HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 923

SPONSOR(S): Fiorentino

Prescriptions/Medicinal Drugs

TIED BILLS: None. IDEN./SIM. BILLS: SB 1738 (s)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Standards (Sub)	7 Y, 0 N	Mitchell	Collins
2) Health Care	_		
3) Health Appropriations (Sub)	_		
4) Appropriations	<u></u>		
5)	<u> </u>		<u></u>

SUMMARY ANALYSIS

HB 923 prohibits persons from requiring the use of a federally issued registration number for controlled substances on a prescription, when it is not required by federal or state laws or rules. The bill establishes a penalty of a second degree misdemeanor for violating this prohibition.

The bill addresses problems faced by Advanced Registered Nurse Practitioners (ARNPs) and Physician Assistants (PAs) who do not have a federal Drug Enforcement Agency (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. Because ARNPs and PAs are not authorized by Florida law to prescribe controlled substances, they can not obtain DEA numbers. Insurance companies do not reimburse claims for their prescriptions. The result is that pharmacists must either include the DEA number of the supervising physician on the prescription, not the person who signed the prescription, or patients are required to pay for the prescription.

The bill has the effect of prohibiting insurers, pharmaceutical companies and community pharmacies from using the DEA number of prescribing practitioners as a billing number for non-controlled drugs when it is not otherwise required.

The effective date of the bill is July 1, 2003.

On April 2, 2003, the Health Standards Subcommittee adopted a "strike-all" amendment to the bill. See: Section IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES for details.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

1.	Reduce government?	Yes[]	No[X]	N/A[]
2.	Lower taxes?	Yes[]	No[]	N/A[X]
3.	Expand individual freedom?	Yes[X]	No[]	N/A[X]
4.	Increase personal responsibility?	Yes[]	No[]	N/A[X]
5.	Empower families?	Yes[]	No[]	N/A[X]

For any principle that received a "no" above, please explain:

The bill provides a criminal penalty for the existing practice of using federal identification numbers on prescriptions. It will allow Advanced Registered Nurse Practitioners and Physician Assistants to prescribe medications for their patients as authorized by law.

B. EFFECT OF PROPOSED CHANGES:

HB 923 prohibits persons from requiring the use of a federally issued registration number for controlled substances on a prescription when it is not required by federal or state laws or rules. The bill establishes a penalty of a second degree misdemeanor for violating this prohibition as provided in ss. 775.082 and 775.083, F.S. The effective date of the bill is July 1, 2003.

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CURRENT SITUATION

Currently both ARNPs and PAs are authorized under their practice acts and through rules of their regulatory boards to prescribe legend, non-controlled drugs in Florida.

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

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.

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Authorization of Advanced Registered Nurse Practitioners and Physician Assistants 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.

Physician Assistants are authorized by s. 458.347, F.S., relating to medical practice and s. 459.022, F.S., relating to osteopathic medicine to prescribe any medications delegated by the supervising physician, that are used in the supervisory physician's practice, except medications listed on the formulary. The formulary is established in Rule 64B8-30.008, Florida Administrative Code. It provides that physician assistants are not authorized to prescribe:

- (a) Controlled substances, as defined in Chapter 893, F.S.
- (b) Antipsychotics
- (c) General, spinal or epidural anesthetics
- (d) Radiographic contrast materials
- (e) Any parenteral preparation except insulin and epinephrine.

Controlled Substances and the DEA Registration Number

The federal Controlled Substances Act (CSA), Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 places all substances regulated under existing federal law, including the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illegal production of controlled substances, into 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 CSA 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. The chapter 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.

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Inability of ARNPs and PAs to Obtain DEA Registration Numbers

Because ARNPs and PAs cannot prescribe controlled substances by statute or rule, they cannot obtain a DEA number. Nurse Practitioners and Physician Assistants 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 and PAs in other states where these practitioners are authorized to prescribe controlled substances. For Nurse Practitioners that includes 43 states and the District of Columbia.

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

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

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 or PA 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 and PA prescriptions. Medicaid converted to a system that utilizes the practitioner's license number rather than a DEA number and the program is working.

Provisions for Use of DEA Registration Numbers with Suffixes

Federal code, 21 U.S.C. s. 1301.22 allows affiliated practitioners, including ARNPs and PAs, to administer, but not prescribe, controlled substances using the DEA number of the supervising physician. It also provides for an individual practitioner who is an agent or employee of a hospital or other institution to prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself. There are specific requirements for when such prescribing can be done, but they include use of a specific internal code number for each individual practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., APO123456-10 or APO123456-A12).

C. SECTION DIRECTORY:

Section 1. Prohibits persons from requiring the use of a federally issued prescriber identification number on a prescription when such use is not otherwise required.

Section 2. Provides an effective date of July 1, 2003.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

Revenues:

None

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2. Expenditures:

See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

See Fiscal Comments.

D. FISCAL COMMENTS:

The fiscal impact on the Department of Health is indeterminate. According to the department, there may be an increase in disciplinary actions against pharmacists if they are convicted of a misdemeanor for violating this prohibition.

Fiscal impacts on the private sector are also indeterminate. According to the department, costs for prescriptions could increase as the costs for prescriptions not reimbursed by third party payers for lack of a DEA number are passed on to them. Pharmacies could see an increase in costs related to changes in software to accommodate the new billing system.

Criminal penalties imposed by the bill are a second degree misdemeanor punishable by up to 60 days in jail as provided for by s. 775.082, F.S., or a fine of up to \$500 as provided by s. 775.083, F.S.

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:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

According to the department, this proposal penalizes a pharmacist for using the DEA number as an identifier for reimbursement/billing purposes, which is a billing practice mandated by third party payers. If insurance companies were prohibited from using the DEA number as an identifier, and instead, used the state issued practitioner license number, as used in the Medicaid program, the problem would be alleviated.

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IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On April 2, 2003, the Health Standards Subcommittee adopted a "strike-all" amendment which:

- Removes the criminal penalties from the bill.
- Provides that Advanced Registered Nurse Practitioners (ARNPs) and Physician Assistants (PAs) shall be issued a DEA registration number for the purposes of prescribing non-controlled substances.
- States that the bill does not authorize ARNPs or PAs receiving such DEA numbers to prescribe controlled substances.

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