The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1472
INTRODUCER:	Senator Ring
SUBJECT:	Prescription Medication
DATE:	February 5, 2016
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	**Pre-meeting**
2.			AHS	
3.			FP	

I. Summary:

SB 1472 amends several sections of law to require health care practitioners to include on all prescriptions for medicinal drugs or controlled substances, and the labels for the containers used to dispense those prescriptions, the medical condition for which the drug or controlled substance is prescribed.

II. Present Situation:

Current Florida law allows allopathic physicians (MDs), osteopathic physicians (DOs), podiatric physicians (POs), dentists (DMDs or DDSs) and veterinarians (DVM) to prescribe medicinal drugs and controlled substances.[1] A supervising physician (MD, DO) may delegate to a physician assistant (PA) the authority to prescribe medicinal drugs for the practitioner's patients.[2] A supervising physician or dentist may delegate to an advanced registered nurse practitioner (ARNP) the authority to prescribe medicinal drugs under a protocol filed with the Department of Health (DOH).[3] A practitioner's prescriptions for medicinal drugs and controlled substances for a patient can be in oral, written, or electronic formats.[4]

Written and Electronic Medicinal Prescriptions

Section 456.42, F.S., requires that all written or electronic prescriptions for medicinal drugs must be legible and contain the following:

- The name of the prescribing practitioner;
- The name and strength of the drug prescribed;

[1] Chapters 458, 459, 461, 466, 455 and 893, F.S.
[2] Sections 458.347(4) and 459.022(4), F.S.
[3] Section 464.012, F.S.
[4] Section 465.003(14), F.S.

- The quantity of the drug prescribed;
- The directions for use of the drug;
- The dated prescribed; and
- The signature of the prescribing practitioner, either manually or electronically.

If the substance prescribed is a controlled substance listed under ch, 893, F.S., the following additional requirements apply to an oral,[5] written, or electronic prescription:

- The quantity is written both textually and numerically;
- Must be dated numerically with the month, day and year, or with month abbreviated, or written out in whole; and
- Must be written on counterfeit-proof prescription paper or electronically prescribed as that term is defined in s. 408.0611, F.S.[6]

Drug Dispensing Practitioners

A dispensing practitioner authorized to prescribe drugs may also dispense such drugs to her or his patients in the regular course of her or his practice.[7] If the practitioner dispenses the drugs in the manufacturer's package the following information must be added, legibly, to the label:

- Practitioner's name;
- Patient's name; and
- Date dispensed.

If a dispensing practitioner dispenses drugs that are not in the manufacturer's labeled package, they must be dispensed in a container which states the following information:

- Practitioner's name;
- Patient's name;
- Date dispensed;
- Name of drug;
- Strength of drug; and
- Directions for use.

Section 893.05, F.S., authorizes a dispensing practitioner to dispense a controlled substance; but the label of the original container must contain the following:

- The date of delivery;
- The directions for use;
- The name and address of the practitioner;
- The name of the patient, or owner and species of animal, for which a controlled substance is prescribed; and
- A warning that it is a crime to transfer the controlled substance to another person.

[5] A prescription for a controlled substance listed in Schedule II may generally be dispensed only upon a written prescription of a practitioner. However, in an emergency situation a Schedule II controlled substance may be dispensed upon oral prescription but is limited to a 72-hour supply and may not be refilled. See 893.04(1)(f), F.S.

[6] "Electronic prescribing" means, at a minimum, the electronic review of the patient's medication history, the electronic generation of the patient's prescription, and the electronic transmission of the patient's prescription to a pharmacy. Section 408.0611(2)(a), F.S.

[7] Section 456.0276, F.S.

Pharmacists Ordering and Dispensing Drugs

Section 465.186, F.S., permits a pharmacist to order and dispense medicinal drugs[8] under certain terms and limitations[9] from a formulary[10] approved of by the Board of Pharmacy, Formulary Committee. Any drug ordered by a pharmacist must be selected and dispensed by the pharmacist ordering the drug. The order may not be refilled. The pharmacist may not order another medicinal drug for the same condition unless it is consistent with dispensing procedures. Referral to another health care provider is appropriate if, at completion of a drug regime, there is no improvement. The pharmacist must create and maintain a prescription record and a patient profile on all patients for whom he or she prescribes and dispenses medicinal drugs.[11]
The label for the container for a medicinal drug ordered and dispensed by a pharmacist must contain the following information:

- The name of the pharmacist ordering the medication;
- The name and address of the pharmacy from which the medication was dispensed;
- The date of dispensing;
- The order number or other identification to readily identify the order;
- The name of the patient;
- The directions for use; and
- A statement that the order will not be refilled.

Section 893.04, F.S., authorized a pharmacist, in the course of his or her professional practice, to dispense controlled substances upon a written or oral[12] prescription of a practitioner.[13] The oral prescriptions must be promptly reduced to writing by the pharmacist, or recorded electronically. The written prescription must be dated and signed by the prescribing practitioner on the day when issued. The oral, written, or electronic prescription for a controlled substance must contain the following information:

- The full name and address of the person for whom the controlled substance is dispensed;
- The name and address of the owner, and species of the animal, for whom the controlled substance is dispensed;
- The full name and address of the prescribing practitioner and the practitioner's federal controlled substance registry number;
- The name of the controlled substance and the strength, quantity, and directions for use;
- The prescription number;
- The date and initials of the pharmacist filling the prescription;

The label of the container in which a controlled substance is initially delivered, or refilled, must contain the following information:

[8] Rules 64B8-36.002-004, and 64B16-27.210- 230, F.A.C., implement s. 465.186, F.S. These rules set forth which medicinal drug products may be ordered and dispensed by pharmacists and the terms and conditions under which said drugs may be ordered and dispensed.
[9] Rule 64B16-27.210, and Rule 64B8-36.002, F.A.C.
[10] Rule 64B16-27.220, and Rule 64B8-36.003, F.A.C.
[11] Rule 64B16-27.210(7), F.A.C.
[12] Any controlled substance listed in Schedule III or Schedule IV may be dispensed by a pharmacist upon an oral prescription if, before filling the prescription, the pharmacist reduces it to writing or records the prescription electronically if permitted by federal law. Such prescriptions must contain the date of the oral authorization. Section 893.04(2)(c), F.S.
[13] *Supra* note 5.

- The name and address of the dispensing pharmacy;
- The date filled;
- The prescription number as recorded in the pharmacy;
- The name of the prescribing practitioner;
- The name of the patient, or owner and species of the animal;
- The directions for the use; and
- A warning that it is a crime to transfer the controlled substance to any person other than the patient for whom prescribed.

The Health Insurance Portability and Accountability Act (HIPPA)

The Health Insurance Portability and Accountability Act (HIPAA) was enacted in 1996.[14] HIPAA requires the Secretary of HHS to publicize standards for the electronic exchange, privacy and security of health information.[15] The *Standards for Privacy of Individually Identifiable Health Information* (Privacy Rule) establishes a set of national standards for the protection of certain health information. The U.S. Department of Health and Human Services (HHS) issued the Privacy Rule to implement HIPAA. The Privacy Rule standards address the use and disclosure of individuals' *protected health information* by organizations subject to the Privacy Rule as well as standards for individuals' privacy rights to understand and control how their health information is used. Within HHS, the Office for Civil Rights (OCR) has responsibility for implementing and enforcing the Privacy Rule with respect to voluntary compliance activities and civil money penalties.

The Privacy Rule covers a health care provider whether it electronically transmits these transactions directly or uses a billing service or other third party. Health care providers include all "providers of services" (e.g., hospitals) and "providers of medical or health services" (e.g., physicians, dentists and other practitioners) as defined by Medicare, and any other person or organization that furnishes, bills, or is paid for health care. The Privacy Rule protects all *"individually identifiable health information"* held or transmitted by a covered person or entity, in any form or media, whether electronic, paper, or oral. The Privacy Rule calls this information "protected health information (PHI)." PHI is information, including demographic data (e.g., name, address, birth date, social security number) that relates to:

- The individual's past, present or future physical or mental health or condition;
- The provision of health care to the individual; or
- The past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual.[16]

A central aspect of the Privacy Rule is the principle of "minimum necessary" use and disclosure. A covered person or entity must make reasonable efforts to use, disclose, and request only the minimum amount of PHI needed to accomplish the intended purpose of the use, disclosure, or request.[17]

[14] Pub. Law No. 104-191, H.R. 3103, 104th Cong. (Aug. 21, 1996)
[15] U.S. Department of Health and Human Services, *Summary of the HIPAA Privacy Rule* (last revised May 2003) *available at* http://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html, (last visited Feb. 3, 2016).
[16] 45 C.F.R. s. 160.103.
[17] See 45 C.F.R. ss. 164.502(b) and 164.514 (d).

Exceptions to HIPPA

In general, State laws that are contrary to the Privacy Rule are preempted by the federal law.[18] However, preemption of a state law will not occur if HHS determines, in response to a request from a state, entity or person, that the state law:

- Is necessary to prevent fraud and abuse related to the provision of or payment for health care;
- Is necessary to ensure appropriate state regulation of insurance and health plans to the extent expressly authorized by statute or regulation;
- Is necessary for state reporting on health care delivery or costs;
- Is necessary for purposes of serving a compelling public health, safety, or welfare need, and, if a Privacy Rule provision is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or
- Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances or that is deemed a controlled substance by state law.

In addition, a covered person or entity is permitted, but not required, to use and disclose protected health information, without an individual's authorization, for the following purposes or situations:

- To the Individual, or his or her legal representative;
- Treatment, payment, and health care operations;
- Opportunity to agree or object;
- Incident to an otherwise permitted use and disclosure;
- Public interest and benefit activities; and
- As a limited data set for the purposes of research, public health or health care operations.[19]

Covered persons and entities may rely on professional ethics and best judgments in deciding which of these permissive uses and disclosures to make.

III. Effect of Proposed Changes:

SB 1472 amends ss. 456.42, 465.0276, 465.186, 893.04, and 893.05, F.S., to require physicians, dentists, ARNP's and PAs to include on all written or electronic prescriptions, and some oral prescriptions, issued by a health care practitioners licensed by law to prescribe medicinal drugs, or controlled substances listed in ch. 893, F.S., and on the labels for the containers used to dispense those prescriptions, the medical condition for which the drug or controlled substance is prescribed.

The bill is effective July 1, 2016.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

[18] 45 C.F.R. s. 160.203.
[19] 45 C.F.R. s. 164.502(a)(1).

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Displaying the condition for which a particular medication was prescribed might prevent patients from incorrectly taking their medications.

The bill adds an additional requirement for physicians, dentists, ARNPs and PAs to comply with when writing prescriptions which may impact practitioner efficiency in the delivery of health care services.

The label on the dispensed medication could be viewed by other unanticipated and unintended members of the public, such as the clerk at the register when the prescription is paid for, or the visitor who sees the bottle on the patient's kitchen table.

C. Government Sector Impact:

None

VI. Technical Deficiencies:

None.

VII. Related Issues:

Notwithstanding the HIPAA exceptions pertaining to discussing a patient's medical condition without expressed patient consent, the bill may require an unauthorized disclosure of PHI and be ruled a HIPPA violation of the "minimally necessary" principles of the act. The bill may need an amendment to express the state's compelling public health purpose for the disclosure requirements in this bill.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 456.42, 465.0276, 465.186, 893.04, and 893.05.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.