

**HOUSE . . . . . No. 2182**

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**The Commonwealth of Massachusetts**

PRESENTED BY:

**Steven M. Walsh**

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*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 safeguarding and monitoring prescription drugs. .

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Brian P. Wallace	4th Suffolk
Jennifer M. Callahan	18th Worcester
Denise Provost	27th Middlesex
John D. Keenan	7th Essex

[SIMILAR MATTER FILED IN PREVIOUS SESSION  
SEE HOUSE, NO. 66 OF 2007-2008.]

## The Commonwealth of Massachusetts

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In the Year Two Thousand and 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 amended by  
3    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 meanings:

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

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

9           hospital care or the dispensing of prescriptions for controlled substances at the time of discharge  
10          from such a facility; or

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

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

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

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

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

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

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

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

28 (a) pharmacy prescription number;

29 (b) pharmacy number (NABP);

30 (c) patient identifier including name and one of the following:

31 (i) driver's license number,

32 (ii) social security number,

33 (ii) Mass ID number.

34 (d) patient address;

35 (e) patient date of birth;

36 (f) prescription is new or is a refill;

37 (g) national drug code (NDC) of controlled substance dispensed;

38 (h) metric quantity of controlled substance dispensed;

39 (i) estimated days supply of controlled substance dispensed;

40 (j) practitioner's U.S. drug enforcement administration (DEA) registration number;

41 (k) practitioner's license number;

42 (l) date prescription issued by practitioner;

43 (m) date the controlled substance is dispensed;

44 (n) name of person who receives the prescription from the dispenser, if other than  
45 the patient and one of the following:

46 (i) driver's license number,

47 (ii) social security number,

48 (ii) Mass ID number;

49 (o) source of payment for prescription

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

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

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

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

64 (2) Any practitioner or dispenser shall keep for at least 2 years from the date of preparation, every report,  
65 inventory, and record regarding the procuring, use, storage and dispensing for all drugs included under  
66 paragraph (1) of subsection A.

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

70 (2) The Department and the Diversion Investigation Unit shall maintain procedures to ensure that the  
71 privacy and confidentiality of patients and patient information collected, recorded, transmitted, and  
72 maintained is not disclosed to persons except as in paragraphs (3), (4) and (5) of this subsection.

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

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

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

82 (b) an individual who requests the individual's own prescription monitoring information in  
83 accordance with procedures established under Chapter 66A of the General Laws.

84 (c) persons authorized to act on behalf of state boards and regulatory agencies that supervise or

85 regulate a profession that is authorized to prescribe controlled substances, including but not  
86 limited to the following:

87 (i) board of registration in pharmacy;

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

89 service professions;

90 (iii) board of registration in medicine;

91 (iv) board of registration in veterinary medicine;

92 (v) board of registration in dentistry,

93 (vi) board of physician assistants

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

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

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

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

101 of Chapter 94C of the General Laws.

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

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

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

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

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

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

116 H. (1) Whoever violates a provision of this section shall be punished by imprisonment for not more than 2  
117 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

118 \$2,000, or by both; and, for a second or subsequent offense in this section or in Chapter 94C, by  
119 imprisonment for not more than 2 1/2 in a house of correction or by imprisonment in a state prison for 10  
120 years or by a fine of not more than \$10,000, or by both.

121 **SECTION 2**

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

123 Section 22A.

124 A.(1) The department shall designate an official Massachusetts prescription form. The form shall be  
125 serialized and tamper-resistant. For the purposes of this section “tamper-resistant” is defined as unable to  
126 be altered, copied, or counterfeited; “prescription form” is defined as either a pad of paper used by  
127 practitioners and facilities to hand write prescriptions or paper used in a computer printer by practitioners  
128 and facilities to produce a print out of the prescription. The department may contract with a private  
129 vendor to develop and print the official prescription form from a third party vendor, provided the printer  
130 has met security regulations promulgated by the commissioner.

131 (2) The official prescription forms shall be provided by the department or by the private vendor to  
132 registered practitioners and facilities without charge. Each series of prescriptions shall be issued to a  
133 specific practitioner in consecutively numbered blocks of 50 and shall only be used by that practitioner.  
134 The commissioner shall establish security regulations for the department and the private vendor  
135 concerning the procurement of the official prescription forms.

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

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

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

146 A practitioner's or facility's registration shall be subject to approval by the department, pursuant to rules  
147 promulgated by the commissioner. Any change to a practitioner's or a facility's registered information  
148 shall be promptly reported to the department in a manner promulgated by the commissioner.

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

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

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

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

156 (d) practitioner's license number.

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

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

168 (7) A registered practitioner or facility shall immediately notify the department, in a manner promulgated  
169 by the commissioner, upon their knowledge of the loss, destruction, theft or unauthorized use of an  
170 official prescription form. A registered practitioner or facility shall report the failure to receive official  
171 prescription forms to the department within a reasonable time after ordering the forms. A registered  
172 practitioner or facility shall immediately notify the department and the diversion investigation unit of the  
173 Massachusetts state police upon their knowledge of prescription diversion or suspected diversion pursuant  
174 to the loss, theft, or unauthorized use of an official prescription form.

175 (8) Whoever violates a provision of this section shall be punished by imprisonment for not more than 2  
176 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  
177 than \$2,000, or by both; and, for a second or subsequent offense in this section or in Chapter 94C, by  
178 imprisonment for not more than 2 1/2 years in a house of correction or by imprisonment in a state prison  
179 for 10 years or by a fine of not more than \$10,000, or by both.

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

### 183 **SECTION 3.**

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

### 186 **SECTION 4.**

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