to physicians, veterinarians, dentists and podiatric physicians authorized to prescribe controlled substances.⁶

Affiliated practitioners, including advanced registered nurse practitioners and physician assistants, are authorized to administer, but not prescribe, controlled substances using the DEA number of the supervising physician.⁷ An individual practitioner who is an agent or employee of a hospital or other institution may prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered himself or herself. There are specific requirements for use when such prescribing is done. The requirements include the use of a specific internal code number for each individual practitioner authorized by the facility to administer controlled substances. The code number must consist of numbers, letters, or a combination thereof and must be a suffix to the institution's DEA registration number, preceded by a hyphen.

Practitioner Identifiers

According to the Department of Health, 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. Because advanced registered nurse practitioners and physician assistants do not have DEA numbers, these insurance companies do not reimburse claims for their prescriptions, resulting in two scenarios:

- Pharmacists include the DEA number of the supervising physician on the prescription, or
- Patients are required to pay for the prescription.

It has become a common procedure for pharmacies to use the federal DEA number as a unique identifier for billings seeking reimbursement from insurance companies and other third party payers.⁸

⁴ See 21 U.S.C. 822.

⁵ See 21 U.S.C. 823.

⁶ See 21 C.F.R. 1306.05.

⁷ See 21 U.S.C. 1301.22.

⁸ According to the Department of Health, the Medicaid program uses the practitioner's license number rather than a DEA number .

III. Effect of Proposed Changes:

The bill requires a prescription written by a practitioner who is authorized under the laws of Florida to write prescriptions for drugs that are not controlled substances but who is not eligible for a federal drug enforcement administration number to include that practitioner's name and professional license number. The pharmacist or dispensing practitioner must include the practitioner's name on the container of the drug that is dispensed. A pharmacist must be permitted, upon verification by the prescriber, to document any required information.

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The bill provides an effective date of July 1, 2004.

IV. Constitutional Issues:**A. Municipality/County Mandates Restrictions:**

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

B. Public Records/Open Meetings Issues:

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

C. Trust Funds Restrictions:

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

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

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.
