SENATE . . . . . No. 2100

The Commonwealth of Massachusetts

In the Year Two Thousand Fourteen

An Act to reduce prescription drug tampering and abuse.

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. Section 13 of Chapter 17 of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by inserting after the third paragraph the following 2 new paragraphs:-

"The commission shall also prepare a drug formulary of abuse deterrent interchangeable opioid drug products, which shall be adopted by regulations of the department, and which shall list commercially available abuse deterrent products that serve as equivalent alternatives to non-abuse deterrent opioid products. Said formulary shall include formulations of opioid drugs of schedules II through V that are considered interchangeable by virtue of chemical equivalence, or similarity in active ingredient or moiety, and that also incorporate abuse deterrent technology satisfying at least two of the following criteria:

(i) Physical and chemical barriers that can prevent chewing, crushing, cutting, grating, grinding, melting or other physical manipulations that enable abuse, and resist extraction of the opioid by common solvents such as water, alcohol or other organic solvents;

(ii) Agonist/antagonist combinations that interfere with, reduce or defeat the euphoria associated with abuse;

(iii) Aversion qualities that produce an unpleasant effect if the dosage form is manipulated or altered, or a higher dose than directed is used;

(iv) Delivery systems that, pursuant to United States Food and Drug Administration guidance, offer resistance to abuse;

(v) Prodrug techniques that limit opioid activity until transformed in the gastrointestinal tract; or

(vi) Other techniques as may be identified or recommended by the Food and Drug Administration that offer significant abuse deterrence.

In preparing a formulary of abuse deterrent interchangeable opioid drug products, the commission shall consider information contained in drug applications approved by the United States Food and Drug Administration, and other regulatory and guidance documents distributed by said administration; provided further, that the commission may exclude any drug product that incorporates abuse deterrent technology if the commission deems said technology to be ineffective against or inconsistent with common forms of abuse of the drug product; and provided further, that a determination of interchangeability between two drug products shall not require that both products incorporate the same methods of abuse deterrence. Inclusion of a drug on this formulary shall not be construed to authorize labeling or marketing claims of abuse deterrence potential, unless such claims are authorized by the Food and Drug Administration."

SECTION 2. Said section 13 is hereby further amended by striking from lines 29, 34, and 39 the word "formulary" and inserting in place thereof, in each instance, the word:- "formularies"

SECTION 3. Section 1 of Chapter 94C of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by inserting the following new definitions:-

"Extended-release and long-acting opioid" or "in an extended release form" shall mean a drug that is subject to the federal Food and Drug Administration's Risk Evaluation and Mitigation Strategy for Extended-Release and Long-Acting Opioid Analgesics.

"Non-abuse deterrent opioid" or "in a non-abuse deterrent form" shall mean any opioid drug product that is approved for medical use but that does not meet the requirements for listing as a abuse deterrent interchangeable opioid drug product, pursuant to section 13 of chapter 17.

SECTION 4. Section 7 of chapter 94C of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by inserting after subsection (a) the following new subsection:

-"(a ½) The department shall, by regulation, establish a specialty designation to registrations issued pursuant to subsection (a), which shall give authorization to a physician to issue a prescription for narcotic substances in schedule II that are subject to the federal Risk Evaluation and Mitigation Strategy for Extended-Release and Long-Acting Opioid Analgesics and that are formulated without abuse deterrent or abuse deterrent features. This designation may be issued only to physicians licensed pursuant to chapter 112; who are actively practicing in Massachusetts and board certified and actively practicing in the fields of oncology, chronic pain management, hospice and palliative care, or neurology; and who have completed appropriate continuing medical education credits in pain management and in substance abuse prevention pursuant to section 5N of chapter 112.

SECTION 5. Section 18 of chapter 94C of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by striking, in the first sentence of section (d ½), the words "A prescription" and inserting in place thereof the following:

-"Except as further restricted by subsection (g), a prescription"

SECTION 6. Said section 18 is hereby further amended by inserting after subsection (e) the following two new subsections:-

"(f) A prescription shall not be issued or filled for any opioid product or substance contained in schedule II or III that is formulated as a non-abuse deterrent opioid drug, as defined in section 12D of chapter 112 of the General Laws, unless the drug formulary commission has determined, pursuant to section 13 of chapter 17 of the General Laws, that no abuse deterrent interchangeable opioid drug product is available as a substitute for the indicated product or substance.

"(g) A prescription for a narcotic substance contained in schedule II of section 3, that is in an extended release form and that is a non-abuse deterrent opioid drug, shall not be issued or filled except upon the prescription of a physician who:

(1) is licensed and actively practicing in Massachusetts and;

(2) is board certified and actively practicing in the fields of oncology, chronic pain management, hospice and palliative care, or neurology; and

(3) has received a specialty designation under subsection (a ½) of section 7; and

(4) is currently enrolled in the Prescription Drug Monitoring Program and compliant with all regulations relating to the use of said program.

A registered pharmacist filling a prescription under this subsection shall determine, in accordance with professional standards and personal judgment, that such prescription is authentic and valid, and shall verify the prescription by telephonic or other means. A pharmacist shall not fill a prescription for which a verification cannot be obtained. A pharmacist shall not be liable for refusing to fill a prescription for which a verification cannot be obtained, provided that documented good faith efforts were made to determine the authenticity and validity of such prescription. In no case shall a prescription subject to this subsection be issued in an emergency department setting."

SECTION 7. Section 22 of chapter 94C of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by inserting the following new subsection:

-"(c) A physician who dispenses, by issuing a written prescription, extended-release and long-acting opioid drugs of schedule II that are formulated in a non-abuse deterrent form shall, in addition to the requirements of subsection (a), write on the prescription, in his or her own hand,

the words “medically necessary, alternatives not suitable” and shall also indicate his or her specialty designation for such prescriptions pursuant to subsection (a ½) of section 7. The physician shall further prepare appropriate documentation, as determined in regulation by the board of registration in medicine, of the medical need for said product, and a statement of the physician’s professional judgment that other treatments or products are not suitable for the patient. Said documentation shall be placed in the patient’s medical file in a manner consistent with the regulations of said board.

SECTION 8. Section 24A of Chapter 94C, as amended by Chapter 38 of the Acts of 2013, is hereby amended in subsection (c) by inserting after the words “schedule II or III” the following words:

-“, and shall further include requiring participants who are duly authorized to prescribe a narcotic drug in schedule II in an extended-release form and non-abuse deterrent form to utilize the prescription monitoring program prior to each issuance of such a prescription.”

SECTION 9. Said section 24A is hereby further amended by inserting the following two new subsections:

-“(l) When submitting the report required by subsection (k), the department shall also report on trends in prescriptions issued for extended-release and long-acting opioid drugs of schedule II that are formulated in a non-abuse deterrent form.

(m) On at least a bi-annual basis, and utilizing the monitoring program established by this section, the department shall conduct a random audit of prescriptions for extended-release and long-acting opioid drugs of schedule II that are formulated in a non-abuse deterrent form, to determine whether such prescriptions have been issued in compliance with the requirements of subsection (g) of section 18. Any violations discovered through said audit process shall be reported to the board of registration in medicine.”

SECTION 10. Chapter 112 of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by inserting after section 5M the following new section:

-“Section 5N. The board shall promulgate regulations requiring that any physician intending to prescribe extended-release and long-acting opioid drugs of schedule II that are formulated in a non-abuse deterrent form must complete appropriate continuing medical education credits in pain management and in substance abuse prevention before seeking authorization, pursuant to section 7 of chapter 94C, to prescribe said drugs. Said regulations shall also include protocols for documenting the medical necessity for each prescription of said drugs, and for including such documentation in the medical file of any patient being prescribed said drugs.

Any physician issuing a prescription for said drug products shall ensure that said prescription complies with the requirements of chapter 94C, including section 7, section 18 and section 22 of said chapter 94C and any other relevant provisions."

SECTION 11. Section 12D of Chapter 112 of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by inserting after the definition of "Practitioner" the following two new definitions:-

"Non-abuse deterrent opioid", any opioid drug product that is approved for medical use but that does not meet the requirements for listing as a abuse deterrent interchangeable opioid drug product.

"Abuse deterrent interchangeable opioid drug product", an opioid drug that is rated by the U.S. Food and Drug Administration as pharmaceutically and therapeutically equivalent to the prescribed product or substance, and that also incorporates abuse deterrent technology and has been identified as such by the drug formulary commission in accordance with section 13 of chapter 17 of the General Laws."

SECTION 12. Said section 12D is hereby further amended by inserting after the word "practitioner" in line 32 the following new paragraph:-

"Notwithstanding the substitution requirements of this section, or any brand name or "no substitution" indication by the practitioner, the pharmacist shall not, in any case, dispense an opioid drug of schedule II or schedule III that is formulated as a non-abuse deterrent opioid drug product, unless the drug formulary commission has determined that no abuse deterrent interchangeable opioid drug product is available as a substitute for the indicated product or substance.

SECTION 13. Chapter 176O of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by inserting after Section 16 the following new section:

Section 16A. A carrier may not exclude or deny reimbursement for abuse deterrent opioid drug products dispensed in accordance with section 12D of chapter 112 of the General Laws solely due to the cost of said abuse deterrent products; provided however that this section shall not be construed to prohibit a carrier from applying prior authorization requirements and utilization reviews for opioid drug products when such measures, and any service denials made pursuant thereto, are established in consideration of a drug's potential for abuse and addiction and are applied equally to abuse deterrent and non-abuse deterrent products.