By Senator Bennett

21-01257-09 20091356

A bill to be entitled

An act relating to monitoring the dispensing of controlled substances; creating s. 893.055, F.S.; providing definitions; requiring the Department of Health to establish a comprehensive electronic system to monitor the dispensing of certain controlled substances; requiring those who dispense certain controlled substances to submit specified information to the department; providing exceptions to reporting requirements; requiring that information be submitted in an approved electronic format; providing time periods for information submission; providing criminal penalties for violations; requiring rulemaking; providing requirements for system funding; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 893.055, Florida Statutes, is created to read:

893.055 Electronic monitoring system for the dispensing of certain controlled substances.—

(1) As used in this section, the term:

(a) "Health care practitioner" or "practitioner" means any practitioner subject to licensure or regulation by the department under chapter 458, chapter 459, chapter 461, or chapter 466.

(b) "Pharmacy" means any pharmacy subject to licensure or regulation by the department under chapter 465, or that would be

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subject to such licensure if it were located in this state, that dispenses a controlled substance listed in Schedule II, Schedule III, or Schedule IV to an individual or address in this state.

- (2) No later than June 30, 2010, the department shall design and establish a comprehensive electronic system, consistent with standards of the American Society for Automation in Pharmacy, to monitor the prescribing and dispensing of controlled substances listed in Schedule II, Schedule III, and Schedule IV by health care practitioners and the dispensing of such controlled substances to an individual or address in this state by a pharmacy required to be permitted or registered by the Board of Pharmacy or through a dispensing transaction with a pharmacy not located in this state that is otherwise subject to the jurisdiction of this state as to that dispensing transaction. The department may contract with another state agency or with a private vendor to establish and maintain the system.
- (3) Except as provided in subsection (4), each time a controlled substance listed in Schedule II, Schedule III, or Schedule IV is dispensed to an individual or address in this state, the pharmacy or dispensing practitioner shall report to the department information determined by rule of the department that shall include, but not be limited to, the following:
- (a) 1. The full name, address, date of birth, and social security number of the patient for whom, or the owner of the animal for which, the controlled substance is dispensed.
- 2. If the prescription is for an animal, the species of the animal for which the controlled substance is prescribed.
 - (b) The name, strength, quantity, and National Drug Code

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(NDC) number of the controlled substance dispensed.

- (c) The full name, address, and federal controlled substance registry number of the prescribing practitioner.
- (d) The date the prescription was issued by the prescribing practitioner.
- (e) The full name, address, and federal controlled substance registry number of the pharmacy or dispensing practitioner.
- (f) The date the prescription was filled by the pharmacy or dispensing practitioner.
- (g) The number of the prescription as recorded in the prescription files of the pharmacy in which it is filled.
 - (4) This section does not apply to controlled substances:
- (a) Administered by a health care practitioner directly to a patient.
- (b) Dispensed by a health care practitioner authorized to prescribe controlled substances directly to a patient and limited to an amount adequate to treat the patient for a period of not more than 72 hours.
- (c) Dispensed by a health care practitioner or a pharmacist to an inpatient of a facility that holds an institutional pharmacy permit.
- (d) Ordered from an institutional pharmacy permitted under s. 465.019 in accordance with the institutional policy for such controlled substances.
- (e) Administered by a health care practitioner to a patient or resident receiving care from a hospital, nursing home, assisted living facility, home health agency, hospice, or intermediate care facility for the developmentally disabled that

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is licensed in this state.

(5) A practitioner or pharmacist whose dispensing of a controlled substance is required to be reported under this section must submit the information required by this section in an electronic or other format approved by rule of the department. The cost to the practitioner or pharmacist in submitting the information required by this section may not be material or extraordinary.

- (6) A practitioner or pharmacist who dispenses a controlled substance under this section must, unless an extension is approved by the department for cause, submit the information required by subsection (3) within 14 days after dispensing a controlled substance during the first year of the system's operation and within 7 days after dispensing a controlled substance in each year thereafter.
- (7) Any person who knowingly fails to report the dispensing of a controlled substance as required by this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.
- (8) The department and the regulatory boards for the health care practitioners subject to this section shall adopt rules pursuant to ss. 120.536(1) and 120.54 to administer this section.
- (9) All costs incurred by the department in administering the system shall be funded through federal, private, or grant funding. State funds may be used to the extent that they are available.
 - Section 2. This act shall take effect July 1, 2009.