By Senator Aronberg

27-00714-09 2009614

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 and to collect biometric identifiers of recipients; requiring health care practitioners and pharmacies who dispense certain controlled substances to have an active and operational biometric scanning device connected to a database and to submit specified information to the database before dispensing such substances; requiring the database to assign a unique identifier to each prescription and to provide specified information concerning any conflicting or overlapping prescriptions to the prescribing practitioner; providing exceptions to reporting requirements; requiring that data be submitted in an approved electronic format; providing for data retention; requiring that data transmissions comply with privacy and security laws; providing for rulemaking concerning data to be reported and for reporting formats; providing criminal penalties for violations; specifying an effective date for criminal penalties; 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

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30 read:

4.3

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

- (1) As used in this section and s. 893.0551, the term:
- (a) "Biometric identifier" means an established unique form of biological identification readily compared and matched, such as a fingerprint, retinal scan, or other means of similar biometric identification approved by the department and authorized for retention in a database.
- (b) "Biometric scan" means an electronic scan of a biometric identifier.
- (c) "Biometric scanning device" means an electronic scanning device approved by the department that is designed to accurately capture a biometric identifier.
- (d) "Database" means an electronic database, or network of databases, that is maintained by or contracted for by the department and that maintains and compares each biometric scan and the information contained therewith in conformity with the provisions of this section.
- (e) "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.
- (f) "Pharmacy" means a pharmacy subject to licensure or regulation by the department under chapter 465.
- (2) By March 1, 2011, the department shall adopt an electronic monitoring system to monitor the collection of biometric identifiers and to record and store, in a secure database, the following:

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(a) The dispensing of controlled substances listed in Schedule II, Schedule III, and Schedule IV by health care practitioners within the state.

- (b) The dispensing or delivering of controlled substances listed in Schedule II, Schedule III, and Schedule IV to individuals in this state by any pharmacy licensed in this state and by any health care practitioner registered with the department as a dispensing practitioner.
- (3) Any health care practitioner who dispenses or delivers a controlled substance listed in Schedule II, Schedule III, or Schedule IV must have in the practitioner's office an active and operational biometric scanning device connected to the database. Any such practitioner who dispenses or delivers such a controlled substance to a person in this state must first obtain a biometric scan of an approved biometric identifier of the person through use of the biometric scanning device and submit the same to the database.
- (4) Any pharmacy that dispenses or delivers a prescription for a controlled substance listed in Schedule II, Schedule III, or Schedule IV must have in the pharmacy an active and operational biometric scanning device connected to the database. Any pharmacy that dispenses or delivers a prescription for such a controlled substance to a person in this state must first obtain a biometric scan of an approved biometric identifier of the person through use of the biometric scanning device and submit the same to the database.
- (5) Prior to dispensing or delivering a controlled substance listed in Schedule II, Schedule III, or Schedule IV to a person in this state, every health care practitioner and

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prescribing pharmacy must submit the following information to
the database:

- (a) The biometric scan of the person's biometric identifier.
- (b) The full name and address of the prescribing practitioner.
 - (c) The date of each prescription.
- (d) The name of the controlled substance prescribed and the strength, quantity, and directions for use thereof.
- (6) After receiving the information required under subsection (5), the database shall assign the prescription a unique identifying number and shall immediately transmit the following to the prescribing practitioner:
 - (a) The unique identifying number.
- (b) The names of controlled substances listed in Schedule II, Schedule III, and Schedule IV that have been prescribed in connection with the biometric scan submitted that may conflict with or overlap the prescribing practitioner's prescription.
- (c) The full name and address of the practitioner whose prescription may conflict with or overlap the prescribing practitioner's prescription and the full name and address of the practitioner or pharmacy that dispensed or delivered the conflicting or overlapping prescription.
- (7) Prior to dispensing or delivering a prescription for a controlled substance listed in Schedule II, Schedule III, or Schedule IV, the pharmacist or dispensing health care practitioner shall submit the biometric scan of the person's biometric identifier to the database and the database shall immediately transmit the following to the pharmacy or dispensing

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117 health care practitioner:

(a) The names of controlled substances listed in Schedule II, Schedule III, and Schedule IV that have been prescribed in connection with the biometric scan submitted that may conflict with or overlap the prescription to be dispensed or delivered.

- (b) The full name and address of the practitioner whose prescription may conflict with or overlap the prescription to be dispensed or delivered and the full name and address of the practitioner or pharmacy that dispensed or delivered the conflicting or overlapping prescription.
- (8) The database shall not retain personal protected health care information other than the biometric scans and the prescription information provided to the database pursuant to subsections (6) and (7). This section shall not preclude health care practitioners and pharmacies from retaining personal information on their patients that is collected and maintained in their regular course of business in compliance with applicable law.
- (9) This section does not apply to controlled substances listed in Schedule II, Schedule III, or Schedule IV:
- (a) Administered by a health care practitioner directly to his or her patient;
- (b) Dispensed or delivered 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 no more than 72 hours;
- (c) Dispensed or delivered by a health care practitioner or a pharmacist to an inpatient of a facility that holds an institutional pharmacy permit;

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(d) Ordered from an institutional pharmacy licensed under s. 465.019 in accordance with internal policy and procedure for controlled substances listed in Schedule II, Schedule III, and Schedule IV;

- (e) Dispensed or delivered 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 care agency, hospice, or intermediate care facility for the developmentally disabled that is licensed in this state;
- (f) Prescribed by a health care practitioner for a patient younger than 16 years of age;
- (g) Prescribed or dispensed pursuant to rule adopted by the department; or
- (h) Administered, prescribed, dispensed, or delivered under circumstances in which the pharmacist or practitioner cannot, in good faith, comply with the provisions of this section.
- (10) A dispensing practitioner or pharmacist who dispenses or delivers a controlled substance listed in Schedule II,

 Schedule III, or Schedule IV shall submit the information required under this section to the department, or any person or agency authorized by the department, in an electronic format approved by the department. The department, or the person or agency authorized by the department, shall maintain the information for no longer than 24 months from the date of receipt and shall thereafter expunge the information unless otherwise directed by a court of competent jurisdiction.
- (11) All transmissions required by this section must comply with relevant federal and state privacy and security laws.
 - (12) By March 1, 2010, the department, together with the

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175 Board of Pharmacy and the Board of Medicine, shall adopt rules 176 pursuant to ss. 120.536(1) and 120.54 governing the 177 administration of this section, including rules governing access 178 to the database by practitioners and pharmacists and 179 implementing procedures to be employed when a biometric scanning 180 device is inoperable or the database is inaccessible. 181 (13) Any person who knowingly fails to comply with any 182 provision of this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. 183 Section 2. The penalties in s. 893.055(13), Florida 184 185 Statutes, as created by this act, shall take effect March 1, 186 2011, or upon the adoption of the rules pursuant to s. 187 893.055(12), Florida Statutes, as created by this act, whichever 188 occurs first, and shall apply to acts or omissions on or after 189 that date.

Section 3. This act shall take effect July 1, 2009.

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