

HOUSE No.
44784478

The Commonwealth of Massachusetts

By Mr. Sánchez of Boston, for the committee on Public Health, on House Nos. 1116, 2089, 2115, 2182, and 3599, a Bill relative to the enhancement of the prescription monitoring program (House No. 4478). February 8, 2010.

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the passage of the accompanying bill:
An Act RELATIVE TO THE ENHANCEMENT OF THE PRESCRIPTION MONITORING PROGRAM.

FOR THE COMMITTEE

NAME:

Jeffrey Sánchez

DISTRICT/ADDRESS:

15th Suffolk

The Commonwealth of Massachusetts

In the Year Two Thousand and Ten

An Act RELATIVE TO THE ENHANCEMENT OF THE PRESCRIPTION MONITORING PROGRAM.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. Section 1 of chapter 94C of the General Laws, as appearing in the 2008 Official Edition, is hereby amended by inserting after the definition "Dispense" the following definition:-
"Dispenser", a person who delivers a schedule II to V, inclusive, controlled substance to the ultimate user, but shall not include: (a) a licensed hospital pharmacy that distributes such substances for the purpose of inpatient hospital care or the dispensing of prescriptions for controlled substances at the time of discharge from such a facility; or (b) a wholesale distributor of a schedule II to V, inclusive, controlled substance.

SECTION 2. Said section 1 of said chapter 94C, as so appearing, is hereby further amended by inserting after the definition "Nurse practitioner" the following definition:-

"Official prescription forms", the serialized and tamper-resistant prescription forms provided by the department pursuant to section 49.

SECTION 3. Said chapter 94C, as so appearing, is hereby further amended by inserting after section 24 the following section:-

Section 24A. (a) The department shall establish and maintain an electronic system to monitor the prescribing and dispensing of all Schedule II to V, inclusive, controlled substances and certain additional drugs by all professionals licensed to prescribe or dispense such substances. "Additional drugs" shall mean substances determined by the department in conjunction with the executive office of public safety that demonstrate a bona fide potential of abuse. The department shall enter into reciprocal agreements with any other state to share prescription drug monitoring information if the other state's prescription drug monitoring program is compatible with the program as set forth in this section.

(b) The requirements of this section shall not apply to the dispensing of controlled substances to inpatients in a hospital or long term facility or at the time of discharge from said hospital or facility.

(c) Each dispenser shall submit to the department, by electronic means, information regarding each prescription dispensed for a drug included pursuant to subsection (a) as required by rules and regulations promulgated by the department. Each dispenser shall submit the information in accordance with

transmission methods and frequency promulgated by the department, but at least once every 7 days. The department may issue a waiver to a dispenser that is unable to submit prescription information by electronic means. Such waiver shall permit the dispenser to submit prescription information by other means promulgated by the department, provided all information required in this section is submitted in this alternative format.

(d) Any practitioner or dispenser shall keep for at least 2 years from the date of preparation, every report, inventory and record regarding the procuring, use, storage and dispensing for all drugs included under subsection (a).

(e) Prescription information submitted to the department pursuant to this section shall be confidential and exempt from disclosure under chapter 66 and clause Twenty-sixth of section 7 of chapter 4 and not subject to public or open records laws. The department shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted and maintained is not disclosed to persons except as provided for in this chapter.

(f) The department shall review the prescription and dispensing monitoring information. If there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the department shall notify the appropriate law enforcement or professional licensing, certification or regulatory agency or entity, and provide prescription information required for an investigation.

(g) The department shall, upon request, provide data from the prescription monitoring program to the following:-

- (1) persons authorized to prescribe or dispense controlled substances, for the purpose of providing medical or pharmaceutical care for their patients;
- (2) individuals who request their own prescription monitoring information in accordance with procedures established under chapter 66A;
- (3) persons authorized to act on behalf of state boards and regulatory agencies that supervise or regulate a profession that is authorized to prescribe controlled substances; provided, that the data request is in connection with a bona fide specific drug related investigation;
- (4) local, state and federal law enforcement or prosecutorial officials working with the executive office of public safety engaged in the administration, investigation or enforcement of the laws governing prescription drugs; provided, that the data request is in connection with a bona fide specific drug related investigation;
- (5) personnel of the executive office of health and human services regarding Medicaid program recipients, provided, that the data request is in connection with a bona fide specific drug related investigation; or
- (6) personnel of the United States attorney, office of the attorney general or the district attorneys; provided, that the data request is in connection with a bona fide specific drug related investigation.

- (h) The department may provide de-identified, aggregate information to public or private entities for statistical, research or educational purposes.
- (i) The department may contract with another agency of this state or with a private vendor, as necessary, to ensure the effective operation of the prescription monitoring program. Any contractor shall be bound to comply with the provisions regarding confidentiality of prescription information in this section and shall be subject to the penalties specified in this section.
- (j) The department shall promulgate rules and regulations setting forth the procedures and methods for implementing this section.
- (k) The department in conjunction with the executive office of public safety shall submit an annual report on the effectiveness of the prescription monitoring program with the clerks of the house and senate who shall forward the same to the chairs of the joint committee on public health and the chairs of the joint committee on public safety and homeland security.
- (l) Whoever violates this section shall be punished by imprisonment in a state prison for not more than 3 years or in a jail or house of correction for not more than 2½ years or by a fine of not more than \$2,000, or both; and, for a second or subsequent offense of this section or in this chapter, by imprisonment in a state prison for not more than 10 years or in a jail or house of correction for not more than 2 1/2 years, or by a fine of not more than \$10,000, or both.

SECTION 4. Said chapter 94C, as so appearing, is hereby further amended by adding the following 2 sections:-

Section 49. (a) As used in this section "facility" shall, unless the context clearly requires otherwise, mean any individual, partnership, association, corporation or trust that employs more than one health care provider who can prescribe controlled substances, including but not limited to: a hospital or clinic licensed or maintained by the department, a public medical institution as defined in section 8 of chapter 118E or an institution licensed or maintained by the department of mental health.

(b) The department shall designate an official Massachusetts prescription form. The form shall be serialized and tamper-resistant. For the purposes of this section, tamper-resistant is defined as having one or more of the following industry-recognized features designed to prevent: (i) unauthorized copying of a completed or blank prescription form; (ii) the erasure or modification of information written on the prescription by the prescriber; and (iii) the use of counterfeit prescription forms. The department may contract with a private vendor to develop and print the official prescription form from a third party vendor; provided, the printer has met security regulations promulgated by the department.

(c) The official prescription forms shall be provided by the department or by the private vendor to registered practitioners and facilities without charge. Each series of prescriptions shall be issued to a specific practitioner in consecutively numbered blocks and shall only be used by that practitioner. The department shall establish security regulations for the procurement and dissemination of the official prescription forms.

(d) A practitioner authorized to write a prescription shall issue all written prescriptions upon an official prescription form. A pharmacist shall not fill a written prescription from a practitioner unless issued upon an official prescription form. Nothing in this section shall be construed to impact regulations regarding oral, electronic or out-of-state prescription practices.

(e) A practitioner or facility shall register with the department in order to be issued official prescription forms. Registration shall be without charge. Registration shall include, but not be limited to:-

- (1) the name of a practitioner authorized to prescribe controlled substances;
- (2) the primary address and the address of additional places of business;
- (3) the practitioner's drug enforcement agency number; and
- (4) practitioner's license number.

A practitioner's or facility's registration shall be subject to approval in a manner promulgated by the department. Any change to a practitioner's or a facility's registered information shall be promptly reported to the department in a manner promulgated by the department.

(f) A registered facility shall obtain official Massachusetts prescription forms for use at the facility and shall assign the forms to registered staff practitioners. The department shall issue a reasonable quantity of prescription forms to registered practitioners or facilities upon request. Official prescription forms shall be imprinted with:

- (1) the name of the registered practitioner or facility;
- (2) the registered practitioner's drug enforcement agency's identification number;
- (3) the primary address and the address of additional places of business of the registered practitioner; and
- (4) the registered practitioner's license number.

An official prescription form is not transferable and shall be used only by the registered practitioner to whom it was issued.

(g) A registered practitioner or facility shall undertake adequate safeguards and security measures promulgated by the department to assure against destruction, theft or unauthorized use of an official prescription form. A registered practitioner shall, at minimum, maintain a record of official prescription forms received and establish a system requiring forms be secure pursuant to security measures promulgated by the department. A registered facility shall, at minimum, maintain a record of official prescription forms received, maintain a record of forms assigned to its registered staff practitioners, establish a system requiring forms be secure pursuant to security measures promulgated by the department and require a registered staff practitioner to surrender their assigned forms when the practitioner terminates affiliation with the registered facility.

(h) A registered practitioner or facility shall immediately notify the department, in a manner promulgated by the department, upon their knowledge of the loss, destruction, theft or unauthorized use of an official

prescription form. A registered practitioner or facility shall report the failure to receive official prescription forms to the department within a reasonable time after ordering the forms. A registered practitioner or facility shall immediately notify the department upon their knowledge of prescription diversion or suspected diversion pursuant to the loss, theft or unauthorized use of an official prescription form.

(i) Whoever violates a provision of this section shall be punished by imprisonment in a state prison for not more than 3 years or in a jail or house of correction for not more than 2 ½ years or by a fine of not more than \$2,000, or both; and, for a second or subsequent offense in this section or in this chapter, by imprisonment in a state prison for not more than 10 years or in a jail or house of correction for not more than 2 ½ years or by a fine of not more than \$10,000, or both.

(j) The department in conjunction with the executive office of public safety shall submit an annual report on the effectiveness the official Massachusetts prescription form with the clerks of the house and senate who shall forward the same to the chairs of the joint committee on public health and the chairs of the joint committee on public safety and homeland security.

Section 50. The executive office of public safety, in consultation with the department, shall enforce sections 24A and 49. To carry out this purpose, the executive office of public safety shall:-

(a) inspect, copy and audit records, inventories of controlled substances and reports required under said sections 24A and 49 and rules and regulations adopted under said sections;

(b) enter the premises of regulated distributors and dispensers during normal business hours to conduct administrative inspections;

(c) assist law enforcement agencies in enforcing this chapter;

(d) conduct investigations to enforce this chapter;

(e) present evidence obtained from investigations conducted in conjunction with the office of the attorney general and the appropriate district attorneys for civil or criminal prosecution or for administrative action against regulated distributors, dispensers and licensees; and

(f) work in cooperation with the department to accomplish the purposes of said sections 24A and 49.

SECTION 5. Notwithstanding any general or specific law to the contrary, the department of public health shall promulgate rules and regulations relative to the prescription monitoring program established by section 24A of chapter 94C (i) requiring dispensers to report data to the prescription monitoring program at the time the substance is dispensed and (ii) providing real-time access for persons authorized to prescribe or dispense controlled substances in the course of their professional duties not later than October 1, 2012.

SECTION 6. The department of public health and the executive office of public safety shall submit a report on the status of this act with the clerks of the house and senate who shall forward the same to the chairs of the joint committee on public health and the chairs of the joint committee on public safety and homeland security not later than September 1, 2010.

SECTION 7. Section 3 shall take effect on January 1, 2011.