HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: SPONSOR(S): TIED BILLS:	HB 103 Quinones None.	Medicinal Drug Prescriptions IDEN./SIM. BILLS: SB 132 (i)				
	REFERENC	E	ACTION	ANALYST	STAFF DIRECTOR	
1) Health Care			<u>23 Y, 0 N</u>	Mitchell	Collins	
2)						
3)						
4)						
5)						

SUMMARY ANALYSIS

The bill creates s. 456.0392, F.S., relating to prescription labeling. The effect of the bill is to allow advanced registered nurse practitioners (ARNPs) and physician assistants (PAs) to prescribe medications for their patients as authorized by statutes, and allow pharmacies to be reimbursed for such prescriptions by insurance companies. The bill requires practitioners who do not have authority to prescribe controlled substances to list their professional license number and name on prescriptions.

Currently, both ARNPs and PAs in Florida are authorized under their practice acts and through rules of their regulatory boards (Board of Nursing and Board of Medicine, respectively) to prescribe non-controlled, legend drugs. ARNPs and PAs are not eligible for a federal Drug Enforcement Administration (DEA) controlled substance registration number under s. 893.02(19), F.S., that is required to write prescriptions for controlled substances.

Currently, some insurance companies require pharmacies to include a federal DEA number as an identifier for each prescription submitted for claim reimbursement, regardless of whether or not it is for a controlled substance. The DEA opposes this practice and supports a consensus statement with physician, nurse and pharmacy associations to eliminate the improper use of DEA numbers. Because ARNPs and PAs are not authorized by Florida law to prescribe controlled substances, they can not obtain DEA numbers. As a result, insurance companies do not reimburse claims for their prescriptions. To obtain reimbursement pharmacists are forced to use the DEA number of the supervising physician, who is not the person who signed the prescription. This is a violation of rules of the Florida Board of Pharmacy.

This bill follows the practice established by Florida Medicaid to allow reimbursement for pharmaceuticals without requiring a DEA number on the prescription.

For the pharmacist, the bill provides that a prescription written by a PA or an ARNP is presumed to be valid and within the parameters of their prescriptive authority when it is not written for a controlled substance. For the consumer, the bill requires the pharmacist or dispensing practitioner to include the prescribing practitioner's name on the container of the drug.

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

According to the Department of Health, the effective date of July 1, 2004, may pose a problem to pharmacists and practitioners who will have to change policies and procedures to comply with the provisions of the bill.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

1.	Reduce government?	Yes[]	No[]	N/A[X]
2.	Lower taxes?	Yes[]	No[]	N/A[X]
3.	Expand individual freedom?	Yes[X]	No[]	N/A[]
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:

B. EFFECT OF PROPOSED CHANGES:

The bill provides that practitioners who do not have authority to prescribe controlled substances, including physician assistants (PA) and advanced registered nurse practitioners (ARNP), shall list their professional license number and name on their prescriptions.

The bill gives pharmacists a better opportunity to fill prescriptions from PAs and ARNPs by creating a presumption, subject to rebuttal, that the prescriptions are valid and within the prescriptive authority of the practitioner, when they are not written for controlled substances.

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

CURRENT SITUATION

Some insurance companies require pharmacies, when submitting claims for prescriptions, to include a federal Drug Enforcement Administration (DEA) number as an identifier for each prescription submitted, regardless of whether or not it is for a controlled substance. Federal DEA numbers are issued to track the prescription of controlled substances by practitioners with such prescribing authority.

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 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 when billing for reimbursement from insurance companies and managed care companies.

Because ARNPs and PAs are not authorized by Florida law to prescribe controlled substances (s. 893.02(19), F.S.), they can not obtain DEA numbers. As a result, some insurance companies do not reimburse claims for prescriptions written by ARNPs and PAs. Pharmacists must either include the DEA number of the supervising physician on the prescription, who is not the person who signed the prescription, or patients are required to pay full price for the prescription and seek reimbursement from the insurance company.

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; or
- (e) Any parenteral preparation except insulin and epinephrine.

Pharmacist's 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 which requires that the name of the actual prescribing practitioner be on each prescription label.

Federal Drug Enforcement Administration Opposition to Use of DEA Numbers for Other than Controlled Substances

The U.S. Department of Justice, Drug Enforcement Administration has notified states of its opposition to any policies that use DEA numbers for other than certification in transactions involving controlled substances. In a letter to the State of Tennessee, Bureau of TennCare (the state Medicaid program), dated June 14, 2002, for example, the Drug Enforcement Administration stated its opposition to TennCare's proposed requirement that a practitioner's DEA registration number be included on all pharmacy claims submitted for payment.

The letter states: "DEA is strongly opposed to the use of DEA registration numbers for any purpose other than to provide certification of DEA registration in transactions involving controlled substances. The Controlled Substances Act of 1970 (CSA) established a closed system of distribution for licit controlled substances which requires those individuals or firms desiring to handle controlled substances to be registered with the DEA. This closed system facilitates an accurate accountability of all controlled substances from their manufacture through and including the dispensing pharmacy. The sole purpose of the DEA registration is to permit a registrant to engage in transactions involving controlled substances. The use of the DEA registration number for any purpose other than to provide certification of registration in transactions involving controlled substances is inappropriate."

Florida Medicaid Already Uses the Practitioner License Number Instead of the DEA Registration Number

According to the Department of Health, in the past, when the Florida Medicaid program used DEA numbers as identifiers for claims, 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.

Efforts to Eliminate Improper Use of DEA Registration Numbers

In 2003, the Drug Enforcement Administration and physician, nurse and pharmacy associations (American Academy of Family Physicians, American College of Physicians—American Society of Internal Medicine, American Academy of Nurse Practitioners, National Association of Boards of Pharmacy, and the American Academy of Physicians) prepared a consensus statement on elimination of the improper use of DEA numbers. The agreement states that the improper use of DEA registration numbers by insurance companies and other health care providers for identification purposes is contrary to national drug control policies and the spirit of the Controlled Substance Act of 1970. The statement argues that improper use for identification purposes results in the unnecessary proliferation of registrations and increases the probability of prescription fraud and diversion. The agreement also states that the use of "fake" or "dummy" DEA registration numbers in pharmacies increases the probability that improper DEA numbers will be used for controlled substance, which is a violation of DEA regulations.

C. SECTION DIRECTORY:

Section 1. Creates section 456.0392, F.S., relating to prescription labeling and presumptive prescribing authority for advance registered nurse practitioners and physician assistants to require certain information on the prescription.

Section 2. Provides an effective date of July 1, 2004.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

- A. FISCAL IMPACT ON STATE GOVERNMENT:
 - 1. Revenues:

None.

2. Expenditures:

None.

- B. FISCAL IMPACT ON LOCAL GOVERNMENTS:
 - 1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Patients and pharmacies will be able to obtain reimbursement from insurance companies for the costs of prescriptions that are written by advanced registered nurse practitioners and physician assistants.

D. FISCAL COMMENTS:

There may be some costs to pharmacies and insurance companies to make changes to recordkeeping systems to allow for reimbursement without the use of federal DEA numbers.

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:

According to the Department of Health, the department has sufficient rule authority to implement this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

According to the Department of Health, the effective date of July 1, 2004, may pose a problem to pharmacists and practitioners who will have to change policies and procedures to comply with the provisions of the bill.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES