A bill to be entitled

An act relating to monitoring controlled substance prescriptions; creating s. 893.055, F.S.; providing a definition; requiring the Department of Health to establish, initially within specified counties, a comprehensive electronic system to monitor the dispensing of specified controlled substances; requiring the department to phase in implementation statewide; requiring the dispensing of such controlled substances to be reported to the department through the system; providing exceptions; providing for rulemaking concerning data to be reported and for reporting formats; providing that costs for required reporting by dispenser may not be material or extraordinary; providing that specified costs are not material or extraordinary; authorizing transmission of data to certain persons or agencies; providing for data retention; requiring that data transmissions comply with privacy and security laws; providing penalties for violations; requiring that the department and regulatory boards adopt rules; requiring the department to obtain financial assistance through grants; providing an effective date.

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

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

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893.055 Electronic monitoring system for dispensing of controlled substances listed in Schedules II, III, and IV.--

- (1) As used in this section, the term "pharmacy" means any pharmacy subject to licensure or regulation by the department under chapter 465 that dispenses or delivers a controlled substance listed in Schedule II, Schedule III, or Schedule IV to a patient in this state.
- establish an 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, or Schedule IV by health care practitioners and the dispensing of such controlled substances to an individual by a pharmacy permitted or registered by the Board of Pharmacy. Initially, the system shall be implemented in Broward County and Palm Beach County only. The department shall implement expansion of the program to include the remaining counties of the state in accordance with a plan to be developed by the department.
- (3) Each time a controlled substance listed in Schedule II, Schedule III, or Schedule IV is dispensed to an individual in the county, the controlled substance must be reported to the department through the system as soon thereafter as possible but not more than 35 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 department, in a format approved by the department as provided

in subsection (6), each controlled substance listed in Schedule II, Schedule III, or Schedule IV that it dispenses.

- (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) 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 that is licensed in this state.
- (5) The data required to be reported under this section shall be determined by the department by rule but may include any data required under s. 893.04.
- (6) A practitioner or pharmacist who dispenses a controlled substance under this section must submit the information required by this section in a written or electronic or other format approved by rule of the department. The cost to the dispenser in submitting the information required by this

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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 department under this section may be transmitted to any person or agency authorized to receive it under 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 the 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.

- (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 prescription monitoring system shall be paid through a grant applied for by the county or the state. The department and local government will cooperate in seeking grant funds at no cost to the department.

111 Section 2. This act shall take effect July 1, 2008.

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