By Senator Fasano

11-00424-09 2009462__

A bill to be entitled

An act relating to controlled substances; creating s. 893.055, F.S.; providing definitions; requiring the Agency for Health Care Administration to establish a statewide, comprehensive electronic system to monitor the prescribing and dispensing of controlled substances listed in Schedule II, Schedule III, or Schedule IV; providing reporting requirements; requiring the agency to notify certain dispensers and prescribers of the implementation date for the reporting of controlled substances; specifying circumstances under which a pharmacy or practitioner is exempt from participating in the system; requiring prescribing or dispensing pharmacists and practitioners to submit information in a certain format; providing a penalty; requiring that the department and regulatory boards adopt rules; requiring that all costs incurred by the agency be paid through federal, private, or grant funding sources; 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 prescription of controlled substances listed in Schedule II, Schedule III, or Schedule IV.—

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

(a) "Agency" means the Agency for Health Care Administration.

(b) "Department" means the Department of Health.

(c) "Pharmacy" means any pharmacy that is subject to licensure or regulation by the department pursuant to chapter 465 and that dispenses or delivers a controlled substance included in Schedule II, Schedule III, or Schedule IV in s. 893.03 to a patient in this state.

(2) By June 30, 2010, the agency shall design and establish an electronic system consistent with standards of the American Society for Automation in Pharmacy to monitor the prescribing of controlled substances listed in Schedule II, Schedule III, or Schedule IV in s. 893.03 by health care practitioners and the dispensing of such controlled substances to an individual by a dispensing practitioner pursuant to chapter 465 or a pharmacy permitted or registered by the Board of Pharmacy pursuant to chapter 465.

(3) Each time a controlled substance listed in Schedule II, Schedule III, or Schedule IV is dispensed to an individual, the controlled substance must be reported to the agency through the system as soon thereafter as possible, but not more than 15 days after the date the controlled substance is dispensed. A pharmacy or dispensing practitioner may meet the reporting requirements of this section by providing to the agency in written or any electronic or magnetic format, including, but not limited to, electronic submission via the Internet or magnetic disc or tape, each controlled substance listed in Schedule II, Schedule III, or Schedule IV which it dispenses.

(4) The agency shall notify each dispenser and prescriber

subject to the reporting requirements in this section of the implementation date for the reporting requirements as set forth in the rules of the agency.

(5) 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 or drugs.

(e) Dispensed by a pharmacist or 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 which is licensed in this state.

(6) The data required to be reported under this section shall be determined by the department by rule and may include, but is not limited to, any data required under s. 893.04.

(7) A practitioner or pharmacist who dispenses a controlled substance listed in Schedule II, Schedule III, or Schedule IV in s. 893.03 must submit the information required by this section in an electronic or other format approved by rule of the agency. The cost to the dispenser in submitting the information required

by this section may not be material or extraordinary. Costs not considered to be material or extraordinary include, but are not limited to, regular postage, compact discs, zip-drive storage, regular electronic mail, magnetic tapes, diskettes, and facsimile charges. The information submitted to the agency under this section may be transmitted to any person or agency authorized to receive it pursuant to chapter 119, and that person or agency may maintain the information received for up to 24 months before purging the information from its records. All transmissions required by this subsection must comply with relevant privacy and security laws of the state and federal government. However, any authorized agency receiving such information may maintain it for longer than 24 months if the information is pertinent to an ongoing investigation or prosecution.

(8) Any person who knowingly fails to report the dispensing of a controlled substance listed in Schedule II, Schedule III, or Schedule IV as required by this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(9) The department and the regulatory boards for the health care practitioners subject to this section shall adopt rules to administer this section.

(10) All costs incurred by the agency in administering the prescription-monitoring system shall be through federal, private, or grant funding applied for by the state. The agency and state government shall cooperate in seeking grant funds at no cost to the agency.

Section 2. This act shall take effect July 1, 2009.