

HOUSE No. 4478

The Commonwealth of Massachusetts

In the Year Two Thousand 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:

1 SECTION 1. Section 1 of chapter 94C of the General Laws, as appearing in the 2008
2 Official Edition, is hereby amended by inserting after the definition “Dispense” the following
3 definition:-

4 “Dispenser”, a person who delivers a schedule II to V, inclusive, controlled substance to
5 the ultimate user, but shall not include: (a) a licensed hospital pharmacy that distributes such
6 substances for the purpose of inpatient hospital care or the dispensing of prescriptions for
7 controlled substances at the time of discharge from such a facility; or (b) a wholesale distributor
8 of a schedule II to V, inclusive, controlled substance.

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

11 “Official prescription forms”, the serialized and tamper-resistant prescription forms
12 provided by the department pursuant to section 49.

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

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

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

26 (c) Each dispenser shall submit to the department, by electronic means, information
27 regarding each prescription dispensed for a drug included pursuant to subsection (a) as required
28 by rules and regulations promulgated by the department. Each dispenser shall submit the
29 information in accordance with transmission methods and frequency promulgated by the
30 department, but at least once every 7 days. The department may issue a waiver to a dispenser
31 that is unable to submit prescription information by electronic means. Such waiver shall permit
32 the dispenser to submit prescription information by other means promulgated by the department,
33 provided all information required in this section is submitted in this alternative format.

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

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

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

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

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

52 (2) individuals who request their own prescription monitoring information in accordance
53 with procedures established under chapter 66A;

54 (3) persons authorized to act on behalf of state boards and regulatory agencies that
55 supervise or regulate a profession that is authorized to prescribe controlled substances; provided,
56 that the data request is in connection with a bona fide specific drug related investigation;

57 (4) local, state and federal law enforcement or prosecutorial officials working with the
58 executive office of public safety engaged in the administration, investigation or enforcement of
59 the laws governing prescription drugs; provided, that the data request is in connection with a
60 bona fide specific drug related investigation;

61 (5) personnel of the executive office of health and human services regarding Medicaid
62 program recipients, provided, that the data request is in connection with a bona fide specific drug
63 related investigation; or

64 (6) personnel of the United States attorney, office of the attorney general or the district
65 attorneys; provided, that the data request is in connection with a bona fide specific drug related
66 investigation.

67 (h) The department may provide de-identified, aggregate information to public or private
68 entities for statistical, research or educational purposes.

69 (i) The department may contract with another agency of this state or with a private
70 vendor, as necessary, to ensure the effective operation of the prescription monitoring program.
71 Any contractor shall be bound to comply with the provisions regarding confidentiality of
72 prescription information in this section and shall be subject to the penalties specified in this
73 section.

74 (j) The department shall promulgate rules and regulations setting forth the procedures and
75 methods for implementing this section.

76 (k) The department in conjunction with the executive office of public safety shall submit
77 an annual report on the effectiveness of the prescription monitoring program with the clerks of
78 the house and senate who shall forward the same to the chairs of the joint committee on public
79 health and the chairs of the joint committee on public safety and homeland security.

80 (l) Whoever violates this section shall be punished by imprisonment in a state prison for
81 not more than 3 years or in a jail or house of correction for not more than 2½ years or by a fine
82 of not more than \$2,000, or both; and, for a second or subsequent offense of this section or in this
83 chapter, by imprisonment in a state prison for not more than 10 years or in a jail or house of
84 correction for not more than 2 1/2 years, or by a fine of not more than \$10,000, or both.

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

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

93 (b) The department shall designate an official Massachusetts prescription form. The form
94 shall be serialized and tamper-resistant. For the purposes of this section, tamper-resistant is
95 defined as having one or more of the following industry-recognized features designed to prevent:

96 (i) unauthorized copying of a completed or blank prescription form; (ii) the erasure or
97 modification of information written on the prescription by the prescriber; and (iii) the use of
98 counterfeit prescription forms. The department may contract with a private vendor to develop
99 and print the official prescription form from a third party vendor; provided, the printer has met
100 security regulations promulgated by the department.

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

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

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

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

114 (2) the primary address and the address of additional places of business;

115 (3) the practitioner's drug enforcement agency number; and

116 (4) practitioner's license number.

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

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

125 (1) the name of the registered practitioner or facility;

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

127 (3) the primary address and the address of additional places of business of the registered
128 practitioner; and

129 (4) the registered practitioner's license number.

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

132 (g) A registered practitioner or facility shall undertake adequate safeguards and security
133 measures promulgated by the department to assure against destruction, theft or unauthorized use
134 of an official prescription form. A registered practitioner shall, at minimum, maintain a record of
135 official prescription forms received and establish a system requiring forms be secure pursuant to
136 security measures promulgated by the department. A registered facility shall, at minimum,
137 maintain a record of official prescription forms received, maintain a record of forms assigned to

138 its registered staff practitioners, establish a system requiring forms be secure pursuant to security
139 measures promulgated by the department and require a registered staff practitioner to surrender
140 their assigned forms when the practitioner terminates affiliation with the registered facility.

141 (h) A registered practitioner or facility shall immediately notify the department, in a
142 manner promulgated by the department, upon their knowledge of the loss, destruction, theft or
143 unauthorized use of an official prescription form. A registered practitioner or facility shall report
144 the failure to receive official prescription forms to the department within a reasonable time after
145 ordering the forms. A registered practitioner or facility shall immediately notify the department
146 upon their knowledge of prescription diversion or suspected diversion pursuant to the loss, theft
147 or unauthorized use of an official prescription form.

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

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

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

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

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

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

166 (d) conduct investigations to enforce this chapter;

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

171 (f) work in cooperation with the department to accomplish the purposes of said sections
172 24A and 49.

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

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

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