

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

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**The Commonwealth of Massachusetts**

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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: \_\_\_\_\_

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

## The Commonwealth of Massachusetts

—————  
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

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

5

6    Section 15A.

7

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

9

10   A.

11   (1) "Dispenser" a person who delivers a Schedule II–V controlled substance to the ultimate user, but  
12   does

13   not include:

14         (a) a licensed hospital pharmacy that distributes such substances for the purpose of inpatient

15 hospital care or the dispensing of prescriptions for controlled substances at the time of  
16 discharge  
17 from such a facility; or  
18 (b) a wholesale distributor of a Schedule II–V controlled substance.

19

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

21

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

24

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

26

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

29

30 B.

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

36

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

39

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

43 (a) pharmacy prescription number;

44 (b) pharmacy number (NABP);

- 45 (c) patient identifier including name and one of the following:
- 46 (i) driver's license number,
  - 47 (ii) social security number,
  - 48 (ii) Mass ID number.
- 49 (d) patient address;
- 50 (e) patient date of birth;
- 51 (f) prescription is new or is a refill;
- 52 (g) national drug code (NDC) of controlled substance dispensed;
- 53 (h) metric quantity of controlled substance dispensed;
- 54 (i) estimated days supply of controlled substance dispensed;
- 55 (j) practitioner's U.S. drug enforcement administration (DEA) registration number;
- 56 (k) practitioner's license number;
- 57 (l) date prescription issued by practitioner;
- 58 (m) date the controlled substance is dispensed;
- 59 (n) name of person who receives the prescription from the dispenser, if other than
- 60 the patient and one of the following:
- 61 (i) driver's license number,
  - 62 (ii) social security number,
  - 63 (ii) Mass ID number;
- 64 (o) source of payment for prescription
- 65 (p) state issued serial number corresponding to official Massachusetts prescription form

66

67 (4) Each dispenser shall submit the information in accordance with transmission methods and frequency

68 promulgated by the department and the diversion investigation unit but shall report at least every 30

69 days, before the 15<sup>th</sup> of the month following the month the prescription was dispensed.

70

71 (5) The department and the diversion investigation unit may issue a waiver to a dispenser that is unable

72 to submit prescription information by electronic means. Such waiver may permit the dispenser to

73 submit prescription information by other means promulgated by the Department, provided all

74 information required in paragraph (3) of this subsection is submitted in this alternative format.

75

76 C.

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

83

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

87

88 D.

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

92

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

96

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

102

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

105 (a) persons authorized to prescribe or dispense controlled substances, for the purpose of  
106 providing

107 medical or pharmaceutical care for their patients.

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

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

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

111 regulate a profession that is authorized to prescribe controlled substances, including but not

112 limited to the following:

113 (i) board of registration in pharmacy;

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

115 service professions;

116 (iii) board of registration in medicine;

117 (iv) board of registration in veterinary medicine;

118 (v) board of registration in dentistry,

119 (vi) board of physician assistants

120 (d) local, state and federal law enforcement or prosecutorial officials working with the diversion

121 investigation unit engaged in the administration, investigation or enforcement of the laws governing

122 prescription drugs.

123 (e) personnel of the executive office of health and human services regarding medicaid program

124 recipients.

125 (f) personnel of the United States Attorney, Attorney General or the District Attorneys under subpoena

126 or court order.

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

128 of Chapter 94C of the General Laws.

129

130 (5) The department or the diversion investigation unit may provide data to public or private entities for

131 statistical, research, or educational purposes after removing information that could be used to identify

132 individual patients or persons who received prescriptions from dispensers.

133

134 E.

135 The department and the diversion investigation unit are authorized to contract with another

136 agency of this

137 state or with a private vendor, as necessary, to ensure the effective operation of the prescription

138 monitoring program. Any contractor shall be bound to comply with the provisions regarding

139 confidentiality of prescription information in

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

141

142 F.

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

145

146 G.

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

149

150 H.

151 (1) Whoever violates a provision of this section shall be punished by imprisonment for not more than 2  
152 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  
153 \$2,000, or by both; and, for a second or subsequent offense in this section or in Chapter 94C, by  
154 imprisonment for not more than 2 1/2 in a house of correction or by imprisonment in a state prison for  
155 10 years or by a fine of not more than \$10,000, or by both.

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157

158 **SECTION 2**

159

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

161

162 Section 22A.

163

164 A.

165 (1) The department shall designate an official Massachusetts prescription form. The form shall be  
166 serialized and tamper-resistant. For the purposes of this section "tamper-resistant" is defined as unable  
167 to be altered, copied, or counterfeited; "prescription form" is defined as either a pad of paper used by  
168 practitioners and facilities to hand write prescriptions or paper used in a computer printer by  
169 practitioners and facilities to produce a print out of the prescription. The department may contract with

170 a private vendor to develop and print the official prescription form from a third party vendor, provided  
171 the printer has met security regulations promulgated by the commissioner.

172

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

178

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

183

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

186

187 (a) the name of a practitioner authorized to prescribe controlled substances;

188 (b) the primary address and the address of additional places of business and;

189 (c) the practitioner's drug enforcement agency number; and

190 (d) practitioner's license number.

191

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

195

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

200



- 201 (a) the name of the registered practitioner or the registered practitioners at a registered facility;  
202 (b) the registered practitioner's drug enforcement agency's identification number;  
203 (c) the primary address and the address of additional places of business and  
204 (d) practitioner's license number.

205

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

208

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

218

219 (7) A registered practitioner or facility shall immediately notify the department, in a manner  
220 promulgated by the commissioner, upon their knowledge of the loss, destruction, theft or unauthorized  
221 use of an official prescription form. A registered practitioner or facility shall report the failure to receive  
222 official prescription forms to the department within a reasonable time after ordering the forms. A  
223 registered practitioner or facility shall immediately notify the department and the diversion  
224 investigation unit of the Massachusetts state police upon their knowledge of prescription diversion or  
225 suspected diversion pursuant to the loss, theft, or unauthorized use of an official prescription form.

226

227 (8) Whoever violates a provision of this section shall be punished by imprisonment for not more than 2  
228 1/2 years in a house of correction or by imprisonment in a state prison for 3 years or by a fine of not  
229 more that \$2,000, or by both; and, for a second or subsequent offense in this section or in Chapter 94C,  
230 by imprisonment for not more than 2 1/2 years in a house of correction or by imprisonment in a state  
231 prison for 10 years or by a fine of not more that \$10,000, or by both.

232

233 B.

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

237

238 **SECTION 3.**

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

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242 **SECTION 4.**

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

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