SENATE . . . . . No. 2020

The Commonwealth of Massachusetts

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

SENATE, September 28, 2015

The committee on Ways and Means to whom was committed the Senate Bill to improve the accessibility and affordability of naloxone and other pharmaceutical drugs of public health concern (Senate, No. 603) (the committee on Rules having recommended that the bill be amended by substituting a new draft with the same title (Senate, No. 2010)),-- reports recommending that the proposed Rules amendment be amended by substituting a new draft entitled "An Act relative to substance use prevention" (Senate, No. 2020) [Estimated cost: $1,200,000] (Senator Keenan dissenting)

For the committee,
Karen E. Spilka

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

An Act relative to substance use prevention.

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 116F the following section:-

Section 116G. The municipal police training committee may 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 and section 12FF of chapter 112 and on responding to calls for assistance for drug-related overdoses.

The committee may 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.

The executive office of public safety and security, in collaboration with the department of public health, shall facilitate the collection and sharing of resources regarding the application of said section 34A of said chapter 94C.

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

(e) The commission shall also identify and publish a list of non-opioid drug products that have been approved by the United States Food and Drug Administration that are effective pain management alternatives and have a lesser potential for abuse than an opioid drug product contained in schedules II and III of section 3 of chapter 94C.

The commission shall provide for distribution, including electronic distribution, of copies of the list and revisions to the list among all prescribers and dispensers licensed to practice in the commonwealth and to other appropriate individuals and shall supply a copy to any person on request upon payment of the cost of printing.

The list shall be revised not less frequently than annually to include new pertinent information on non-opioid drug products approved for inclusion or non-opioid drug products to be deleted and to reflect current information as to the therapeutic efficacy of drugs and pharmaceuticals.

SECTION 3. Section 14 of said chapter 17 is hereby repealed.

SECTION 4. Section 19 of said chapter 17, as appearing in the 2014 Official Edition, is hereby amended by striking out, in lines 27 and 28, the words “and (6)” and inserting in place thereof the following words:-

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

(7).

SECTION 5. Section 57 of chapter 71 of the General Laws, as so appearing, is hereby amended by inserting after the word “results,”, in line 15, the following words: - to screen pupils for substance use disorders through a verbal screening tool approved by the department of public health.

SECTION 6. The first paragraph of said section 57 of said chapter 71, as so appearing, is hereby amended by inserting after the third sentence the following sentence:- Verbal substance use disorder screenings shall be performed by nurses, physicians or other personnel approved by the department of public health and shall be conducted at least once annually in grades 7 and 10.

SECTION 7. Said first paragraph of said section 57 of said chapter 71, as so appearing, is hereby further amended by adding the following sentence:- A child or the child’s parent or guardian may opt out of the verbal substance use disorder screening at any point prior to or during the screening.

SECTION 8. Said section 57 of said chapter 71, as so appearing, is hereby further amended by adding the following paragraph:-

Results of verbal substance use disorder screenings shall be reported to the department of public health without identifying information not later than 30 days after completion of the screening.

SECTION 9. Said chapter 71 is hereby further amended by inserting after section 57 the following section:-

Section 57A. (a) As used in this section, the following words shall have the following meanings unless the context clearly requires otherwise:

"Confidential information", any statement, response or disclosure provided in confidence by a child to a school employee during a verbal substance use disorder screening under section 57.

"School employee", a person who is employed or volunteers in a public school to conduct the verbal substance use disorder screening under section 57.

(b) Except as required under state and federal law and as provided in this paragraph, a school employee shall not disclose confidential information provided during a verbal substance use disorder screening under section 57. Confidential information shall not be subject to discovery or subpoena in any civil, criminal, legislative or administrative proceeding without the prior written consent of the child or the child's parent or guardian.

SECTION 10. 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 in a non-abuse deterrent form", a drug that is: (i) subject to the United States Food and Drug Administration's Extended Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy; (ii) an opioid 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; and (iii) identified pursuant to said section 13 of said chapter 17 as posing a heightened level of public health risk.

SECTION 11. 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 provided in section 18A, a prescription.

SECTION 12. Said section 18 of said chapter 94C, as so appearing, is hereby further amended by striking out subsection (e) and inserting in place thereof the following subsection:-

(e) Practitioners who prescribe controlled substances, except veterinarians, shall be required, as a prerequisite to obtaining or renewing their professional licenses, to complete appropriate training relative to: (i) effective pain management; (ii) identification of patients at risk for substance use disorders; (iii) counseling patients about the side effects, addictive nature and proper storage and disposal of prescription medications; and (iv) appropriate prescription quantities for prescription medications that have an increased risk of abuse. The boards of registration for each professional license that requires this training shall develop the standards for appropriate training programs.

SECTION 13. Said chapter 94C is hereby further amended by inserting after section 18 the following 2 sections:-

Section 18A. Prior to issuing an extended-release long-acting opioid in a non-abuse deterrent form for outpatient use for the first time, a practitioner registered under section 7 shall: (i) evaluate the patient's current condition, risk factors, history of substance abuse, if any, and current medications; (ii) provide a statement that the prescription, in the prescriber's medical opinion, is an appropriate course of treatment based on the medical need of the patient; (iii) utilize the prescription drug monitoring program established under section 24A prior to issuing the prescription; and (iv) in the event of long term pain management, 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 statement and the agreement, if applicable, in the patient's medical file and interoperable electronic health record.

Section 18B. (a) The secretary of health and human services shall establish a voluntary non-opiate directive form that shall indicate to all prescribers, health care providers and facilities that an individual shall not be administered or offered a prescription or medication order for an opiate. A person may execute and file a voluntary non-opiate directive form with a practitioner registered under section 7 or other authority authorized by the secretary to accept the directive for filing. A voluntary non-opiate directive form may be revoked by the participant for any reason.

(b) The secretary shall promulgate regulations for the implementation of the voluntary non-opiate directive form, which shall include, but need not be limited to:

(i) procedures to record the voluntary non-opiate directive form in the person's interoperable electronic health record and in the prescription drug monitoring program established under section 24A;

(ii) a standard form for the recording and transmission of the voluntary non-opiate directive form, which shall include verification by a practitioner registered under said section 7 and which shall comply with the written consent requirements of the Public Health Service Act, 42 U.S.C. § 290dd-2(b), and 42 CFR Part 2; provided, however, that the form shall also provide in plain language information on the process to revoke the directive;

(iii) requirements for an individual to appoint a duly authorized guardian or health care proxy to override a previously recorded voluntary non-opiate directive form and circumstances under which a treating practitioner registered under said section 7 may override a previously

recorded voluntary non-opiate directive form based on documented medical judgment which shall be recorded in the patient's interoperable electronic health record;

(iv) 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 voluntary non-opiate directive form;

(v) procedures to ensure that any recording, sharing or distribution of data relative to the voluntary non-opiate directive form complies with all state and federal confidentiality laws; and

(vi) appropriate exemptions for emergency medical personnel.

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

(d) No health care provider or employee of a health care provider acting in good faith shall be subject to criminal or civil liability or be considered to have engaged in unprofessional conduct for failing to offer or administer a prescription or medication order for an opiate under the voluntary non-opiate directive form.

No person acting as an agent pursuant to a health care proxy shall be subject to criminal or civil liability for making a decision under clause (iii) of subsection (b) in good faith.

SECTION 14. The second paragraph of section 21A of said chapter 94C, as appearing in the 2014 Official Edition, is hereby amended by adding the following sentence:- A pharmacist or a pharmacist's designee shall give notice to any person who presents for filling a prescription for an opiate contained in schedule III of section 3 that the person may choose to receive a lesser quantity of the prescribed substance than the quantity indicated on the prescription.

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 prescription drug monitoring system established under 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 of practitioners of a similar specialty or practice type as determined by the department.

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 the mean or median within the practitioner's category shall be sent notice of the practitioner's 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, 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.

The department shall also coordinate with the respective boards of licensure to make resources available to prescribers regarding ways to change prescribing practices and incorporate alternative pain management options into a prescriber's practice.

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

CHAPTER 94G

DRUG STEWARDSHIP PROGRAM

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 name or generic opioid 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 United States 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 (v) 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.

"Pharmaceutical product manufacturer" or "manufacturer", an entity that manufactures a controlled substance under a United States Food and Drug Administration manufacturer's license; provided, however, that "pharmaceutical product manufacturer" or "manufacturer" shall not include an institutional pharmacy, as defined in section 39D of chapter 112.

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

"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: (i) that is no longer wanted or intended to be consumed or that is abandoned, discarded, expired or surrendered by the person to whom it was prescribed; or (ii) voluntarily deposited at collection points co-located with a law enforcement agency; provided, however, that "unwanted drug" shall not include: (A) waste or unused drug products from a pharmacy, hospital or health clinic or other commercial sources that the

department may determine by regulation to be a nonresidential source; or (B) drug products 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 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 renewal of a manufacturer's drug stewardship plan and 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 file 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 not later than March 1.

(d) The department shall review for renewal each drug stewardship program at least once 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 every 2 months.

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

Section 3. A manufacturer or stewardship organization seeking approval for a drug stewardship program shall submit, in a manner and form determined by the department, a plan that meets, but is not limited to, the following requirements:

(i) a collection system to provide convenient, ongoing collection services to all persons seeking to dispose of unwanted drugs; 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; provided further, that the system shall offer reasonable access to persons across all geographic regions; provided further, that the collection system shall include at least 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) additional collection kiosks; (C) drop-off day events at regional locations; (D) in-home disposal methods that render a product safe from misuse and that comply with applicable controlled substance regulations and environmental safety regulations; or (E) any other method recommended by the department or pursuant to United States Drug Enforcement Administration guidelines;

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

(iii) a plan for public outreach and education about the drug stewardship program, which shall include, but not be limited to, 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 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 drug products 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 that provides 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) incentives provided by the manufacturer, group of manufacturers or stewardship organization to consumers to return unwanted drugs;

(vi) an attestation that the program shall comply with all applicable state and federal requirements for the collection, security, transport and disposal of drug products, including any requirements established by rule or regulation of either the United States Drug Enforcement Administration or the United States Environmental Protection Agency; and

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

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

(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. A manufacturer in receipt of a notice of noncompliance shall take all required corrective steps to reestablish compliance with this chapter or submit a written appeal of the notice of noncompliance to the department within 30 days of receipt of the notice of noncompliance.

(c) If, after consideration of an appeal or if the manufacturer does not appeal within 30 days of receipt of the notice of noncompliance, 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; provided, however, that not more than 3 per cent of assessments collected pursuant to this section shall be expended to support the administration of the drug stewardship program.

(e) The department shall report any persistent violations of this chapter to the attorney general who may enforce this chapter.

Section 5. (a) The requirements established by the department pursuant to this chapter may exceed, but shall not conflict with, any obligations imposed on a manufacturer by a Risk Evaluation and Mitigation Strategy approved by the United States Food and Drug Administration.

(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 unwanted drugs.

(c) No stewardship program shall require an outpatient pharmacy in the commonwealth to participate in the collection, securing, transport or disposal of unwanted drugs or to provide a space for or to maintain a collection kiosk within an outpatient pharmacy unless the pharmacy certifies, in writing, that this participation is voluntary.

Section 6. There shall be a prescription drug awareness program administered by the department. The program shall be open to all manufacturers of covered drugs. A manufacturer who opts into the program shall be exempt from sections 2 to 5, inclusive.

Each participating manufacturer shall pay an assessment which shall be collected by the department and deposited into the Prescription Drug Awareness Trust Fund established in section 2J of chapter 111.

A participating manufacturer's assessment shall be paid over 3 calendar years according to a payment schedule established by the department and shall be based on a sliding scale not less than $10,000 per year but not to exceed $100,000 per year. The assessment shall be based on the ratio of the average volume of covered drugs sold by the manufacturer over the previous 3 calendar years to the total volume of covered drugs sold in the commonwealth for the same 3 calendar year period. For the purposes of this section, "volume" shall mean the number of pills, capsules or other unit of a covered drug prescribed and entered into the prescription drug monitoring program established under section 24A of chapter 94C. Any funds unexpended from an assessment at the end of the 3-year assessment period shall be applied as a credit to a

manufacturer's assessment for the subsequent 3-year period. This assessment shall not be passed on to the consumer or a health insurance carrier.

Not more than 9 months prior to the date of the first assessment payment, the department shall provide each manufacturer with a projected assessment amount and schedule. The manufacturer shall have 90 days from the receipt of the projected assessment to notify the department of its acceptance of the assessment and that it is opting into the program. Upon receiving notice of acceptance, the department shall enter the manufacturer into the program and provide an assessment schedule to the manufacturer.

SECTION 17. Chapter 111 of the General Laws is hereby amended by inserting after section 2I the following section:-

Section 2J. (a) There shall be established and set upon the books of the commonwealth a Prescription Drug Awareness Trust Fund to be expended, without further appropriation, by the department. The commissioner shall, as trustee, administer the fund. The fund shall consist of revenues collected by the commonwealth, including: (i) assessments collected by the department as part of the prescription drug awareness program established in section 6 of chapter 94G; (ii) any revenue from appropriations or other monies authorized by the general court and specifically designated to be credited to the fund; (iii) any funds from public and private sources, including gifts, grants and donations to provide awareness and education about prescription drug use; (iv) any interest earned on these revenues; and (v) any funds provided from other sources. Money remaining in the fund at the end of a fiscal year shall not revert to the General Fund. Notwithstanding mandatory deductions for indirect costs, not more than 1% of any assessment shall be used to support the administration costs of the program, including fringe benefits.

(b) All expenditures from the fund shall support initiatives to encourage public and professional awareness of the potential for the abuse of prescription drugs and to reduce the number of unwanted drugs in the commonwealth including, but not limited to: (i) evidence-based outreach and education programs designed to provide information on the therapeutic and cost effective utilization of prescription drugs for physicians, pharmacists and other health care professionals authorized to prescribe and dispense prescription drugs; (ii) public education and outreach on the dangers of prescription drug addiction; (iii) providing grants to law enforcement agencies interested in providing controlled substance collection boxes or drug take back days; (iv) school programs; (v) safe prescription drug disposal education; and (vi) providing grants to cities and towns in the commonwealth to engage in activities that support the purposes of the fund.

(c) Not later than March 1 of each year, the commissioner shall report to the executive office for administration and finance, the joint committee on mental health and substance abuse and the house and senate committees on ways and means including, but not limited to: (i) an itemized accounting of the way funds were spent in the previous calendar year; (ii) descriptions of the programs and activities supported by the fund; (iii) the amount of assessments deposited into the fund by each participant; and (iv) goals for the fund over the 3 calendar year assessment period.

SECTION 18. Section 3 of chapter 111E of the General Laws is hereby repealed.

SECTION 19. Chapter 112 of the General Laws is hereby amended by inserting after section 12EE the following section:-

Section 12FF. Any person who, in good faith, attempts to render emergency care by administering naloxone or other opioid antagonist as defined in section 19B of chapter 94C to a person reasonably believed to be experiencing an opiate-related overdose shall not be liable for acts or omissions, other than gross negligence or willful or wanton misconduct, resulting from the attempt to render this emergency care.

SECTION 20. Said chapter 112 is hereby further amended by inserting after section 24G the following section:-

Section 24H. (a) The board of registration in pharmacy shall establish a rehabilitation program for registered pharmacists, pharmacy interns and pharmacy technicians who have a substance use issue.

(b) The rehabilitation program shall: (i) serve as a voluntary alternative to traditional disciplinary actions; (ii) establish criteria for the acceptance, denial or termination of registered pharmacists, pharmacy interns and pharmacy technicians in the program; and (iii) establish an outreach program to identify registered pharmacists, pharmacy interns and pharmacy technicians who may have a substance use disorder and to provide education about the rehabilitation program.

Only a registered pharmacist, pharmacy intern or pharmacy technician who has requested rehabilitation and supervision shall be eligible to participate in the program.

(c) The board shall appoint a rehabilitation evaluation committee consisting of 7 members, 2 of whom shall be registered pharmacists with demonstrated experience in the field of substance use disorders, 1 of whom shall be a medical doctor with experience in the treatment of substance use disorders, 1 of whom shall be a pharmacy technician with demonstrated

experience in the field of substance use disorders, 1 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 5 years and 2 of whom shall be representatives of the public who are knowledgeable about substance use disorders or mental health. The committee shall elect a chairperson and a vice chairperson. Members of the committee shall serve for terms of 4 years. At the time of appointment or reappointment to the committee, no member of the committee who is licensed to practice by the department of public health, division of professional licensure or by the board of registration in medicine shall have had any type of disciplinary or enforcement action taken against them by their respective licensing board, the United States Food and Drug Administration or the United States Drug Enforcement Administration during the 5 years preceding their appointment to the committee. No member of the board shall serve on the committee.

(d) The board shall employ a pharmacist supervisor with demonstrated professional expertise in the field of substance use disorders to oversee participants in the rehabilitation program. The supervisor shall serve as a liaison among the board, the committee, approved treatment programs and providers and participants. Any information obtained by a supervisor pursuant to this section shall be exempt from disclosure and shall be confidential, subject to 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. The committee shall have the following duties and responsibilities:

(i) to evaluate, according to guidelines established by the board, registered pharmacists, pharmacy interns or pharmacy technicians who request to participate in the program and consider the recommendations of the pharmacist supervisor regarding the admission of a registered pharmacist, pharmacy intern or pharmacy technician into the program;

(ii) to review and designate treatment facilities and services to which participants may be referred;

(iii) to receive and review information concerning a participant in the program;

(iv) to consider, for each participant, whether the participant may continue or may resume practice within the full scope of the participant's the license;

(v) to call meetings as necessary to review the request of a registered pharmacist, pharmacy intern or pharmacy technician to participate in the program and review reports regarding participants;

(vi) to prepare reports to be submitted to the board;

(vii) to provide each participant with an individualized rehabilitation plan with requirements for supervision and surveillance; and

(viii) to provide information to pharmacists, pharmacy interns or pharmacy technicians who request to participate in the program.

(f) A registered pharmacist, pharmacy intern or pharmacy technician who requests to participate in the program shall agree to cooperate with the individualized rehabilitation plan recommended by the rehabilitation evaluation committee and approved by the board. Any failure to comply with the rehabilitation program may result in termination of the participant from the

rehabilitation program. The committee shall report to the board the name and license number of a registered pharmacist, pharmacy intern or pharmacy technician terminated from the program for failure to comply with the provisions of an individualized rehabilitation plan.

(g) After the committee, in its discretion, has determined that a registered pharmacist, pharmacy intern or pharmacy technician has successfully completed an individualized rehabilitation plan through the program, the board shall seal all records pertaining to the participation of the registered pharmacist, pharmacy intern or pharmacy technician in the program. No record shall be sealed sooner than 5 years from the participant's date of entry into the program. All board and committee records and records of a participant's involvement in the program shall be kept confidential and shall not be subject to discovery or subpoena in any civil, criminal, legislative or administrative proceeding without the prior written consent of the participant.

SECTION 21. Chapter 175 of the General Laws is hereby amended by inserting after section 47GG the following section:-

Section 47HH. (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 111M, shall provide for:

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

(ii) 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: (A) 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 these programs shall be appropriately notified and have rights to appeal; (B) establishing administrative safeguards on the prescribing of drugs identified pursuant to section 13 of chapter 17 as posing a heightened risk to the public health; (C) requirements that beneficiaries provide informed consent prior to receiving opiate prescriptions based on clinically accurate information about the risks and benefits of opiate drugs; or (D) 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 clauses (i) and (ii) of subsection (a) 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 prescribing opiates over other pain management modalities.

(c) Each carrier shall distribute educational materials to providers within their networks about the plans described in clauses (i) and (ii) of subsection (a) and shall post information about the plans on its public website.

SECTION 22. Chapter 176A of the General Laws is hereby amended by inserting after section 8II the following section:-

Section 8JJ. (a) 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:

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

(ii) 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 (A) 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 these programs shall be appropriately notified and have rights to appeal; (B) establishing administrative safeguards on the prescribing of drugs identified pursuant to section 13 of chapter 17 as posing a heightened risk to the public health; (C) 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; or (D) 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 clauses (i) and (ii) of subsection (a) 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 prescribing opiates over other pain management modalities.

(c) Each carrier shall distribute educational materials to providers within their networks about the plans described in clauses (i) and (ii) of subsection (a) and shall post information about the plans on its public website.

SECTION 23. Chapter 176B of the General Laws is hereby amended by inserting after section 4II the following section:-

Section 4JJ. (a) Any subscription certificate under an individual or group medical service agreement delivered, issued or renewed within the commonwealth shall provide for:

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

(ii) 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 (A) 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 shall be appropriately notified and have rights to appeal; (B) establishing administrative safeguards on the prescribing of drugs identified pursuant to section 13 of chapter 17 as posing a heightened risk to the public health; (C) 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; or (D) 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 clauses (i) and (ii) of subsection (a) 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 prescribing opiates over other pain management modalities.

(c) Each carrier shall distribute educational materials to providers within their networks about the plans described in clauses (i) and (ii) of subsection (a) and shall post information about the plans on its public website.

SECTION 24. Chapter 176G of the General Laws is hereby amended by inserting after section 4AA the following section:-

Section 4BB. (a) Any individual or group health maintenance contract that is issued or renewed shall provide for:

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

(ii) 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 (A) 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 shall be appropriately notified and have rights to appeal; (B) establishing 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; (C) 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; or (D) 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 clauses (i) and (ii) of subsection (a) 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 prescribing opiates over other pain management modalities.

(c) Each carrier shall distribute educational materials to providers within their networks about the plans described in clauses (i) and (ii) of subsection (a) and shall post information about said plans on its public website.

SECTION 25. 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 26. Said chapter 176O is hereby further amended by inserting after section 6 the following section:-

Section 6A. (a) Each carrier shall provide for:

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

(ii) 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: (A) 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 shall be appropriately notified and have rights to appeal; (B) establishing administrative safeguards on the prescribing of drugs identified pursuant to section 13 of chapter 17 as posing a heightened risk to the public health; (C) 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; or (D) 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 clauses (i) and (ii) of subsection (a) 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 prescribing opiates over other pain management modalities.

(c) Each carrier shall distribute educational materials to providers within their networks about the plans described in clauses (i) and (ii) of subsection (a) and shall post information about the plans on its public website.

SECTION 27. Section 7 of said chapter 176O, as appearing in the 2014 Official Edition, is hereby amended by striking out, in line 59, the word “and”.

SECTION 28. Said section 7 of said chapter 176O, as so appearing, is hereby further amended by inserting after the word “age”, in line 68, the following words:- ; 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; and (v) medical or surgical claims and mental health or substance use disorder claims denied by the carrier because: (A) the insured failed to obtain pre-treatment authorization or referral for services; (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 carrier does not cover the service or the provider under the insured’s plan; (F) duplicate claims had been submitted; (G) incomplete claims had been submitted; (H) coding errors had occurred; or (I) of any other specified reason.

SECTION 29. 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; and

(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.

SECTION 30. Within 180 days after the effective date of this act, the commissioner of public health shall provide a report on the feasibility of the creation of programs similar to the program established in section 20 for other health professional boards of registration. The commissioner shall file the report, along with any recommendations to effectuate the findings, with the chairs of the joint committee on public health, the chairs of the joint committee on health care financing, the chairs of the house and senate committees on ways and means and the chairs of the house and senate committees on rules.

SECTION 31. The department of public health shall promulgate regulations to classify gabapentin and its chemical equivalents as "additional drugs" for the purposes of section 24A of chapter 94C of the General Laws.

SECTION 32. The first distribution to individual practitioners of the prescribing trends and profiles set forth in section 15 shall occur not later than March 1, 2017. The department of

public health shall establish educational resources on prescribing practices and alternative pain management options not later than March 1, 2017.

SECTION 33. (a) There shall be a special commission to examine the feasibility of establishing a pain management access program, with the goal of increasing access to pain management for patients in need of comprehensive pain management resources.

(b) The commission shall review: (i) the development of a referral process to make pain management specialists accessible to primary care providers, including a process similar to the Massachusetts child psychiatry access project; (ii) the establishment of a pain management specialty certification through the board of registration in medicine to refer a primary care provider through the referral system described in clause (i); (iii) ways to incorporate a full spectrum of pain management methods into provider care practices including, but not limited to, acupuncture, exercise and other non-pharmaceutical interventions; (iv) the current coverage of pain management through commercial and public insurers; and (v) ways to ensure a full spectrum of pain management interventions are covered through commercial and public insurance health plans.

(c) The special commission shall consist of the following members or their designees: the secretary of health and human services, who shall serve as co-chair; the chancellor of the University of Massachusetts medical school, who shall serve as co-chair; the assistant director of Medicaid; the commissioner of the group insurance commission; the commissioner of insurance; the executive director of the health policy commission; the executive director of the center for health information and analysis; the commissioner of public health; the chair of the board of registration in medicine; the chair of the board of registration in nursing; 1 representative of the

Massachusetts Association of Health Plans, Inc.; 1 representative of the Massachusetts Medical Society; 1 representative of the Massachusetts Hospital Association, Inc.; 1 representative of the Massachusetts Pain Initiative; and 6 members who shall be appointed by the governor, 1 of whom shall be an oncologist, 1 of whom shall be a physician, 1 of whom shall be an advanced practice nurse, 1 of whom shall be a health economist, 1 of whom shall be a physician specializing in pain management and 1 of whom shall be a professor of medicine.

(d) The special commission shall file an initial report of its recommendations and drafts of proposed legislation or regulations, if any, on clauses (i) and (ii) of subsection (b) with the clerks of the house of representatives and the senate, the chairs of the joint committee on health care financing, the chairs of the joint committee on mental health and substance abuse, the chairs of the joint committee on public health and the chairs of the house and senate committees on ways and means not later than November 1, 2016. The special commission shall file a final report providing a full report regarding said subsection (b) not later than November 1, 2017.

SECTION 34. The department of public health and the bureau of substance abuse services, in consultation with the division of insurance, shall recommend a universal intake form to streamline the administrative process for intake of a behavioral health or substance use disorder patient. The form shall: (i) ensure adequate recordkeeping; (ii) lessen the current documentation burden for providers of behavioral health or substance use disorder services; (iii) be available in electronic form. The form may be incorporated by all payers of behavioral health and substance use disorder services. The department shall hold not fewer than 4 public hearings on the development of the universal intake form. The department shall post the universal intake form on its website not later than March 1, 2016.

SECTION 35. Notwithstanding any general or special law to the contrary, the attorney general shall seek a letter not later than 30 days from the effective date of this act from the United States Drug Enforcement Administration providing guidance on whether it is a violation of 21 U.S.C. § 829 and 21 C.F.R. 1306.13 if a pharmacist dispenses an amount less than the prescribed amount of a schedule II drug included in section 3 of chapter 94C of the General Laws on a valid prescription.

SECTION 36. Section 2 shall take effect March 1, 2016.

SECTION 37. Sections 4, 15, 31 and proposed section 18B of chapter 94C of the General Laws shall take effect December 1, 2016.

SECTION 38. Sections 16, 17, 21 to 24, inclusive, and section 26 shall take effect January 1, 2017.