

HOUSE No. 2182

The Commonwealth of Massachusetts

In the Year Two Thousand Nine

An Act relative to safeguarding and monitoring prescription drugs. ..

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

1 SECTION 1

2 Chapter 94C of the General Laws, as appearing in the 2006 Official Edition, is hereby
3 amended by inserting following Section 15 the following section:-

4 Section 15A.

5 As used in the sections 15A and 22A, the following words shall have the following
6 meanings:

7 A. (1) “Dispenser” a person who delivers a Schedule II–V controlled substance to the
8 ultimate user, but does

9 not include: (a) a licensed hospital pharmacy that distributes such substances for the
10 purpose of inpatient

11 hospital care or the dispensing of prescriptions for controlled substances at the time of
12 discharge

from such a facility; or

(b) a wholesale distributor of a Schedule II–V controlled substance.

(2) “Diversion investigation unit” the diversion investigation unit of the Massachusetts state police.

(3) “Facility” a health care provider, registered with the department of public health, which employs more than one person who can prescribe drugs.

(4) “Official prescription forms” the serialized and tamper-resistant prescription pads.

(5) “Patient” the person or animal who is the ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed.

B. (1) The department and the diversion investigation unit shall establish and maintain a program for the monitoring of prescribing and dispensing of all Schedule II, III, IV and V controlled substances and additional drugs identified by the department and the diversion investigation unit as demonstrating a potential for abuse by all professionals licensed to prescribe or dispense such substances in Massachusetts.

(2) 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 the hospital or facility.

(3) Each dispenser shall submit to the department and the diversion investigation unit by electronic means information regarding each prescription dispensed for a drug included under paragraph (1) of this subsection. The information submitted for each prescription shall include, but not be limited to:

- 34 (a) pharmacy prescription number;
- 35 (b) pharmacy number (NABP);
- 36 (c) patient identifier including name and one of the following:
- 37 (i) driver's license number,
- 38 (ii) social security number,
- 39 (ii) Mass ID number.
- 40 (d) patient address;
- 41 (e) patient date of birth;
- 42 (f) prescription is new or is a refill;
- 43 (g) national drug code (NDC) of controlled substance dispensed;
- 44 (h) metric quantity of controlled substance dispensed;
- 45 (i) estimated days supply of controlled substance dispensed;
- 46 (j) practitioner's U.S. drug enforcement administration (DEA) registration number;
- 47 (k) practitioner's license number;
- 48 (l) date prescription issued by practitioner;
- 49 (m) date the controlled substance is dispensed;
- 50 (n) name of person who receives the prescription from the dispenser, if other than

the patient and one of the following:

(i) driver's license number,

(ii) social security number,

(ii) Mass ID number;

(o) source of payment for prescription

(p) state issued serial number corresponding to official Massachusetts prescription form

(4) Each dispenser shall submit the information in accordance with transmission methods and frequency promulgated by the department and the diversion investigation unit but shall report at least every 30 days, before the 15th of the month following the month the prescription was dispensed.

(5) The department and the diversion investigation unit may issue a waiver to a dispenser that is unable to submit prescription information by electronic means. Such waiver may permit the dispenser to submit prescription information by other means promulgated by the Department, provided all information required in paragraph (3) of this subsection is submitted in this alternative format.

C.(1) Persons registered to manufacture, distribute, dispense, or possess controlled substances shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of the Federal "Comprehensive Drug Prevention and Control Act of 1970" or as amended, and the Federal Food, Drug and Cosmetic Act, and with any additional rules or regulations promulgated by the board of registration in pharmacy in the case of a retail drug business or wholesale druggist or by the commissioner in all other cases.

(2) 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 paragraph (1) of subsection A.

D. (1) Prescription information submitted to the Department and the Diversion Investigation Unit shall be confidential and not subject to public or open records laws, except as provided in paragraphs (3), (4) and (5) of this subsection.

(2) The Department and the Diversion Investigation Unit 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 in paragraphs (3), (4) and (5) of this subsection.

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

(4) The department and the diversion investigation unit shall be authorized to provide data in the prescription monitoring program to the following persons:

(a) persons authorized to prescribe or dispense controlled substances, for the purpose of providing medical or pharmaceutical care for their patients.

(b) an individual who requests the individual's own prescription monitoring information
in

accordance with procedures established under Chapter 66A of the General Laws.

(c) 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, including but
not

limited to the following:

(i) board of registration in pharmacy;

(ii) board of registration of allied mental health and human

service professions;

(iii) board of registration in medicine;

(iv) board of registration in veterinary medicine;

(v) board of registration in dentistry,

(vi) board of physician assistants

(d) local, state and federal law enforcement or prosecutorial officials working with the
diversion investigation unit engaged in the administration, investigation or enforcement of the
laws governing prescription drugs.

110 (e) personnel of the executive office of health and human services regarding medicaid
111 program recipients.

112 (f) personnel of the United States Attorney, Attorney General or the District Attorneys
113 under subpoena or court order.

114 (h) personnel of the department or the state police for purposes of administration and
115 enforcement

116 of Chapter 94C of the General Laws.

117 (5) The department or the diversion investigation unit may provide data to public or
118 private entities for statistical, research, or educational purposes after removing information that
119 could be used to identify individual patients or persons who received prescriptions from
120 dispensers.

121 E. The department and the diversion investigation unit are authorized to contract with
122 another agency of this

123 state or with a private vendor, as necessary, to ensure the effective operation of the
124 prescription monitoring program. Any contractor shall be bound to comply with the provisions
125 regarding confidentiality of prescription information in

126 subsection D of section 22A and shall be subject to the penalties specified in subsection I
127 of section 22A.

128 F. The Department and the Diversion Investigation Unit shall promulgate rules and
129 regulations setting forth the procedures and methods for implementing this Act.

G. The commissioner in conjunction with the head of the Diversion Investigation Unit of the Massachusetts State Police shall issue an annual report on the effectiveness of the Prescription Monitoring Program.

H. (1) Whoever violates a provision of this section shall be punished by imprisonment for not more than 2 1/2 in a house of correction or by imprisonment in a state prison for 3 years or by a fine of not more than \$2,000, or by both; and, for a second or subsequent offense in this section or in Chapter 94C, by imprisonment for not more than 2 1/2 in a house of correction or by imprisonment in a state prison for 10 years or by a fine of not more than \$10,000, or by both.

SECTION 2

Chapter 94C of the General Laws is hereby amended by inserting after Section 22 the following section:-

Section 22A.

A.(1) 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 unable to be altered, copied, or counterfeited; “prescription form” is defined as either a pad of paper used by practitioners and facilities to hand write prescriptions or paper used in a computer printer by practitioners and facilities to produce a print out of the prescription. 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 commissioner.

(2) 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 of 50 and shall only be used by that practitioner. The commissioner shall establish security regulations for the department and the private vendor concerning the procurement of the official prescription forms.

(3) A practitioner authorized to write a prescription in the Commonwealth shall issue all written prescriptions upon an official prescription form. A pharmacist shall not fill a written prescription from a Massachusetts 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.

(4) 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:

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

A practitioner's or facility's registration shall be subject to approval by the department, pursuant to rules promulgated by the commissioner. 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 commissioner.

(5) A registered facility shall obtain official Massachusetts prescription forms for use at the facility and shall assign the forms to registered staff practitioners. The number of official prescription forms issued to a registered practitioner or facility, by the department or the private vendor, shall be a reasonable quantity and at the discretion of the commissioner. Official prescription forms shall be imprinted with:

(a) the name of the registered practitioner or the registered practitioners at a registered facility;

(b) the registered practitioner's drug enforcement agency's identification number;

(c) the primary address and the address of additional places of business and

(d) practitioner's license number.

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

(6) A registered practitioner or facility shall undertake adequate safeguards and security measures promulgated by the commissioner 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 commissioner. 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 commissioner and require a registered staff

practitioner to surrender their assigned forms when the practitioner terminates affiliation with the registered facility.

(7) A registered practitioner or facility shall immediately notify the department, in a manner promulgated by the commissioner, 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 and the diversion investigation unit of the Massachusetts state police upon their knowledge of prescription diversion or suspected diversion pursuant to the loss, theft, or unauthorized use of an official prescription form.

(8) Whoever violates a provision of this section shall be punished by imprisonment for not more than 2 1/2 years in a house of correction or by imprisonment in a state prison for 3 years or by a fine of not more than \$2,000, or by both; and, for a second or subsequent offense in this section or in Chapter 94C, by imprisonment for not more than 2 1/2 years in a house of correction or by imprisonment in a state prison for 10 years or by a fine of not more than \$10,000, or by both.

B. The commissioner in conjunction with the head of the diversion investigation unit of the Massachusetts state police shall issue an annual report on the effectiveness of the official Massachusetts prescription form.

SECTION 3.

211 Section 1 shall take effect no later than July 31, 2008. The department and the diversion
212 investigation unit shall report to the General Court on the status of this act 6 months after
213 passage.

214 SECTION 4.

215 Section 2 shall take effect no later than January 31, 2009. The department and the
216 diversion investigation unit shall report to the General Court on the status of this act 9 months
217 after passage.