Part I ADMINISTRATION OF THE GOVERNMENT

Title XV REGULATION OF TRADE

Chapter 94C CONTROLLED SUBSTANCES ACT

Section 7 REGISTRATION OF PERSONS WHO MANUFACTURE, DISTRIBUTE, DISPENSE OR POSSESS CONTROLLED SUBSTANCES **(see pages 4-5 for CRNA's)**

[Subsection (a) effective until July 1, 2016. For text effective July 1, 2016, see below.]

Section 7. (a) Except in the case of a pharmacy, wholesale druggist or outsourcing facility, 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 and outsourcing facility 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.

[Subsection (a) as amended by 2016, 133, Sec. 64 effective July 1, 2016. See 2016, 133, Sec. 203. For text effective until July 1, 2016, see above.]

(a) Except in the case of a pharmacy, wholesale druggist or outsourcing facility, 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 and outsourcing facility 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 or outsourcing facility 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 or outsourcing facility 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 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;

(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 80C of chapter 112, to issue written prescriptions in accordance with regulations under said section 80G of said chapter 112. Prior to promulgating such regulations, the commissioner shall consult with the board of registration in nursing and the board of registration in medicine 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.

The commissioner shall issue regulations authorizing pharmacists, who have been duly registered in accordance with section 24 1/2 of chapter 112, to engage in collaborative drug therapy management and to issue written prescriptions in accordance with the provisions of said section 24 1/2 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 24 1/2 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.

The commissioner shall promulgate regulations which provide for the registration of nurse anesthetists in an advanced practice nursing role, as defined in section 80B of chapter 112, to issue written prescriptions for patients under section 80H of chapter 112 and under guidelines mutually-developed and agreed upon by the nurse and supervising physician in accordance with said section 80H and regulations approved by the board of registration in nursing and the board of registration in medicine. Prior to promulgating the regulations, the commissioner shall consult with the board of registration in nursing, board of registration in medicine and the board of registration in pharmacy with regard to those schedules of controlled substances for which nurse anesthetists may be registered.

(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.