HOUSE DOCKET, NO. 03062 FILED ON: 01/21/2011

HOUSE . . . . . No. 02814

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 bill:

An Act to increase access to vaccines.

PETITION OF:

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

HOUSE . . . . . No. 02814

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

The Commonwealth of Massachusetts

In the Year Two Thousand Eleven

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;

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

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

"Qualified Medical Assistant,"

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

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

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

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

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

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

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

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

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

(c) A nurse who has obtained from a physician, dentist, physician assistant, podiatrist, certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical specialist, pharmacist or veterinarian a controlled substance for dispensing to an ultimate user pursuant to subsection

(b) or for administration to a patient pursuant to subsection (a) during the absence of the physician, physician assistant, dentist, podiatrist, certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical specialist, pharmacist or veterinarian, shall return to the physician, physician assistant, dentist, podiatrist, certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical specialist, pharmacist or veterinarian any unused portion of the controlled substance which is no longer required by the patient.

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

(d) Every physician, physician assistant, dentist, podiatrist, certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical specialist, pharmacist or veterinarian shall, in the course of a professional practice, keep and maintain records, open to inspection by the commissioner during reasonable business hours, which shall include the following: the names and quantities of any controlled substances in schedules I, II or III received by the practitioner; the name and address of each patient to whom such controlled substance is administered or dispensed; the name, dosage and strength per dosage unit of each such controlled substance; and the date of such administration or dispensing.

(e) Notwithstanding subsection (b), a physician, nurse practitioner, physician assistant, pharmacist as limited by subsection (g) of section 7 and section 24B1/2/ of said chapter 112 or certified nurse-midwife, when acting in good faith and providing care under a program funded in whole or in part by 42 U.S.C. 300, or in a clinic licensed by the department to provide

comparable medical services or a registered nurse, registered pursuant to section 74 of said chapter 112 and authorized by such physician, nurse practitioner, physician assistant, pharmacist as limited by said subsection (g) of said section 7 and section 24B1/2/ of said chapter 112, or certified nurse-midwife, may lawfully dispense controlled substances pursuant to schedule VI to recipients of such services in such quantity as needed for treatment and shall be exempt from the requirement that such dispensing be in a single dosage or as necessary for immediate and proper treatment under subsection (b). A registered nurse shall dispense under this subsection only as provided in section 17. The department may establish rules and regulations controlling the dispensing of these medications, including, but not limited to, the types and amounts of medications dispensed and appropriate safeguards for dispensing.

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

Section 7. (a) Except in the case of a pharmacy or wholesale druggist, every person who manufactures, distributes or dispenses, or possesses with intent to manufacture, distribute or dispense any controlled substance within the commonwealth shall upon payment of a fee, the amount of which shall be determined annually by the commissioner of administration under the provision of section three B of chapter seven, register with the commissioner of public health, in accordance with his regulations, said registration to be effective for one year from the date of issuance. Every wholesale druggist shall register with the board of registration in pharmacy in accordance with its regulations. Such registration shall be effective until July first, nineteen hundred and seventy-four, if such registration is issued prior to July first, nineteen hundred and seventy-four. Such registration shall be effective until January first, nineteen hundred and seventy-six, if such registration is issued between July first, nineteen hundred and seventy-four,

and January first, nineteen hundred and seventy-six. Such registration shall be effective until the end of the calendar year in which said registration is issued if registration is issued subsequent to December thirty-first, nineteen hundred and seventy-five; provided, that such wholesale druggist shall pay a registration fee of twenty-five dollars for any initial registration issued prior to July first, nineteen hundred and seventy-four, and shall pay any registration fee of thirty-seven dollars and fifty cents for a registration which is issued between July first, nineteen hundred and seventy-four, and January first, nineteen hundred and seventy-six. Such wholesale druggist shall, commencing January first, nineteen hundred and seventy-six, pay an annual registration fee, the amount of which shall be determined by the commissioner of administration, for each year or any part thereof. For the purposes of this section, "wholesale druggist" shall mean any person who distributes controlled substances at wholesale. Every pharmacy shall register with the said board in accordance with its regulations. Such registration shall be effective until July first, nineteen hundred and seventy-four, if any registration is issued prior to July first, nineteen hundred and seventy-four. Such registration shall be effective until January first, nineteen hundred and seventy-six, if such registration is issued between July first, nineteen hundred and seventy-four, and January first, nineteen hundred and seventy-six. Such registration shall be effective until the end of the first uneven numbered year following the date of issuance of such registration if such registration is issued subsequent to December thirty-first, nineteen hundred and seventy-five; provided, that such pharmacy shall pay a registration fee of twenty-five dollars for an initial registration issued prior to midnight of July first, nineteen hundred and seventy-four, and shall pay a registration fee of thirty-seven dollars and fifty cents for any registration issued between July first, nineteen hundred and seventy-four, and January first, nineteen hundred and seventy-six, and shall, commencing January first, nineteen hundred and seventy-six, pay a

biennial registration fee, the amount of which shall be determined by the commissioner of administration, for every two years, or any part thereof.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(f) Notwithstanding any other provision of this section, the commissioner shall, upon receipt of the fee as hereinbefore provided, automatically issue to any physician, dentist, podiatrist or veterinarian who is duly authorized to practice his profession in the commonwealth a registration to dispense, other than for research pursuant to section eight, unless the registration of such physician, dentist, podiatrist, or veterinarian has been suspended or revoked pursuant to the provisions of sections thirteen or fourteen or unless said registration is denied for cause by the commissioner pursuant to the provisions of chapter thirty A. Such registration shall continue in full force and effect unless it is suspended or revoked, or unless it is recalled and a new registration issued in accordance with the rules and regulations of the commissioner.

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

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

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

The commissioner shall promulgate regulations which provide for the registration of physicians assistants to issue written prescriptions for patients pursuant to guidelines mutually developed and agreed upon by the supervising physician and the physician assistant. Prior to promulgating such regulations, the commissioner shall consult with the board of registration of physician assistants, the board of registration in medicine and the board of registration in pharmacy with

regard to those schedules of controlled substances for which physician assistants may be registered to issue written prescriptions therefor; provided, however, that a physician assistant who has not successfully passed the national certification examination for physician assistants or who does not meet all of the current requirements for obtaining an initial physician assistant's registration as listed in section nine I of chapter one hundred and twelve may not be authorized to write prescriptions under any circumstances.

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

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

The commissioner may gather patient outcome and cost-savings data if available from objective sources and review community retail drug business-based collaborative drug therapy management. If the commissioner finds that sufficient data and funding sources exist to conduct a valid study, he shall conduct a study within 2 years after that finding. The study shall include representatives of the board of registration in medicine and the board of registration in pharmacy.

In conducting the study, the commissioner shall hold at least 1 public hearing to receive testimony from the public, including representatives of pharmacy and medicine and other concerned parties.

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