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: CS/SB 2084

SPONSOR: Health, Aging, and Long-Term Care Committee and Senator Wasserman Schultz

SUBJECT: Drug Prescriptions

DATE: April 15, 2003 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HC	Favorable/CS
2.				
3.				
4.				
5.				
6.				

I. Summary:

The bill requires a written prescription for a medicinal drug issued by a health care practitioner licensed by law to prescribe such drug to be legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription. The prescription must also contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity in both textual and numerical formats, and directions for use. The prescription must be dated with the month written out in textual letters and signed by the prescribing practitioner on the day when issued.

This bill creates section 456.42, Florida Statutes.

II. Present Situation:

The Practice of Pharmacy and Medication Errors

Chapter 465, F.S., authorizes the regulation of the practice of pharmacy by the Florida Board of Pharmacy. Section 465.0276, F.S., requires any person who is not a licensed pharmacist to register with her or his regulatory board and meet other specified requirements in order to dispense drugs to her or his patients in the regular course of her or his practice for a fee or remuneration. Under s. 465.0276(5), F.S., an exception to these requirements allows a practitioner to dispense drug samples to his or her patients. Under the exception, the practitioner must confine her or his activities to the dispensing of complimentary packages of medicinal drugs to the practitioner's own patients in the regular course of her or his practice, without the payment of fee or remuneration of any kind.

The Florida Board of Pharmacy, pursuant to s. 465.0155, F.S., must adopt by rule standards of practice relating to the practice of pharmacy which shall be binding on every state agency and

must be applied by such agencies when enforcing or implementing any authority granted by any applicable statute, rule, or regulation, whether federal or state. The Florida Board of Pharmacy has adopted an administrative rule[1] relating to pharmacy practice standards that provides requirements for institutional pharmacies to implement a system to identify and evaluate quality-related events and improve patient care.

According to a recent survey developed by the United States Department of Health and Human Services, prescription errors by physicians and pharmacists could cause up to 7,000 deaths this year. In 1983, prescription errors accounted for 2,900 deaths. Some experts are calling for more education, focusing on understanding why medication errors occur, instead of trying to cover up the errors or punishing pharmacists for reporting individual mistakes. In an effort to end the silence surrounding medical errors, 56 of the nation's 6,000 hospitals -- recently joined by more that 200 additional facilities -- have "openly report[ed]" pharmaceutical "blunders" in a "first-of-its-kind" database called MedMarx®, providing a "glimpse into causes of medication errors." During the first year of the program, designed to "curb the miscues" in prescribing and administering drugs, the hospitals reported 6,224 drug therapy errors that injured 187 patients and killed one. During 2001, 368 facilities reported 105,603 medication errors to MedMarx® that resulted in 2,539 patient injuries and 14 deaths.[2]

Health Care Practitioners/Prescribing

Chapter 456, F.S., provides the general regulatory provisions for health care professions within the Division of Medical Quality Assurance in the Department of Health. Section 456.001, F.S., defines "health care practitioner" to mean any person licensed under: ch. 457, F.S., (acupuncture); ch. 458, F.S., (medicine); ch. 459, F.S., (osteopathic medicine); ch. 460, F.S., (chiropractic medicine); ch. 461, F.S., (podiatric medicine); ch. 462, F.S., (naturopathic medicine); ch. 463, F.S., (optometry); ch. 464, F.S., (nursing); ch. 465, F.S., (pharmacy); ch. 466, F.S., (dentistry and dental hygiene); ch. 467, F.S., (midwifery); parts I, II, III, IV, V, X, XIII, and XIV of ch. 468, F.S., (speech-language pathology and audiology, nursing home administration, occupational therapy, radiologic technology, respiratory therapy, dietetics and nutrition practice, athletic trainers, and orthotics, prosthetics, and pedorthics); ch. 478, F.S., (electrology or electrolysis); ch. 480, F.S., (massage therapy); parts III and IV of ch. 483, F.S., (clinical laboratory personnel or medical physics); ch. 484, F.S., (opticianry and hearing aid specialists); ch. 486, F.S., (physical therapy); ch. 490, F.S., (psychology); and ch. 491, F.S. (psychotherapy).

[1] The Florida Board of Pharmacy has adopted 64B16-27.300, Florida Administrative Code. The rule requires each institutional pharmacy to establish a "Continuous Quality Improvement Program," which must be described in the pharmacy's policy and procedure manual and which must include a process for review of events relating to the inappropriate dispensing of prescribed medication. Records maintained as a component of the Continuous Quality Improvement Program are confidential as medical-review activities under s. 766.101, F.S., and are not discoverable or admissible in any disciplinary proceeding against a licensed health care practitioner. Licensed health care practitioners who furnish information to a medical review committee, hospital internal risk management program, the Department of Health or the Agency for Health Care Administration under s. 766.101, F.S., are granted limited immunity to a civil action, if the information is not intentionally fraudulent and is within the scope of the functions of such entities.

[2] See "Administering Drugs Using Wrong Technique Harmful to Patients and Costly to Insurers," U.S. Pharmacopeia at <http://www.onlinepressroom.net/uspharm/>.

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 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. Although advanced registered nurse practitioners may prescribe medications in accordance with a protocol, they cannot prescribe controlled substances.

Physician assistants may prescribe any medication used in the supervisory physician's practice unless it is listed on a "negative" formulary[3] 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.

Under the pharmacy practice act[4], a pharmacist may only dispense a prescription that meets the statutory requirements of a "prescription." A "prescription" includes any order for drugs or medicinal supplies written or transmitted by any means or communication by a duly licensed practitioner authorized by the laws of Florida to prescribe such drugs or medicinal supplies and intended to be dispensed by a pharmacist.[5] The term includes an orally transmitted order by the lawfully designated agent of such practitioner. "Prescription" also includes an order written or transmitted by a practitioner licensed to practice in a jurisdiction other than Florida, but only if the pharmacist called upon to dispense such order determines, in the exercise of her or his professional judgment, that the order is valid and necessary for the treatment of a chronic or recurrent illness. Prescriptions may be retained in written form or the pharmacist may cause them to be recorded in a data system, if the order can be produced in printed form upon lawful request. A pharmacist who dispenses a legend drug without a valid prescription is liable for disciplinary

[3] See ss. 458.347 (4) and 459.022(4), F.S.
[4] See ch. 465, F.S.
[5] See s. 465.003(14), F.S.

action.[6] In practice, the elements of an order for a legend drug should identify the patient, drug to be dispensed, the quantity of the drug, directions for use of the drug, prescriber, and the date of the order.[7]

Disciplinary Procedures for Health Care Practitioners

Section 456.073, F.S., sets forth procedures the Department of Health must follow in conducting disciplinary proceedings against practitioners under its jurisdiction. The department, for the boards under its jurisdiction, must investigate all written complaints filed with it that are legally sufficient. Complaints are legally sufficient if they contain facts, which, if true, show that a licensee has violated any applicable regulations governing the licensee's profession or occupation. Each health care profession's practice act and s. 456.072, F.S., provide grounds for which a health care practitioner may be subject to discipline for failure to comply with applicable professional regulation, including the failure to perform any statutory or legal obligation placed upon a licensee.[8]

Notwithstanding s. 456.073, the board or department if there is no board, must adopt rules to permit the issuance of citations. The citation must clearly state that the subject may choose, in lieu of accepting the citation, to follow the standard procedures for a disciplinary action under s. 456.073, F.S. If the subject does not dispute the matter in the citation within 30 days after the citation is served, the citation becomes a final order and constitutes discipline. The penalty for a citation must be a fine or other conditions as established by rule.

III. Effect of Proposed Changes:

The bill creates s. 456.42, F.S., to require a written prescription for a medicinal drug issued by a health care practitioner licensed by law to prescribe such drug to be legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription. The prescription must also contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity in both textual and numerical formats, and directions for use. The prescription must be dated with the month written out in textual letters and signed by the prescribing practitioner on the day when issued.

The bill provides an effective date of July 1, 2003.

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[6] See s. 465.016(1)(i), F.S.

[7] See e.g., the requirements for an order for controlled substances under s. 893.04, F.S., which 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.

[8] See s. 456.072(1)(k), F.S.

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:

Consumers of health care services will benefit to the extent the bill's requirements on prescriptions reduce medication errors. Health care practitioners who prescribe medications will incur some costs to comply with the bill's requirements.

C. Government Sector Impact:

The Department of Health will incur costs to implement the bill. According to the department, the fiscal impact is unknown because it cannot determine the number of disciplinary complaints that might be received. The department reports that the workload can be handled within existing resources if discipline for violation of the bill is limited to the issuance of a citation.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.