SENATE . . . . . No. 2010

The Commonwealth of Massachusetts

In the One Hundred and Eighty-Ninth General Court
(2015-2016)

SENATE, September 10, 2015

The committee on Rules, to whom was referred the Senate Bill to improve the accessibility and affordability of naloxone and other pharmaceutical drugs of public health concern (Senate, No. 603),-- reports, recommending that the same ought to pass with an amendment substituting a new draft with the same title (Senate, No. 2010).

For the committee,
Mark C. Montigny

SENATE . . . . . No. 2010

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In the One Hundred and Eighty-Ninth General Court
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An Act to improve the accessibility and affordability of naloxone and other pharmaceutical drugs of public health concern.

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

SECTION 1. Chapter 6 of the General Laws is hereby amended by inserting after section 116A the following section:-

Section 116A½. The municipal police training committee shall establish a course within the recruit basic training curriculum for regional and municipal police training schools to train law enforcement officers on the application of section 34A of chapter 94C.

The committee shall periodically include within its in-service training curriculum a course of instruction on the application of said section 34A of said chapter 94C and on responding to calls for assistance for drug-related overdoses.

SECTION 2. Section 13 of chapter 17 of the General Laws, as appearing in the 2014 Official Edition, is hereby amended by inserting the following new subsection:-

(e) The commission shall also identify and publish a list of federally approved non-opioid drugs that provide effective pain management alternatives and that have a lesser potential for

abuse than opioid drugs contained in schedules II and III of section 3 of chapter 94C, and shall provide for distribution copies of such list and revisions thereto amongst physicians and pharmacists licensed to practice within the commonwealth and to other appropriate individuals and shall supply a copy to any person on request upon payment of the cost of printing.

SECTION 3. Section 19 of chapter 17 of the General Laws, as appearing in the 2014 Official Edition, is hereby amended by striking “and (6)” in lines 27 and 28, and inserting in place thereof the following:-

(6) upon discharge, provide information to the patient about their option to voluntarily record a non-opiate directive under section 18B of chapter 94C; and (7)

SECTION 4. Section 57 of Chapter 71 of the General Laws is hereby amended by inserting after the word results, in line 11, the following words: - “including a substance use screening using a validated tool,”

And by inserting after the word department., in line 21, the following words: - “Substance use screenings shall be performed by nurses, physicians, or other personnel who are approved by the department of public health for the purpose, and shall be conducted at least once annually in grades 8 or 9, and 11.”

SECTION 5. Said Section 57 of Chapter 71 is further amended by inserting after the final paragraph the following paragraph:-

“Substance use screening results shall not be recorded in any file subject to inspection under Section 34E of Chapter 71. Results for all students shall be recorded without identifying

information and reported to the Department of Public Health no later than 30 days after completion."

SECTION 6. Section 1 of chapter 94C of the General Laws, as appearing in the 2014 Official Edition, is hereby amended by inserting after the definition of "drug paraphernalia" the following definition:-

"Extended-release long-acting opioid", a drug that is subject to the United States Food and Drug Administration's Extended-Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy; provided, however, that "extended-release long-acting opioid" shall include any opioid in an extended-release form.

SECTION 7. Said section 1 of said chapter 94C, as so appearing, is hereby further amended by inserting after the definition of "narcotic drug" the following definition:-

"Non-abuse deterrent opioid", an opioid drug product that is approved for medical use but does not meet the requirements for listing as a drug with abuse-deterrent properties pursuant to section 13 of chapter 17; provided, however, that "non-abuse deterrent opioid" shall include any opioid in a non-abuse deterrent form.

SECTION 8. Section 18 of said chapter 94C, as so appearing, is hereby amended by striking out, in line 70, the words "A prescription" and inserting in place thereof the following words:- "Except as further restricted by section 18A, a prescription".

SECTION 9. Said section 18 of said chapter 94C, as so appearing, is hereby further amended by adding the following subsection:-

(d¾) A prescription for a narcotic substance contained in schedule II or schedule III of section 3 may be filled by the pharmacist in a lesser quantity of the substance than that quantity indicated on the prescription if the person presenting the prescription requests the lesser quantity. Within a reasonable time following a reduction in quantity, but not to exceed 7 days, the pharmacist or a designee shall notify the prescribing practitioner of the reduction and of the amount actually dispensed. The notification shall be conveyed by a notation in the interoperable electronic health record of the patient as defined by section 1 of chapter 118I or, if the pharmacist does not have the ability to make a notation in the patient's interoperable electronic health record, by facsimile, electronic transmission or by making a notation in the patient's record maintained by the pharmacy which shall be accessible to the practitioner by request. A prescription filled in a lesser quantity pursuant to this subsection shall be considered a partial fill and may subsequently be filled according to federal regulations applicable to partially filled prescriptions; provided, however, that the subsequent fill shall occur at the pharmacy that initially dispensed the partial fill. Nothing in this subsection shall be interpreted to conflict with or supersede any other requirement established in this section for a prescription of a narcotic substance or any requirements or conditions for drug substitutions established in chapter 112.

SECTION 10. Said chapter 94C is hereby further amended by inserting after section 18 the following section:-

Section 18A. For an opioid drug identified pursuant to said section 13 of said chapter 17 as posing a heightened level of public health risk, a practitioner prior to issuing an initial prescription shall: (i) evaluate the patient's current condition, risk factors, history of substance abuse, if any, and current medications; (ii) make a determination that other pain management treatments, including drugs presenting a lower risk for abuse or misuse, are or would be

inadequate for the patient; (iii) utilize the prescription monitoring program prior to issuing the prescription; and (iv) enter into a pain management treatment agreement with the patient that appropriately addresses the risk factors for abuse or misuse of the prescribed substance under guidelines published by the department and document the agreement in the patient's interoperable electronic health record.

SECTION 11. Said Chapter 94C is hereby further amended by inserting the following new section:-

Section 18B. (a) The secretary for health and human services shall establish a program for persons to voluntarily record a non-opiate directive. A person, if they are in recovery from a substance addiction or for any other reason, may request their own inclusion in the program, which shall indicate to all practitioners and health care providers and facilities that the person shall not be administered nor offered a prescription or medication order for an opiate substance. A person recording such a directive may request in a manner determined by the secretary, and the secretary shall comply with said request, for the deletion and expungement of their directive for any reason.

(b) The secretary shall direct all agencies under his or her authority to promulgate appropriate regulations for the implementation of this non-opiate directive program, which shall include but need not be limited to:

(1) Procedures to record the directive in the person's interoperable electronic health record and in the prescription monitoring program established under section 24A of chapter 94C.

(2) A standard form for the recording and transmission of the directive, which shall include verification by a physician, nurse practitioner or physician assistant licensed by the Commonwealth, and which shall comply with the written consent requirements of 42 CFR Part 2. The form shall also present, in plain language, information on the process to request deletion of the directive.

(3) Provisions for a duly authorized guardian or health care proxy to override a previously recorded directive, and circumstances under which a treating clinician may override a previously recorded directive based on documented medical judgment which shall be recorded in the patient's interoperable electronic health record.

(4) Provisions for a board of professional licensure to limit, condition, suspend or revoke the license of, or to assess fines against, a licensed health care professional who knowingly or recklessly fails to comply with a patient's non-opiate directive.

(5) Procedures to ensure that any recording, sharing or distribution of data relative to the non-opiate directive program complies with applicable laws and regulations regarding privacy of health information.

(6) Appropriate exemptions from the requirement to comply with the directive, based on emergency circumstances.

(c) A written prescription that is presented at a retail pharmacy, or a prescription that is electronically transmitted to a retail pharmacy, shall be presumed to be valid for the purposes of this section, and a pharmacist in a retail setting shall not be held in violation of this section for dispensing a controlled substance in contradiction to a non-opiate directive, except upon evidence that the pharmacist acted knowingly and negligently against the directive.

SECTION 12. The first paragraph of section 21 of said chapter 94C, as appearing in the 2014 Official Edition, is hereby amended by adding the following sentence:- If the dispensed substance has a recommended or required expiration date, the label affixed by the pharmacist shall have the expiration date displayed in a print size allowing not more than 10 characters per inch.

SECTION 13. The second paragraph of section 21A of said chapter 94C, as so appearing, is hereby amended by adding the following sentence:- A pharmacist shall give notice to any person who presents for filling a new prescription for a narcotic substance contained in schedule II or schedule III of section 3 of the option to receive a lesser quantity of the prescribed substance than that quantity indicated on the prescription.

SECTION 14. Section 22 of said chapter 94C, as so appearing, is hereby amended by adding the following subsection:-

(c) A practitioner who dispenses, by issuing a written prescription, an extended-release long-acting opioid drug in a non-abuse deterrent form that has been identified pursuant to section 13 of chapter 17 as posing a heightened level of public health risk shall, in addition to the requirements of subsection (a) and, in a manner set forth in department regulations, prepare appropriate documentation of the medical need for the drug and a statement of the practitioner's professional judgment that other treatments or drugs are not suitable for the patient. The documentation shall be placed in the patient's medical file.

SECTION 15. Said chapter 94C is hereby further amended by inserting after section 24A the following section:-

Section 24B. The department shall annually determine, through the electronic monitoring system established pursuant to section 24A, the mean and median quantity and volume of prescriptions for opiates contained in schedule II and schedule III of section 3 issued by practitioners registered under section 7; provided, however, that mean and median prescription quantities and volumes shall be determined within categories determined by the department of practitioners of a similar specialty or practice type.

The department shall work in conjunction with the respective boards of licensure to annually determine each practitioner's schedule II and schedule III opiate prescribing quantity and volume, and the practitioner's standing with regard to the mean and median quantity and volume for the practitioner's category of specialty or practice type; provided, however, that the practitioner's standing shall be expressed as a percentile ranking for the practitioner within the practitioner's category. Each practitioner whose prescribing exceeds said mean or median within their category shall be sent notice of their percentile ranking in a manner determined by the department. The ranking determined for each practitioner shall be distributed by the department or by the relevant board of licensure only to the practitioner to which the information pertains and this information shall be confidential, not considered a public record as defined in clause Twenty-sixth of section 7 of chapter 4 and not subject to disclosure pursuant to chapter 66, not admissible as evidence in a civil or criminal proceeding, and shall not be the sole basis for investigation by a licensure board.

SECTION 16. The General Laws are hereby amended by inserting after chapter 94F the following chapter:-

CHAPTER 94G

PROVISIONS CONCERNING PHARMACEUTICAL PRODUCT MANUFACTURERS

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

"Covered drug", any brand or generic drug placed in schedule II or schedule III of section 3 of chapter 94C; provided, however, that "covered drug" shall also include benzodiazepines; provided further, that "covered drug" shall not include: (i) drugs intended for use solely in veterinary care; (ii) substances that are regulated as cosmetic products under the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et. seq.; (iii) drugs that are compounded under a specialty license pursuant to sections 39G to 39J, inclusive of chapter 112; (iv) hypodermic needles, lancets or other sharps products subject to collection and disposal procedures established in section 27A of chapter 94C; or (e) drugs approved and used primarily for medication-assisted substance addiction treatment.

"Department", the department of public health.

"Drug stewardship program", a program financed by a pharmaceutical product manufacturer or a group of manufacturers to collect, secure, transport and safely dispose of unwanted drugs that complies with the requirements of this chapter.

"Pharmaceutical product manufacturer" or "manufacturer", any entity that engages in the manufacture of a controlled substance under a federal Food and Drug Administration manufacturer's license; provided, however, that "pharmaceutical product manufacturer" or "manufacturer" shall not include a hospital pharmacy.

"Prescription drug", any drug product which pursuant to chapter 94C may be dispensed under a written prescription by an authorized practitioner.

"Stewardship organization", an organization designated by a manufacturer or a group of manufacturers to act as an agent on behalf of the manufacturer or the group of manufacturers to implement and operate a drug stewardship program.

"Unwanted drug", a covered drug that is no longer wanted or intended to be consumed or that is abandoned, discarded or surrendered by the person to whom it was prescribed or any other person; provided, however, that "unwanted drug" shall not apply to waste or unused products from a pharmacy, hospital or health clinic or other commercial sources that the department may determine by regulation to be a nonresidential source; provided further, that "unwanted drug" shall include covered drugs that are voluntarily deposited at collection points co-located with a law enforcement agency; and provided further, that "unwanted drug" shall not include drugs seized by law enforcement officers in the course of their law enforcement duties.

"Wholesaler", an entity licensed pursuant to section 36B of chapter 112.

Section 2. (a) Any pharmaceutical product manufacturer selling or distributing a covered drug contained in schedule II or schedule III of section 3 of chapter 94C to consumers in the commonwealth, whether directly or through a wholesaler, retailer or other agent, shall: (i) operate a drug stewardship plan approved by the department individually or jointly with other manufacturers; or (ii) enter into an agreement with a stewardship organization that shall operate a drug stewardship plan approved by the department.

(b) The department shall establish a process to review applications for approval and re-approval of a manufacturer's drug stewardship plan and through this process the department

shall ensure that the scope and extent of each approved stewardship program is reasonably related to the manufacturer's total sales of covered drugs in the commonwealth.

(c) Each operator of a drug stewardship program shall provide an annual written report to the department describing the program's activities for the prior year and the volume and type of unwanted drugs collected.

(d) The department shall review for re-approval each drug stewardship program, whether operated by a manufacturer, a group of manufacturers or a stewardship organization, not less frequently than every 3 years.

(e) The department shall publish and make publicly available a list and description of each approved drug stewardship program and shall update this list at least bimonthly.

Section 3. An applicant seeking approval for a drug stewardship program shall provide, in a manner and form determined by the department, information on how the program shall meet the following minimum requirements:

(i) a collection system to provide convenient, ongoing collection services to all persons seeking to dispose of an unwanted drug; provided, however, that the collection system may accept any covered drug and any other prescription drug in a pill formulation regardless of its schedule, brand or source of manufacture, shall offer reasonably frequent access to persons across all geographic regions of the commonwealth and shall include any 2 or more of the following: (A) a mail-back program that provides prepaid and preaddressed packaging for a pharmacy to distribute when filling a prescription for a covered drug or upon request by a consumer; (B) collection kiosks; (C) drop-off day events at regional locations; (D) distribution of in-home disposal methods that render a product safe from misuse and that comply with

applicable controlled substance regulations and environmental safety regulations; and (E) any other method recommended by the department or pursuant to federal Drug Enforcement Administration guidelines;

(ii) adequate provisions for the security of the unwanted drugs throughout the collection process and the safety of any persons involved in monitoring, staffing or servicing the stewardship program;

(iii) a program for public outreach and education about the drug stewardship program, which shall include a plan for communicating information about the drug products that may be disposed of through the program, a listing of all available collection methods, participating collectors and the locations, dates and hours of operation for all collection or drop-off locations, educational information on the environmental, health and addiction risks posed by unused or improperly disposed prescription drugs and a means of communication to receive public comments and questions about the program;

(iv) a plan for the manufacturer, group of manufacturers or stewardship organization operating the program to provide for the operational and administrative costs associated with the program; provided, however, that no point-of-sale, point-of-collection, processing fees or other drug cost increases may be charged to individual consumers to recoup program costs;

(v) provisions by the manufacturer, group of manufacturers or stewardship organization operating the program that provide incentives to consumers to return unused drugs;

(vi) an attestation that the program shall comply with all applicable state and federal requirements for the collection, security, transport and disposal of drugs, including any

requirements established by rule or regulation of the federal Drug Enforcement Administration or the federal Environmental Protection Agency; and

(vii) other requirements as may be established by regulation by the department for the safe and effective administration of a drug stewardship program.

Section 4. (a) Any pharmaceutical product manufacturer that sells or distributes a covered drug in the commonwealth and has not submitted an application for approval under section 2 shall receive an initial notice from the department informing the manufacturer of the requirements to comply with this chapter. Any manufacturer in receipt of an initial notice shall submit an application for approval under said section 2 within 180 calendar days.

(b) Upon becoming aware that a pharmaceutical product manufacturer has discontinued its drug stewardship program or has altered the program such that the program no longer fulfills the requirements of this chapter, the department shall send a notice of noncompliance to the manufacturer. Any manufacturer in receipt of a notice of noncompliance shall take all required corrective steps to reestablish compliance with this chapter within 30 days or submit a written appeal of the notice of noncompliance to the department.

(c) If, after consideration of an appeal or after the manufacturer submits no appeal in the prescribed time period, the department determines that the manufacturer has continued to violate this chapter, the department shall assess the manufacturer an initial penalty of not more than $150,000 and a further penalty of not more than $10,000 for each subsequent day that the manufacturer continues to violate this chapter.

(d) Assessments collected pursuant to this section shall be deposited in the Substance Abuse Services Fund established in section 2I of chapter 111.

(e) The department shall report any persistent violations of this chapter to the attorney general who may protect consumers in the health care market under this chapter or any other law.

Section 5. (a) The requirements established by the department pursuant to this chapter may exceed, but shall not conflict with, any obligations which may be imposed on a manufacturer by a federally-approved Risk Evaluation and Mitigation Strategy.

(b) Nothing in this chapter shall require a retail pharmacy or a pharmacist practicing in a retail setting to participate in the collection, securing, transport or disposal of prescription drug products.

(c) No stewardship program developed by a manufacturer or stewardship organization may require a pharmacy in the commonwealth to participate in the collection, securing, transport or disposal of unwanted drugs or provide a space for or maintain a collection kiosk within a retail pharmacy unless the pharmacy licensee provides written consent.

(d) The department shall promulgate regulations to implement this chapter.

SECTION 17. Chapter 112 of the General Laws is hereby amended by inserting after section 5M the following section:-

Section 5N. The board shall by regulation establish qualifications, standards and criteria not less stringent than credentialing criteria by the American Academy for Pain Management, and a process by which licensed physicians may apply, for certification as a pain management specialist and periodic renewal of the certification. This section shall not be construed to prohibit any duly licensed health care practitioner who did not receive certification under this section

from engaging in pain management treatment and services within the scope of the practitioner's license.

SECTION 18. Chapter 112 of the General Laws is hereby amended by inserting after section 24G the following section:-

Section 24H. Notwithstanding any general or special law to the contrary. The board shall establish a rehabilitation program designed to assist its registered pharmacists, pharmacy interns and pharmacy technicians, whose competency has been impaired because of substance abuse disorders, to return to practice. Such program shall be designed in such a manner so that the public health and safety will not be endangered.

(b) The rehabilitation program shall: (1) serve as a voluntary alternative to traditional disciplinary actions; (2) establish criteria for the acceptance, denial, or termination of registered pharmacists, pharmacy interns and pharmacy technicians in said program; and (3) establish an outreach program to help identify registered pharmacists, pharmacy interns and pharmacy technicians who are substance abusers and to educate them about said rehabilitation program.

Only those registered pharmacists, pharmacy interns and pharmacy technicians who have requested rehabilitation and supervision shall participate in said program.

(c) The board shall appoint one or more rehabilitation evaluation committees consisting of at least seven members, two of whom shall be registered pharmacists with demonstrated experience in the field of substance use disorders; one of whom shall be a medical doctor experienced in the treatment of substance use disorders; one of whom shall be a pharmacy technician with demonstrated experience in the field of substance use disorders; one of whom shall be a registered pharmacist who has recovered from drug or alcohol addiction and has been

drug and alcohol free for a minimum of five years; and two of whom shall be representatives of the public who are knowledgeable about the field of substance abuse or mental health. Each committee shall elect a chairperson and a vice chairperson. The members of the committee shall serve for such terms as the board shall determine but in no case shall such term exceed four years. All members of the committee who are pharmacists shall hold licenses as pharmacists in the commonwealth for the duration of their terms and each member of the committee who is a pharmacy technician must be registered in the commonwealth for the duration of their term. No board member may serve on a committee.

(d) The board shall employ a pharmacist specialist with demonstrated professional expertise in the field of substance abuse disorders to serve as supervisor of participants in the rehabilitation program. Such supervisor shall serve as a liaison among the board, the committee, approved treatment programs and providers, and licensees. All information obtained by a supervisor pursuant to this section shall be exempt from disclosure and shall be confidential subject to the provisions of subsections (f) and (g).

(e) All rehabilitation evaluation committee findings shall be submitted to the board as recommendations and shall be subject to final approval of the board. Each committee shall have the following duties and responsibilities:

(1) To evaluate, according to the guidelines prescribed by the board, those registered pharmacists, pharmacy interns or pharmacy technicians who request participation in the program and to consider the recommendations of the pharmacist specialist supervisor in the admission of the registered pharmacist, pharmacy intern or pharmacy technician to the rehabilitation program.

(2) To review and designate those treatment facilities and services to which rehabilitation program participants may be referred.

(3) To receive and review information concerning a registered pharmacist, pharmacy intern or pharmacy technician participating in the program.

(4) To consider in the case of each rehabilitation program participant whether the pharmacist, pharmacy intern or registered pharmacy technician may with safety continue or resume their respective practices.

(5) To call meetings as necessary to consider the requests of registered pharmacists, pharmacy interns or pharmacy technicians to participate in the rehabilitation program, and to consider reports regarding rehabilitation program participants.

(6) To prepare reports to be submitted to the board.

(7) To set forth in writing for each rehabilitation program participant an individualized rehabilitation program with requirements for supervision and surveillance.

(8) To provide information to pharmacists, pharmacy interns or pharmacy technicians requesting participation in the program.

(f) Each registered pharmacist, pharmacy intern or pharmacy technician who requests participation in a rehabilitation program shall agree to cooperate with the rehabilitation program recommended by a rehabilitation evaluation committee and approved by the board. Any failure to comply with the provisions of a rehabilitation program may result in termination of the participant from the rehabilitation program. The name and license number of a registered

pharmacist, pharmacy intern or pharmacy technician terminated for failure to comply with the provisions of a rehabilitation program shall be reported to the board.

(g) After a committee in its discretion has determined that a registered pharmacist, pharmacy intern or pharmacy technician has been rehabilitated and the rehabilitation program is completed, the board shall seal all records pertaining to the registered pharmacist, pharmacy intern or pharmacy technician's participation in the rehabilitation program. No record shall be sealed sooner than five years from the participant's date of entry into the rehabilitation program. All board and committee records and records of a proceeding pertaining to the rehabilitation of a pharmacist, pharmacy intern or pharmacy technician in the rehabilitation program shall be kept confidential and are not subject to discovery.

(h) Within 180 days of passage of this act, the commissioner of public health shall report on which allied health professionals ought to be incorporated into the rehabilitation program established in this section. The commissioner shall file recommendations, as well as any recommended policy changes to effectuate those recommendations, with the chairs of the joint committee on public health, the joint committee on health care financing, the house and senate committees on ways and means, and the house and senate committees on rules.

SECTION 19. Chapter 175 of the General Laws, as appearing in the 2014 Official Edition, is hereby amended by inserting after said section 47GG the following section:-

Section 47HH. Any policy, contract, agreement, plan or certificate of insurance issued, delivered or renewed within the commonwealth, which is considered creditable coverage under section 1 of chapter 111M, shall provide, for any covered drug that is a narcotic substance contained in schedule II or schedule III of section 3 of chapter 94C and that is subject to cost

sharing, a schedule that allows for adjustments and reductions in the cost sharing when a person requests a prescription filled in a lesser quantity pursuant to section 18 of said chapter 94C.

SECTION 20. Chapter 176A of the General Laws, as appearing in the 2014 Official Edition, is hereby amended by inserting after said section 8II the following section:-

Section 8JJ. Any contract between a subscriber and the corporation under an individual or group hospital service plan which is delivered, issued or renewed within the commonwealth shall provide, for any covered drug that is a narcotic substance contained in schedule II or schedule III of section 3 of chapter 94C and that is subject to cost sharing, a schedule that allows for adjustments and reductions in the cost sharing when a person requests a prescription filled in a lesser quantity pursuant to section 18 of said chapter 94C.

SECTION 21. Chapter 176B of the General Laws, as appearing in the 2014 Official Edition, is hereby amended by inserting after said section 4II the following section:-

Section 4JJ. Any subscription certificate under an individual or group medical service agreement delivered, issued or renewed within the commonwealth shall provide, for any covered drug that is a narcotic substance contained in schedule II or schedule III of section 3 of chapter 94C and that is subject to cost sharing, a schedule that allows for adjustments and reductions in the cost sharing when a person requests a prescription filled in a lesser quantity pursuant to section 18 of said chapter 94C.

SECTION 22. Chapter 176G of the General Laws, as appearing in the 2014 Official Edition, is hereby amended by inserting after said section 4AA the following section:-

Section 4BB. An individual or group health maintenance contract that is issued or renewed shall provide, for any covered drug that is a narcotic substance contained in schedule II or schedule III of section 3 of chapter 94C and that is subject to cost sharing, a schedule that allows for adjustments and reductions in the cost sharing when a person requests a prescription filled in a lesser quantity pursuant to section 18 of said chapter 94C.

SECTION 23. Said Chapter 175, as so appearing, is hereby further amended by inserting after section 47HH the following section:-

Section 47II. (a) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or renewed within the commonwealth, which is considered creditable coverage under section 1 of chapter 118M, shall provide for:

(1) a plan for the minimum coverage and provision of adequate access to pain management services that provide alternatives to narcotic substance prescribing, as established pursuant to section 2 of chapter 176O; and

(2) a plan, developed based on clinical evidence and in consultation with health care practitioners, for reasonable controls and safeguards on potentially addictive opiate prescription drugs, which may include, but need not be limited to (i) restricting individual beneficiaries, based on excessive prescribed quantities or other signs of risk, to obtaining prescriptions only from a limited number of providers and pharmacies, provided that beneficiaries restricted under such programs must be appropriately notified and have rights to appeal; (ii) establishing prior authorization requirements and other administrative safeguards on the prescribing of drugs identified pursuant to section 13 of chapter 17 as posing a heightened risk to the public health; (iii) requirements that beneficiaries provide informed consent prior to

receiving an opiate prescription, based on clinically accurate information about the risks and benefits of opiate drugs; (iv) volume thresholds for new prescriptions, above which the carrier may require treatment agreements, pain management consultations, or other authorization requirements.

(b) The plans described in paragraphs (1) and (2) shall be subject to approval, and shall be a component of carrier accreditation by the division of insurance, pursuant to section 2 of chapter 176O. In its review, the division shall consider the adequacy of access to pain management services, and any carrier policies which may create unduly preferential coverage to opiate prescribing over other pain management modalities.

(c) Each carrier shall distribute educational materials to providers within their networks about the plans described in paragraphs (1) and (2) and shall post information about said plans on their public websites.

SECTION 24. Said Chapter 176A, as so appearing, is hereby further amended by inserting after section 87JJ the following section:-

Section 8KK. Any contract between a subscriber and the corporation under an individual or group hospital service plan which is delivered, issued or renewed within the commonwealth shall provide for:

(1) a plan for the minimum coverage and provision of adequate access to pain management services that provide alternatives to narcotic substance prescribing, as established pursuant to section 2 of chapter 176O; and

(2) a plan, developed based on clinical evidence and in consultation with health care practitioners, for reasonable controls and safeguards on potentially addictive opiate prescription drugs, which may include, but need not be limited to (i) restricting individual beneficiaries, based on excessive prescribed quantities or other signs of risk, to obtaining prescriptions only from a limited number of providers and pharmacies, provided that beneficiaries restricted under such programs must be appropriately notified and have rights to appeal; (ii) establishing prior authorization requirements and other administrative safeguards on the prescribing of drugs identified pursuant to section 13 of chapter 17 as posing a heightened risk to the public health; (iii) requirements that beneficiaries provide informed consent prior to receiving an opiate prescription, based on clinically accurate information about the risks and benefits of opiate drugs; (iv) volume thresholds for new prescriptions, above which the carrier may require treatment agreements, pain management consultations, or other authorization requirements.

(b) The plans described in paragraphs (1) and (2) shall be subject to approval, and shall be a component of carrier accreditation by the division of insurance, pursuant to section 2 of chapter 176O. In its review, the division shall consider the adequacy of access to pain management services, and any carrier policies which may create unduly preferential coverage to opiate prescribing over other pain management modalities.

(c) Each carrier shall distribute educational materials to providers within their networks about the plans described in paragraphs (1) and (2) and shall post information about said plans on their public websites.

SECTION 25. Said Chapter 176B, as so appearing, is hereby further amended by inserting after section 4JJ the following section:- Section 4KK. Any subscription certificate

under an individual or group medical service agreement delivered, issued or renewed within the commonwealth shall provide for:

(1) a plan for the minimum coverage and provision of adequate access to pain management services that provide alternatives to narcotic substance prescribing, as established pursuant to section 2 of chapter 176O; and

(2) a plan, developed based on clinical evidence and in consultation with health care practitioners, for reasonable controls and safeguards on potentially addictive opiate prescription drugs, which may include, but need not be limited to (i) restricting individual beneficiaries, based on excessive prescribed quantities or other signs of risk, to obtaining prescriptions only from a limited number of providers and pharmacies, provided that beneficiaries restricted under such programs must be appropriately notified and have rights to appeal; (ii) establishing prior authorization requirements and other administrative safeguards on the prescribing of drugs identified pursuant to section 13 of chapter 17 as posing a heightened risk to the public health; (iii) requirements that beneficiaries provide informed consent prior to receiving an opiate prescription, based on clinically accurate information about the risks and benefits of opiate drugs; (iv) volume thresholds for new prescriptions, above which the carrier may require treatment agreements, pain management consultations, or other authorization requirements.

(b) The plans described in paragraphs (1) and (2) shall be subject to approval, and shall be a component of carrier accreditation by the division of insurance, pursuant to section 2 of chapter 176O. In its review, the division shall consider the adequacy of access to pain management services, and any carrier policies which may create unduly preferential coverage to opiate prescribing over other pain management modalities.

(c) Each carrier shall distribute educational materials to providers within their networks about the plans described in paragraphs (1) and (2) and shall post information about said plans on their public websites.

SECTION 26. Said Chapter 176G, as so appearing, is hereby further amended by inserting after section 4BB the following section:-

Section 4CC. Any individual or group health maintenance contract that is issued or renewed shall provide for:

(1) a plan for the minimum coverage and provision of adequate access to pain management services that provide alternatives to narcotic substance prescribing, as established pursuant to section 2 of chapter 176O; and

(2) a plan, developed based on clinical evidence and in consultation with health care practitioners, for reasonable controls and safeguards on potentially addictive opiate prescription drugs, which may include, but need not be limited to (i) restricting individual beneficiaries, based on excessive prescribed quantities or other signs of risk, to obtaining prescriptions only from a limited number of providers and pharmacies, provided that beneficiaries restricted under such programs must be appropriately notified and have rights to appeal; (ii) establishing prior authorization requirements and other administrative safeguards on the prescribing of drugs identified pursuant to section 13 of chapter 17 as posing a heightened risk to the public health; (iii) requirements that beneficiaries provide informed consent prior to receiving an opiate prescription, based on clinically accurate information about the risks and benefits of opiate drugs; (iv) volume thresholds for new prescriptions, above which the carrier may require treatment agreements, pain management consultations, or other authorization requirements.

(b) The plans described in paragraphs (1) and (2) shall be subject to approval, and shall be a component of carrier accreditation by the division of insurance, pursuant to section 2 of chapter 176O. In its review, the division shall consider the adequacy of access to pain management services, and any carrier policies which may create unduly preferential coverage to opiate prescribing over other pain management modalities.

(c) Each carrier shall distribute educational materials to providers within their networks about the plans described in paragraphs (1) and (2) and shall post information about said plans on their public websites.

SECTION 27. Section 2 of chapter 176O of the General Laws, as appearing in the 2014 Official Edition, is hereby amended by striking out, in lines 8 and 9, the words “and (5)” and inserting in place thereof the following words:-

(5) prescription drug safety and access to pain management; and

(6)

SECTION 28. Chapter 176O of the General Laws, as appearing in the 2014 Official Edition, is hereby further amended by inserting after section 6 the following section:-

Section 6A. Each carrier, as defined in section 1, shall provide for:

(1) a plan for the minimum coverage and provision of adequate access to pain management services that provide alternatives to narcotic substance prescribing, as established pursuant to section 2; and

(2) a plan, developed based on clinical evidence and in consultation with health care practitioners, for reasonable controls and safeguards on potentially addictive opiate prescription

drugs, which may include, but need not be limited to (i) restricting individual beneficiaries, based on excessive prescribed quantities or other signs of risk, to obtaining prescriptions only from a limited number of providers and pharmacies, provided that beneficiaries restricted under such programs must be appropriately notified and have rights to appeal; (ii) establishing prior authorization requirements and other administrative safeguards on the prescribing of drugs identified pursuant to section 13 of chapter 17 as posing a heightened risk to the public health; (iii) requirements that beneficiaries provide informed consent prior to receiving an opiate prescription, based on clinically accurate information about the risks and benefits of opiate drugs; (iv) volume thresholds for new prescriptions, above which the carrier may require treatment agreements, pain management consultations, or other authorization requirements.

(b) The plans described in paragraphs (1) and (2) shall be subject to approval, and shall be a component of carrier accreditation by the division, pursuant to section 2. In its review, the division shall consider the adequacy of access to pain management services, and any carrier policies which may create unduly preferential coverage to opiate prescribing over other pain management modalities.

(c) Each carrier shall distribute educational materials to providers within their networks about the plans described in paragraphs (1) and (2) and shall post information about said plans on their public websites.

SECTION 29. Subsection (b) of section 7 of said chapter 176O, as so appearing, is hereby amended by striking out, in lines 59 to 68, inclusive, the words “and (4) a report detailing, for the previous calendar year, the total number of; (i) filed grievances, grievances that were approved internally, grievances that were denied internally, and grievances that were

withdrawn before resolution; and (ii) external appeals pursued after exhausting the internal grievance process and the resolution of all such external appeals. The report shall identify for each such category, to the extent such information is available, the demographics of such insured, which shall include, but need not be limited to, race, gender and age" and inserting in place thereof the following 2 clauses:-

(4) a report detailing for the previous calendar year the total number of: (i) filed grievances, grievances that were approved internally, grievances that were denied internally and grievances that were withdrawn before resolution; and (ii) external appeals pursued after exhausting the internal grievance process and the resolution of all external appeals; provided, however, that the report shall identify for each category, to the extent information is available, the demographics of the insured, which shall include, but need not be limited to, race, gender and age; and

(5) a report detailing for the previous calendar year the total number of: (i) medical or surgical claims submitted to the carrier; (ii) medical or surgical claims denied by the carrier; (iii) mental health or substance use disorder claims submitted to the carrier; (iv) mental health or substance use disorder claims denied by the carrier; (v) medical or surgical claims and mental health or substance use disorder claims denied by the carrier because: (A) pre-treatment authorization or referral for services was not obtained; (B) the service was not medically necessary; (C) the service was experimental or investigational; (D) the insured was not covered or eligible for benefits at the time services occurred; (E) the service or the provider was not covered; (F) duplicate claims had been submitted; (G) incomplete claims had been submitted; (H) coding errors had occurred; and (I) of any other specified reason.

SECTION 30. Section 13 of said chapter 176O, as so appearing, is hereby amended by adding the following subsection:-

(e) For any grievance involving a denial of coverage or a denial of preauthorization for mental health services, including behavioral health and substance use disorder services, the carrier shall provide to the insured and the insured's authorized representative, if any, in addition to all other notices required under this chapter, a statement certifying and specifically describing:

(i) that the denial of coverage by the carrier, the carrier's utilization review organization or other subcontracted entity complies with applicable state parity requirements for providing coverage on a nondiscriminatory basis under chapter 80 of the acts of 2000;

(ii) the quantitative and non-quantitative treatment limitations applied during review, including both the initial review of the claim and the review of the internal grievance, and how these treatment limitations comply with state and federal parity regulations, including those codified at 42 U.S.C. § 300gg–26 and regulations implemented pursuant to section 8K of chapter 26 of the General Laws; and

(iii) that the carrier's claim processing and utilization review methods complied with the parity requirements set forth in clauses (i) and (ii).

SECTION 31. Section 4 of chapter 258 of the General Laws, as so appearing, is hereby amended by adding the following paragraph:-

No civil action shall be brought and no liability for damages shall be assessed against a public employee, including any first responder or law enforcement personnel, for rendering or attempting to render emergency care in good faith by administering naloxone or a similar opioid

antagonist, as defined in section 19B of chapter 94C, to an individual who has or reasonably appears to have suffered a drug-related overdose.

SECTION 32. Within 90 days of the effective date of this act, the department of public health shall promulgate regulations to classify the drugs commercially referred to as gabapentin, neurontin and other chemical equivalents as “additional drugs” for the purposes of section 24A of chapter 94C of the General Laws.

SECTION 33. The first distribution to individual practitioners of the prescribing trends and profiles set forth in section 15 shall occur not later than January 1, 2017.

SECTION 34. There shall be a special commission to examine the feasibility of establishing a Massachusetts pain management access program, with the goal of increasing access to pain management by allowing primary care providers to arrange pain management consultations and temporary services by specialists certified under section 5N of chapter 111 of the General Laws for their patients in need of comprehensive non-opiate pain management resources.

If the special commission determines that the program is feasible and suitable, recommendations for establishing the program shall include recommended policies for funding the program, including consideration of commercial payer, public payer and federal reimbursement possibilities, and may also include, but need not be limited to, consideration of pilot programs and a timeline for full implementation. The special commission shall examine in its review similar service models in other specialty fields, including the Massachusetts Child Psychiatry Access Program.

The special commission shall consist of: the secretary of health and human services or a designee, who shall serve as co-chair; the chancellor of the University of Massachusetts Medical School or a designee, who shall serve as co-chair; a representative of the Massachusetts Medical Society; a representative of the Massachusetts Hospital Association, Inc.; a representative of the Massachusetts Pain Initiative; and other members as determined by the co-chairs.

The special commission shall file a report of its recommendations and drafts of proposed legislation or regulations, if any, with the clerks of the house of representatives and the senate not later than January 1, 2017.