HOUSE DOCKET, NO. 3062 FILED ON: 1/21/2011

HOUSE . . . . . No. 2814

The Commonwealth of Massachusetts

PRESENTED BY:

Nick Collins

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:

An Act to increase access to vaccines.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Nick Collins	*4th Suffolk*

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HOUSE . . . . . No. 2814

By Mr. Collins of Boston, a petition (accompanied by bill, House, No. 2814) of Nick Collins relative to the dispensing of controlled substances by certain medical professionals. The Judiciary.

The Commonwealth of Massachusetts

An Act to increase access to vaccines.

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

Chapter 94C: Section 1. Definitions

Section 1. As used in this chapter, the following words shall, unless the context clearly requires otherwise, have the following meanings:

"Administer", the direct application of a controlled substance whether by injection, inhalation, ingestion, or any other means to the body of a patient or research subject by—

(a) a practitioner, or

(b) a nurse at the direction of a practitioner in the course of his professional practice, or

(c) an ultimate user or research subject at the direction of a practitioner in the course of his professional practice, or

(d) For the purpose of administering a vaccination or immunization as defined by the Department of Public Health, a qualified medical assistant at the direction of a practitioner in the course of his professional practice.

"Practitioner",

(a) A physician, dentist, veterinarian, podiatrist, scientific investigator, or other person registered to distribute, dispense, conduct research with respect to, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research in the commonwealth;

18 (b) A pharmacy, hospital, or other institution registered to distribute, dispense, conduct
19 research with respect to or to administer a controlled substance in the course of professional
20 practice or research in the commonwealth.

21 (c) An optometrist authorized by sections 66 and 66B of chapter 112 and registered
22 pursuant to paragraph (h) of section 7 to utilize and prescribe therapeutic pharmaceutical agents
23 in the course of professional practice in the commonwealth.

24 "Qualified Medical Assistant,"

25 A medical assistant who has completed a qualified medical assistants program, which
26 program includes training on administration of vaccines and immunizations. The Department of
27 Public Health shall maintain and publish a list of certified medical assistant programs.

28 Chapter 94C: Section 9. Administering and dispensing of controlled substances in course
29 of professional practice; records and inspection

30 [Text of section as amended by 2008, 528, Sec. 1 effective April 15, 2009. For text
31 effective until April 15, 2009, see above.]

32 Section 9. (a) A physician, dentist, podiatrist, optometrist as limited by sections 66 and
33 66B of chapter 112 and subsection (h) of section 7, nurse practitioner and psychiatric nurse
34 mental health clinical specialist as limited by subsection (g) of said section 7 and section 80E of
35 said chapter 112, physician assistant as limited by said subsection (g) of said section 7 and
36 section 9E of said chapter 112, certified nurse-midwife as provided in section 80C of said
37 chapter 112, pharmacist as limited by said subsection (g) of said section 7 and section 24B 1/2/
38 of said chapter 112, or veterinarian when registered pursuant to said section 7, may, when acting
39 in accordance with applicable federal law and any provision of this chapter which is consistent
40 with federal law and in good faith and in the course of a professional practice for the alleviation
41 of pain and suffering or for the treatment or alleviation of disease, possess controlled substances
42 as may reasonably be required for the purpose of patient treatment and may administer controlled
43 substances or may cause the same to be administered under his direction by a nurse.

44 A practitioner may cause controlled substances to be administered under his direction by
45 a licensed dental hygienist, for the purposes of local anesthesia only.

46 A practitioner may cause controlled substances for vaccines and immunizations to be
47 administered under his direction by a qualified medical assistant.

48 (b) Notwithstanding section 17, a physician, physician assistant, dentist, podiatrist,
49 optometrist, certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical
50 specialist, pharmacist as limited by said subsection (g) of said section 7 and section 24B1/2/ of
51 said chapter 112, or veterinarian registered pursuant to said section 7, may, when acting in good
52 faith and in the practice of medicine, dentistry, podiatry, optometry, nurse-midwifery, pharmacy

53 or veterinary medicine or as a nurse or a qualified medical assistant, as the case may be, and
54 when authorized by a physician, dentist, podiatrist, optometrist, nurse practitioner, physician
55 assistant, certified nurse-midwife, psychiatric nurse mental health clinical specialist or
56 veterinarian in the course of such nurse's professional practice, dispense by delivering to an
57 ultimate user a controlled substance in a single dose or in a quantity that is, in the opinion of such
58 physician, dentist, podiatrist, optometrist, nurse practitioner, physician assistant, certified
59 midwife, psychiatric nurse mental health clinical specialist, pharmacist or veterinarian, essential
60 for the treatment of the patient. The amount or quantity of any controlled substance dispensed
61 under this subsection shall not exceed the quantity of a controlled substance necessary for the
62 immediate and proper treatment of the patient until it is possible for the patient to have a
63 prescription filled by a pharmacy. All controlled substances required by the patient as part of his
64 treatment shall be dispensed by prescription to the ultimate user in accordance with this chapter.

65 This section shall not prohibit or limit the dispensing of a prescription medication that is
66 classified by the department as schedule VI and that is provided by the manufacturer as part of
67 an indigent patient program or for use as samples if the prescription medication is: (i) dispensed
68 to the patient by a professional authorized to dispense controlled substances pursuant to this
69 section; (ii) dispensed in the package provided by the manufacturer; and (iii) provided at no
70 charge to the patient. The department shall promulgate rules and regulations governing the
71 dispensing of medication pursuant to this section. These rules and regulations shall include, but
72 not be limited to, those concerning the types and amounts of medications that may be dispensed
73 and the appropriate safeguards for the labeling and dispensing of such medications.

74 (c) A nurse who has obtained from a physician, dentist, physician assistant, podiatrist,
75 certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical specialist,
76 pharmacist or veterinarian a controlled substance for dispensing to an ultimate user pursuant to
77 subsection (b) or for administration to a patient pursuant to subsection (a) during the absence of
78 the physician, physician assistant, dentist, podiatrist, certified nurse-midwife, nurse practitioner,
79 psychiatric nurse mental health clinical specialist, pharmacist or veterinarian, shall return to the
80 physician, physician assistant, dentist, podiatrist, certified nurse-midwife, nurse practitioner,
81 psychiatric nurse mental health clinical specialist, pharmacist or veterinarian any unused portion
82 of the controlled substance which is no longer required by the patient.

83 A licensed dental hygienist or a qualified medical assistant who has obtained a controlled
84 substance from a practitioner for dispensing to an ultimate user pursuant to subsection (a) shall
85 return to such practitioner any unused portion of the substance which is no longer required by the
86 patient.

87 (d) Every physician, physician assistant, dentist, podiatrist, certified nurse-midwife,
88 nurse practitioner, psychiatric nurse mental health clinical specialist, pharmacist or veterinarian
89 shall, in the course of a professional practice, keep and maintain records, open to inspection by
90 the commissioner during reasonable business hours, which shall include the following: the

91 names and quantities of any controlled substances in schedules I, II or III received by the
92 practitioner; the name and address of each patient to whom such controlled substance is
93 administered or dispensed; the name, dosage and strength per dosage unit of each such controlled
94 substance; and the date of such administration or dispensing.

95 (e) Notwithstanding subsection (b), a physician, nurse practitioner, physician assistant,
96 pharmacist as limited by subsection (g) of section 7 and section 24B1/2/ of said chapter 112 or
97 certified nurse-midwife, when acting in good faith and providing care under a program funded in
98 whole or in part by 42 U.S.C. 300, or in a clinic licensed by the department to provide
99 comparable medical services or a registered nurse, registered pursuant to section 74 of said
100 chapter 112 and authorized by such physician, nurse practitioner, physician assistant, pharmacist
101 as limited by said subsection (g) of said section 7 and section 24B1/2/ of said chapter 112, or
102 certified nurse-midwife, may lawfully dispense controlled substances pursuant to schedule VI to
103 recipients of such services in such quantity as needed for treatment and shall be exempt from the
104 requirement that such dispensing be in a single dosage or as necessary for immediate and proper
105 treatment under subsection (b). A registered nurse shall dispense under this subsection only as
106 provided in section 17. The department may establish rules and regulations controlling the
107 dispensing of these medications, including, but not limited to, the types and amounts of
108 medications dispensed and appropriate safeguards for dispensing.

109 Chapter 94C: Section 7. Registration of persons who manufacture, distribute, dispense or
110 possess controlled substances

111 Section 7. (a) Except in the case of a pharmacy or wholesale druggist, every person who
112 manufactures, distributes or dispenses, or possesses with intent to manufacture, distribute or
113 dispense any controlled substance within the commonwealth shall upon payment of a fee, the
114 amount of which shall be determined annually by the commissioner of administration under the
115 provision of section three B of chapter seven, register with the commissioner of public health, in
116 accordance with his regulations, said registration to be effective for one year from the date of
117 issuance. Every wholesale druggist shall register with the board of registration in pharmacy in
118 accordance with its regulations. Such registration shall be effective until July first, nineteen
119 hundred and seventy-four, if such registration is issued prior to July first, nineteen hundred and
120 seventy-four. Such registration shall be effective until January first, nineteen hundred and
121 seventy-six, if such registration is issued between July first, nineteen hundred and seventy-four,
122 and January first, nineteen hundred and seventy-six. Such registration shall be effective until the
123 end of the calendar year in which said registration is issued if registration is issued subsequent to
124 December thirty-first, nineteen hundred and seventy-five; provided, that such wholesale druggist
125 shall pay a registration fee of twenty-five dollars for any initial registration issued prior to July
126 first, nineteen hundred and seventy-four, and shall pay any registration fee of thirty-seven dollars
127 and fifty cents for a registration which is issued between July first, nineteen hundred and
128 seventy-four, and January first, nineteen hundred and seventy-six. Such wholesale druggist shall,
129 commencing January first, nineteen hundred and seventy-six, pay an annual registration fee, the

130 amount of which shall be determined by the commissioner of administration, for each year or
131 any part thereof. For the purposes of this section, "wholesale druggist" shall mean any person
132 who distributes controlled substances at wholesale. Every pharmacy shall register with the said
133 board in accordance with its regulations. Such registration shall be effective until July first,
134 nineteen hundred and seventy-four, if any registration is issued prior to July first, nineteen
135 hundred and seventy-four. Such registration shall be effective until January first, nineteen
136 hundred and seventy-six, if such registration is issued between July first, nineteen hundred and
137 seventy-four, and January first, nineteen hundred and seventy-six. Such registration shall be
138 effective until the end of the first uneven numbered year following the date of issuance of such
139 registration if such registration is issued subsequent to December thirty-first, nineteen hundred
140 and seventy-five; provided, that such pharmacy shall pay a registration fee of twenty-five dollars
141 for an initial registration issued prior to midnight of July first, nineteen hundred and seventy-
142 four, and shall pay a registration fee of thirty-seven dollars and fifty cents for any registration
143 issued between July first, nineteen hundred and seventy-four, and January first, nineteen hundred
144 and seventy-six, and shall, commencing January first, nineteen hundred and seventy-six, pay a
145 biennial registration fee, the amount of which shall be determined by the commissioner of
146 administration, for every two years, or any part thereof.

147 (b) Every person who is engaged in the qualitative or quantitative analysis of controlled
148 substances within a scientific laboratory shall, upon payment of a fee, as determined annually by
149 the commissioner of administration under the provision of section three B of chapter seven
150 obtain a registration issued by the commissioner in accordance with his rules, said registration to
151 be effective for one year from date of issuance.

152 (c) A person registered under this chapter to manufacture, distribute, dispense, or possess
153 controlled substances may possess, manufacture, distribute, or dispense those substances to the
154 extent authorized by his registration and in conformity with the other provisions of this chapter.

155 (d) The following persons shall not require registration and may lawfully possess and
156 distribute controlled substances:

157 (1) an agent or employee of any manufacturer, distributor, or dispenser registered under
158 this chapter, if he is acting in the usual course of his business or employment, except that a
159 salesman, detail man or other field representative of a registered manufacturer, wholesaler,
160 jobber or dealer in controlled substances may not possess any controlled substance in schedule I,
161 II, III, IV, or V of section three for the purpose of demonstrating, displaying, selling, or
162 distributing as samples said controlled substances to a practitioner;

163 (2) a common or contract carrier or warehouseman, or an employee thereof, whose
164 possession of any controlled substance is in the usual course of business or employment;

165 (3) any public official or law enforcement officer acting in the regular performance of his
166 official duties.

167 (4) a registered nurse or licensed practical nurse or a qualified medical assistant or a
168 licensed dental hygienist under the supervision of a practitioner as defined in section 1 for the
169 purposes of administering local anesthesia agents only when acting under the supervision of a
170 practitioner;

171 (5) a graduate of a school for nurses or practical nurses which has been approved in
172 accordance with the provisions of chapter one hundred and twelve, whenever said person is
173 acting under the supervision of a practitioner and is engaged in professional practice during the
174 period from such person's graduation from said school until the announcement of the results of
175 the first licensing examination for registered nurses or licensed practical nurses, as the case may
176 be, thereafter held in accordance with the provisions of said chapter one hundred and twelve;

177 (6) any person duly licensed to practice nursing within any other jurisdiction, whenever
178 such person is acting under the supervision of a practitioner and is discharging official duties as
179 an employee of the federal government;

180 (7) any person covered by clauses (1), (2), (3) and (5) of section eighty B of chapter one
181 hundred and twelve when any such person is acting under the supervision of a
182 practitioner;(NURSE PRACTICE ACT)

183 (8) any therapist, technician, or medical student when performing under the supervision
184 of a practitioner those services which are defined to be functions of their respective callings;

185 (9) any person who belongs to a class of persons which is authorized by regulation of the
186 commissioner to provide services for the purpose of diagnosis, care, treatment, or research.

187 (10) a duly licensed optometrist who utilizes diagnostic pharmaceutical agents, as defined
188 in section sixty-six A of chapter one hundred and twelve, and who qualifies to utilize such agents
189 for the purpose of conducting an examination of the eye as provided in sections sixty-six A and
190 sixty-eight A of chapter one hundred and twelve; provided, however, that a wholesale distributor
191 or pharmacist may dispense such diagnostic pharmaceutical agents to a licensed optometrist for
192 subsequent administration to optometry patients only if such optometrist provides the wholesale
193 distributor or pharmacist with the number of the optometrist's certification of qualification to
194 administer such diagnostic pharmaceutical agents.

195 (e) An ultimate user or research subject may lawfully possess or administer a controlled
196 substance at the direction of a practitioner in the course of his professional practice.

197 (f) Notwithstanding any other provision of this section, the commissioner shall, upon
198 receipt of the fee as hereinbefore provided, automatically issue to any physician, dentist,
199 podiatrist or veterinarian who is duly authorized to practice his profession in the commonwealth
200 a registration to dispense, other than for research pursuant to section eight, unless the registration
201 of such physician, dentist, podiatrist, or veterinarian has been suspended or revoked pursuant to

202 the provisions of sections thirteen or fourteen or unless said registration is denied for cause by
203 the commissioner pursuant to the provisions of chapter thirty A. Such registration shall continue
204 in full force and effect unless it is suspended or revoked, or unless it is recalled and a new
205 registration issued in accordance with the rules and regulations of the commissioner.

206 (g) The commissioner may by regulation authorize the registration for a specific activity
207 or activities requiring registration under this section of such persons as he determines to be
208 qualified for such registration.

209 The commissioner shall promulgate regulations which provide for the registration of
210 nurse practitioners and for psychiatric nurse mental health clinical specialists, as defined in
211 section eighty B of chapter one hundred and twelve, to issue written prescriptions for patients
212 pursuant to guidelines mutually developed and agreed upon by the nurse and supervising
213 physician under regulations approved by the board of registration in nursing and the board of
214 registration in medicine. Prior to promulgating such regulations, the commissioner shall consult
215 with the board of registration in nursing, the board of registration in medicine and the board of
216 registration in pharmacy with regard to those schedules of controlled substances for which nurse
217 practitioners and psychiatric nurse mental health clinical specialists may be registered.

218 The commissioner shall promulgate regulations which provide for the registration of
219 certified nurse-midwives, as provided in section eighty C of chapter one hundred and twelve, to
220 issue written prescriptions for patients pursuant to guidelines mutually developed and agreed
221 upon by the certified nurse-midwife and the supervising physician in accordance with regulations
222 approved by the board of registration in medicine and the board of registration in nursing. Prior
223 to promulgating such regulations, the commissioner shall consult with the board of registration in
224 nursing, the board of registration in medicine and the board of registration in pharmacy with
225 regard to those schedules of controlled substances for which certified nurse-midwives may be
226 registered.

227 The commissioner shall promulgate regulations which provide for the registration of
228 physicians assistants to issue written prescriptions for patients pursuant to guidelines mutually
229 developed and agreed upon by the supervising physician and the physician assistant. Prior to
230 promulgating such regulations, the commissioner shall consult with the board of registration of
231 physician assistants, the board of registration in medicine and the board of registration in
232 pharmacy with regard to those schedules of controlled substances for which physician assistants
233 may be registered to issue written prescriptions therefor; provided, however, that a physician
234 assistant who has not successfully passed the national certification examination for physician
235 assistants or who does not meet all of the current requirements for obtaining an initial physician
236 assistant's registration as listed in section nine I of chapter one hundred and twelve may not be
237 authorized to write prescriptions under any circumstances.

238 [Paragraphs in subsection (g) added by 2008, 528, Sec. 1 effective April 15, 2009.]

239 The commissioner shall issue regulations authorizing pharmacists, who have been duly
240 registered in accordance with section 241/2 of chapter 112, to engage in collaborative drug
241 therapy management and to issue written prescriptions in accordance with the provisions of said
242 section 241/2 of said chapter 112 and guidelines mutually developed and agreed upon by the
243 supervising physician and the pharmacist in a collaborative practice agreement, as defined in
244 section 241/2 of said chapter 112, established in accordance with regulations of the board of
245 registration in medicine and board of registration in pharmacy. Prior to issuing such regulations,
246 the commissioner shall consult with the board of registration in medicine and the board of
247 registration in pharmacy with regard to the schedules of controlled substances for which a
248 pharmacist may be authorized to prescribe within the scope of his collaborative practice.

249 The commissioner may gather patient outcome and cost-savings data if available from
250 objective sources and review community retail drug business-based collaborative drug therapy
251 management. If the commissioner finds that sufficient data and funding sources exist to conduct
252 a valid study, he shall conduct a study within 2 years after that finding. The study shall include
253 representatives of the board of registration in medicine and the board of registration in pharmacy.
254 In conducting the study, the commissioner shall hold at least 1 public hearing to receive
255 testimony from the public, including representatives of pharmacy and medicine and other
256 concerned parties.

257 (h) The commissioner shall promulgate regulations which provide for the automatic
258 registration of optometrists, upon the receipt of the fee as herein provided, to issue written
259 prescriptions in accordance with the provisions of sections 66 and 66B of chapter 112, unless the
260 registration of such optometrist has been suspended or revoked pursuant to the provisions of
261 section 13 or section 14 or unless such registration is denied for cause by the commissioner
262 pursuant to the provisions of chapter 30A. Prior to promulgating such regulations, the
263 commissioner shall consult with the board of registration in optometry.