HOUSE DOCKET, NO. 4373 FILED ON: 5/27/2009

# HOUSE . . . . . No. 1116

## The Commonwealth of Massachusetts

**In the Year Two Thousand Nine**

An Act relative to the monitoring of controlled substances..

*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 2006 Official Edition, is amended by inserting after the definition "Agent" the following definition:-

"Board", the board of registration in pharmacy established pursuant to section 22 of chapter 13.

SECTION 2. Section 1 of said chapter 94C of the General Laws, as so appearing, is amended by inserting after the definition "Dispense" the following two definitions:-

"Dispenser", a person who delivers a schedule II through V, inclusive, controlled substance to the ultimate user, but does 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 through V, inclusive, controlled substance.

"Facility", a health care provider, registered with the department of public health, which employs more than 1 person who can prescribe drugs.

SECTION 3. Said section 1 of said chapter 94C, as so appearing, is further amended by inserting after the definition “Nurse practitioner” the following definition:-

“Official prescription forms”, the serialized and tamper-resistant prescription forms.

SECTION 4. Said section 1 of said chapter 94C, as so appearing, is further amended by inserting after the definition “Oral prescription” the following definition:-

“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.

SECTION 5. Said chapter 94C, as appearing is hereby further amended by adding the following three sections:

Section 49. (a) The board 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 executive office of public safety as demonstrating a potential for abuse by all professionals licensed to prescribe or dispense such substances in Massachusetts. The board 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 the hospital or facility.

(c) Each dispenser shall submit to the board, by electronic means, information regarding each prescription dispensed for a drug included under subsection (a) as required by regulations

promulgated by the board. Each dispenser shall submit the information in accordance with transmission methods and frequency promulgated by the board but at least every 30 days, before the 15th of the month following the month the prescription was dispensed. The board 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 board, provided all information required in this section is submitted in this alternative format.

(d) 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 in the case of a retail drug business or wholesale druggist or by the commissioner in all other cases.

(e) 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).

(f) Prescription information submitted to the board shall be confidential and not subject to public or open records laws. The board 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.

(g) The board 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 board shall notify the appropriate law enforcement or professional licensing, certification or regulatory agency or entity, and provide prescription information required for an investigation.

(h) The board shall be authorized to provide data in the prescription monitoring program to the following persons:-

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

(2) an individual who requests the individual's 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, 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.

(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.

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

(6) personnel of the United States attorney, office of the attorney general or the district attorneys under subpoena or court order.

(i) The board may provide data to public or private entities for statistical, research, or educational purposes after removing information that could be used to identity individual patients or persons who received prescriptions from dispensers.

(j) The board is authorized to 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.

(k) The board shall promulgate rules and regulations setting forth the procedures and methods for implementing this section.

(l) The board in conjunction with the executive office of public safety shall submit an annual report on the effectiveness of the prescription monitoring program.

(m) Whoever violates 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 that $2,000, or both; and, for a second or subsequent offense in this section or in this chapter, 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 both.

Section 50. (a) The board 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. The board 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.

(b) The official prescription forms shall be provided by the board 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.

(c) A practitioner authorized to write a prescription in the cCommonwealth 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.

(d) 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 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.

(e) 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:

(1) the name of the registered practitioner or the registered practitioners at a registered 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 or facility to whom issued.

(f) 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.

(g) 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 board upon their knowledge of prescription diversion or suspected diversion pursuant to the loss, theft, or unauthorized use of an official prescription form.

(h) 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 that $2,000, or both; and, for a second or subsequent offense in this section or in this chapter, 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 that $10,000, or both.

(i) The board in conjunction with the executive office of public safety shall submit an annual report on the effectiveness the official Massachusetts prescription form.

Section 51. The executive office of public safety, in consultation with the board, shall enforce sections 49 and 50. 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 49 and 50 and rules adopted under said sections;

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

(c) assist the law enforcement agencies of the state 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 board, to accomplish the purposes of said sections 49 and 50.

SECTION 6. The board of registration in pharmacy 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 on or before January 1, 2010.

SECTION 7. Section 5 shall take effect on July 1, 2010.