SENATE . . . . . .No. 2008

The Commonwealth of Massachusetts

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REPORT

OF THE

SPECIAL SENATE COMMITTEE

ON

OPIOID ADDICTION PREVENTION,

TREATMENT AND RECOVERY OPTIONS

SUBMITTING ITS FINDINGS AND RECOMMENDATIONS

(pursuant to an Order adopted by the Senate)

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September 9, 2015

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The Commonwealth of Massachusetts

MASSACHUSETTS SENATE

SENATOR JENNIFER L. FLANAGAN
Worcester and Middlesex District

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September 9, 2015

Mr. William F. Welch
Clerk of the Senate
State House, Room 335

Dear Mr. Welch:

Pursuant to an order adopted by the Massachusetts State Senate on March 2nd, 2015, convening the Special Senate Committee on Opioid Addiction Prevention, Treatment and Recovery Options, and directing said committee to:

> *Review existing state statutes and funding, as well as the implementation and enforcement of recently enacted substance abuse legislation, and make recommendations to further strengthen opioid abuse prevention, intervention, treatment and recovery options and access to such programs for all residents of the Commonwealth*

We are pleased to file with you, on behalf of the special committee, the attached documents presenting a legislative proposal for consideration by the Senate, and a summary of said recommended legislation.

Sincerely,

Jennifer L. Flanagan Worcester and Middlesex District Special Committee Chair	**John F Keenan** Norfolk and Plymouth District Special Committee Vice Chair
Michael O. Moore Second Worcester District	**Richard J. Ross** Norfolk, Bristol and Middlesex District
Eric P. Lesser First Hampden and Hampshire District	**Anne M. Gobi** Worcester, Hampden, Hampshire and Middlesex District

Viriato M. deMacedo Plymouth and Barnstable District	**Joan B. Lovely** Second Essex District
Kathleen O'Connor Ives First Essex District	

Summary: Legislative Proposal from the Special Senate Committee on Opioid Addiction

Training and Awareness of Good Samaritan Provisions

- Establish Good Samaritan Awareness program as a required element of MPTC recruit basic training curriculum, and as a periodically reviewed subject for in-service training.

Drug Formulary List of Non-opiate Pain Management Products

- Direct the newly formed Drug Formulary Commission (which exists to develop Brand v. Generic, and Abuse-deterrent v. Non-abuse deterrent substitution lists) to also publish a list of non-opiate pain management products that may be used as lower risk alternatives.

Voluntary Non-opiate Directive

- Direct EOHHS to establish a voluntary program for any person to record a non-opiate directive. This would allow a person in recovery, or for any other reason of personal choice, to have a clear indicator in their patient record and in the PMP, that a health care practitioner or health care facility shall not administer, offer or prescribe opiate drugs to that person.

- A person can have their own non-opiate order deleted and expunged for any reason.

- Recording of a non-opiate directive would be on a standardized form published by EOHHS, and the form must comply with all federal requirements for privacy of addiction treatment records. The form must also present plain language information on how to remove the order.

- Regulations to implement the program must cover health care proxy and guardianship override of the non-opiate directive, and the ability for treating clinicians to override the directive in an emergency situation and based on documented medical judgment. Should also include exemptions for emergency personnel acting in the field during an emergency.

Expanded SBIRT Screening

- Local school departments or boards of health shall require SBIRT screening at least once annually for all students in grades 8 or 9, and in grade 11. These screenings shall be performed by a nurse, physician, or other personnel approved for the purpose by the DPH.

- Screening results shall be recorded without identifying information, and reported to the DPH.

Safeguards on High Risk Drugs

- Chapter 258 of 2014 tasked the Drug Formulary Commission with identifying high-risk ER/LA drugs and alerting the public health commissioner, but the final version did not include any corresponding authority to act or any further safeguards on these high-risk products.

- This bill would limit opioid prescriptions in an emergency department to a 5-day supply, and would prohibit an ED from issuing prescriptions for the identified high-risk drugs. It would also require that prescriptions of these high-risk products be issued only on a determination that lower risk

drugs are unsuitable, and with a pain management treatment agreement in place. The medical determination would be documented and placed in the patient's medical file.

- Language here is similar to what was passed in the Senate version last year, with regard to "heightened risk" drugs identified by the formulary commission.

Patient Choice in Prescription Volume

- Legislation would allow patients to voluntarily reduce the quantity of an opiate drug that they receive, regardless of the quantity indicated on their prescription.

- Pharmacists would be required, in their routine consultation with a patient, to advise them of this option. The pharmacist would be authorized, with no further approval from the prescriber or modification of the prescription, to dispense the drug in a partial quantity.

- Notice of the partial prescription would be recorded and sent to the prescriber in a reasonable time, and the remaining quantity on the prescription would remain valid for 72 hours pursuant to federal regulations.

- Insurance carriers would be required to offer cost-sharing on a sliding scale based on quantity, to accommodate for a patient who voluntarily receives a lesser quantity.

Drug Stewardship

- Establish, as a condition of selling or distributing a schedule II or III drug in Massachusetts, that the manufacturer of the drug establish and fund a stewardship program that allows patients to dispose of unused and unwanted drugs.

- Exemptions are included for veterinary products, drugs compounded on a per-patient basis, sharps products whose disposal is already covered under existing MGL, and drugs approved for use in medication assisted addiction treatment.

- Stewardship plans would be required to include a drug take-back or mail-back component; adequate provisions for the security, transport and disposal of returned products; provisions to incentivize participation; and public outreach and education.

- Plans would be approved by the Department and renewed every three years, with the ability to assess fines for violations or discontinuation of the Stewardship plan, and with repeat violations being sent forward to the Attorney General for enforcement.

Individual Prescriber Trend Notifications

- Utilize PMP data to learn more about the mean and median prescribing volumes for opiates in Massachusetts, and subsequently build individual prescriber profiles showing each prescriber their percentile with regard to their peers.

- Profiles would be confidential, shared only with the prescriber as an educational tool to help them shape their own practices. This would provide objective data about prescribing trends and best

practices, rather than having prescribers rely on "guidance" from pharmaceutical sales teams about appropriate prescribing practices.

Access to Pain Management Specialty Consultation

- Direct the Board of Registration in Medicine to create a pain management specialty certification. This would not restrict the current practice of anyone not certified, but it would identify practitioners who can provide specialized consultations.

- Establish a commission that will develop pain management consultation and temporary service guidelines, mirroring the model of the MCPAP program for child psychiatry. This would allow practitioners to leverage the expertise of their peers, making greater use of the currently limited number of pain management specialists.

Review of Coverage For Non-narcotic Pain Management

- Legislation from the committee could include a requirement for the Division of Insurance to review pain management options; for insurance carriers to develop a pain management plan and post information on their public website about alternative pain management.

- Legislation could also include a requirement for insurance carriers to develop control methods against overprescribing and overreliance on pain medication, and to post this plan on their public website as well.

- Pain management plan, and controlled substance safety plan, would both become a part of the existing DOI accreditation process.

Transparency in Addiction Service Denial Rates

- Require annual reporting on denied claims by each insurance carrier, categorized by medical/surgical and behavioral/addiction

- Require that, with each denial of an internal grievance case relating to behavioral/addiction, the carrier must specifically describe the medical necessity criteria and treatment limitations relied upon for the denial.

Civil Liability Protection for Narcan Administration

- Massachusetts currently provides "Good Samaritan" legal protection to any person to possess and administer Narcan / naloxone. However, this protection does not extend to civil liability. Closing this gap may remove the hesitations of some first responder agencies that have not yet adopted the use of this life saving product.

Gabapentin Monitoring

- Require that Gabapentin – a drug that is increasing in popularity for its enhancing effect on opiate misuse – be reported and monitored by the Prescription Monitoring Program

MassHealth Lock-In Program Correction

- Chapter 244 of 2012 included a section codifying the "Lock-In" program under MassHealth. However, in application and interpretation there are two gaps that can be addressed.

- First, that the lock-in program is intended to limit patients, upon finding of certain risk indicators, to a single pharmacy and a single prescriber for their controlled substances. The language in 244 however has been interpreted to only limit patients to a single pharmacy, not to restrict the number of prescribers.

- In practice, for patients who are enrolled in the lock-in program and who receive coverage through an MCO, those patients are removed from lock-in if they change from one MCO to another. This could be amended so that the person remains in the program regardless of an MCO change.

Proposed Legislation from the Special Senate Committee on Opioid Addiction

Training and Awareness of Good Samaritan Provisions

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.

Drug Formulary List of Non-opiate Pain Management Products

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.

Voluntary non-opiate directive - I

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)

Expanded SBIRT Screening

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."

Safeguards on High Risk Drugs - I

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".

Patient Choice in Prescription Volume - I

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.

Safeguards on High Risk Drugs - II

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.

Voluntary non-opiate directive - II

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.

Drug Stewardship Program - I

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.

Patient Choice in Prescription Volume - II

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.

Safeguards on High Risk Drugs - III

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.

Individual Prescriber Trend Notifications - I

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.

Drug Stewardship Program - II

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 2*I* 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.

Access to Pain Management Specialty Consultation - I

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.

Patient Choice in Prescription Volume - III

SECTION 18. Said chapter 175 is hereby further 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 19. Said chapter 176A is hereby further 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 20. Said chapter 176B is hereby further 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 21. Said chapter 176G is hereby further 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.

Proposed Legislation from the Special Senate Committee on Opioid Addiction

Review of Insurance Coverage For Non-narcotic Pain Management Options

SECTION 22 - 26. (a) *[to be included for each type of insurance carrier, under Ch 175, 176A, 176B, 176G, 176O]* shall establish and implement:

(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) controlled substance safety

Strengthen Access through Transparency in Service Denials

SECTION 28. 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 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;

(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).

Civil Liability Protection for Narcan Administration

SECTION 30. 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.

Gabapentin Monitoring

SECTION 31. 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.

Individual Prescriber Trend Notifications - II

SECTION 32. 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.

Access to Pain Management Specialty Consultation - II

SECTION 33. 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.

Proposed Legislation from the Special Senate Committee on Opioid Addiction

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.