JMG ROBS

L.D. 1646

Date: 4-14-16 Majority (Filing No. S-531)

HEALTH AND HUMAN SERVICES

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STATE OF MAINE

SENATE

127TH LEGISLATURE

SECOND REGULAR SESSION

COMMITTEE AMENDMENT "A" to S.P. 671, L.D. 1646, Bill, "An Act To Prevent Opiate Abuse by Strengthening the Controlled Substances Prescription Monitoring Program"

Amend the bill by striking out everything after the enacting clause and before the summary and inserting the following:

'**Sec. 1. 22 MRSA §7246, sub-§§1-A, 1-B and 1-C** are enacted to read:

1-A. Acute pain. "Acute pain" means pain that is the normal, predicted physiological response to a noxious chemical or thermal or mechanical stimulus. "Acute pain" typically is associated with invasive procedures, trauma and disease and is usually time-limited.

1-B. Administer. "Administer" means an action to apply a prescription drug directly to a person by any means by a licensed or certified health care professional acting within that professional's scope of practice. "Administer" does not include the delivery, dispensing or distribution of a prescription drug for later use.

1-C. Chronic pain. "Chronic pain" means pain that persists beyond the usual course of an acute disease or healing of an injury. "Chronic pain" may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Sec. 2. 22 MRSA §7246, sub-§5, as enacted by PL 2003, c. 483, §1, is amended to read:

5. Prescriber. "Prescriber" means a licensed health care professional with authority to prescribe controlled substances and a veterinarian licensed under Title 32, chapter 71-A with authority to prescribe controlled substances.

Sec. 3. 22 MRSA §7249, sub-§4, as enacted by PL 2003, c. 483, §1, is amended to read:

4. Immunity from liability. A dispenser or prescriber is immune from liability for disclosure of information if the disclosure was made pursuant to and in accordance with this chapter.

Sec. 4. 22 MRSA §7250, sub-§4, ¶G, as amended by PL 2011, c. 657, Pt. O, §3, is further amended to read:

G. The office that administers the MaineCare program pursuant to chapter 855 for the purposes of managing the care of its members, monitoring the purchase of controlled substances by its members, avoiding duplicate dispensing of controlled substances and providing treatment pattern data under subsection 6; ~~and~~

Sec. 5. 22 MRSA §7250, sub-§4, ¶H, as enacted by PL 2011, c. 218, §3, is amended to read:

H. Another state or a Canadian province pursuant to subsection 4-A.~~;~~

Sec. 6. 22 MRSA §7250, sub-§4, ¶¶I and J are enacted to read:

I. Staff members of a licensed hospital who are authorized by the chief medical officer of the hospital, insofar as the information relates to a patient receiving care in the hospital's emergency department or receiving inpatient services from the hospital; and

J. Staff members of a pharmacist who are authorized by the pharmacist on duty, insofar as the information relates to a customer seeking to have a prescription filled.

Sec. 7. 22 MRSA §7250, sub-§4-A, as amended by PL 2011, c. 657, Pt. AA, §69, is further amended to read:

4-A. Information sharing with other states and Canadian provinces. The department may provide prescription monitoring information to and receive prescription monitoring information from another state or a Canadian province that has prescription monitoring information provisions consistent with this chapter and has entered into a prescription monitoring information sharing agreement with the department. The department may enter into a prescription monitoring information sharing agreement with another state or a Canadian province to establish the terms and conditions of prescription monitoring information sharing and interoperability of information systems and to carry out the purposes of this subsection. For purposes of this subsection, "another state" means any state other than Maine and any territory or possession of the United States, but does not include a foreign country.

Sec. 8. 22 MRSA §7251, sub-§1, as amended by PL 2011, c. 657, Pt. AA, §70, is further amended to read:

1. Failure to submit information. A dispenser who knowingly fails to submit prescription monitoring information to the department as required by this chapter commits a civil violation for which a fine of $250 per incident, not to exceed $5,000 per calendar year, may be adjudged and is subject to discipline by the Maine Board of Pharmacy pursuant to Title 32, chapter 117, subchapter 4 or by the applicable professional licensing entity.

Sec. 9. 22 MRSA §§7253 and 7254 are enacted to read:

§7253. Prescribers and dispensers required to check prescription monitoring information

1. Prescribers. On or after January 1, 2017, upon initial prescription of a benzodiazepine or an opioid medication to a person and every 90 days for as long as that prescription is renewed, a prescriber shall check prescription monitoring information for records related to that person.

2. Dispensers. On or after January 1, 2017, a dispenser shall check prescription monitoring information prior to dispensing a benzodiazepine or an opioid medication to a person under any of the following circumstances:

A. The person is not a resident of this State;

B. The prescription is from a prescriber with an address outside of this State;

C. The person is paying cash when the person has prescription insurance on file; or

D. According to the pharmacy prescription record, the person has not had a prescription for a benzodiazepine or an opioid medication in the previous 12-month period.

A dispenser shall notify the program and withhold a prescription until the dispenser is able to contact the prescriber of that prescription if the dispenser has reason to believe that the prescription is fraudulent or duplicative.

3. Exception; hospital setting and facilities. When a licensed or certified health care professional directly orders or administers a benzodiazepine or opioid medication to a person in an emergency room setting, an inpatient hospital setting, a long-term care facility or a residential care facility, the requirements to check prescription monitoring information established in this section do not apply.

4. Violation. A person who violates this section commits a civil violation for which a fine of $250 per incident, not to exceed $5,000 per calendar year, may be adjudged.

5. Rulemaking. Notwithstanding section 7252, the department may adopt routine technical rules as defined in Title 5, chapter 375, subchapter 2-A to implement this section.

§7254. Exemption from opioid medication limits until January 2017; rulemaking

1. Exemption until January 2017. In addition to the exceptions established in Title 32, section 2210, subsection 2; section 2600-C, subsection 2; section 3300-F, subsection 2; section 3657, subsection 2; and section 18308, subsection 2, a licensed health care professional may prescribe opioid medication in an amount greater than the morphine milligram equivalents limited by Title 32, sections 2210, 2600-C, 3300-F, 3657 and 18308 as long as it is medically necessary and the need is documented in the patient's chart.

This subsection is repealed January 1, 2017 or on the effective date of the rules establishing exceptions to prescriber limits as provided in subsection 2, whichever is later. The Commissioner of Health and Human Services shall notify the Secretary of State, Secretary of the Senate, Clerk of the House of Representatives and Revisor of Statutes of this effective date when this effective date is determined.

2. Rulemaking. Notwithstanding section 7252, no later than January 1, 2017, the department shall adopt routine technical rules as defined in Title 5, chapter 375, subchapter 2-A to establish reasonable exceptions to prescriber limits in Title 32, sections 2210, 2600-C, 3300-F, 3657 and 18308, including for chronic pain and acute pain. The rules must take into account clinically appropriate exceptions and include prescribers in the rule-making process including the drafting of draft rules and changes after the public hearing process to the extent permitted by Title 5, chapter 375.

Sec. 10. 32 MRSA §2105-A, sub-§2, ¶H, as amended by PL 1993, c. 600, Pt. A, §116, is further amended to read:

H. A violation of this chapter or a rule adopted by the board; ~~or~~

Sec. 11. 32 MRSA §2105-A, sub-§2, ¶I, as enacted by PL 1983, c. 378, §21, is amended to read:

I. Engaging in false, misleading or deceptive advertising~~.~~; or

Sec. 12. 32 MRSA §2105-A, sub-§2, ¶J is enacted to read:

J. Failure to comply with the requirements of Title 22, section 7253.

Sec. 13. 32 MRSA §2210 is enacted to read:

§2210. Requirements regarding prescription of opioid medication

1. Limits on opioid medication prescribing. Except as provided in subsection 2, an individual licensed under this chapter whose scope of practice includes prescribing opioid medication may not prescribe:

A. To a patient any combination of opioid medication in an aggregate amount in excess of 100 morphine milligram equivalents of opioid medication per day;

B. To a patient who, on the effective date of this section, has an active prescription for opioid medication in excess of 100 morphine milligram equivalents of an opioid medication per day, an opioid medication in an amount that would cause that patient's total amount of opioid medication to exceed 300 morphine milligram equivalents of opioid medication per day; except that, on or after July 1, 2017, the aggregate amount of opioid medication prescribed may not be in excess of 100 morphine milligram equivalents of opioid medication per day;

C. On or after January 1, 2017, within a 30-day period, more than a 30-day supply of an opioid medication to a patient under treatment for chronic pain. "Chronic pain" has the same meaning as in Title 22, section 7246, subsection 1-C; or

D. On or after January 1, 2017, within a 7-day period, more than a 7-day supply of an opioid medication to a patient under treatment for acute pain. "Acute pain" has the same meaning as in Title 22, section 7246, subsection 1-A.

2. Exceptions. An individual licensed under this chapter whose scope of practice includes prescribing opioid medication is exempt from the limits on opioid medication prescribing established in subsection 1 only:

A. When prescribing opioid medication to a patient for:

(1) Pain associated with active and aftercare cancer treatment;

(2) Palliative care, as defined in Title 22, section 1726, subsection 1, paragraph A, in conjunction with a serious illness, as defined in Title 22, section 1726, subsection 1, paragraph B;

(3) End-of-life and hospice care;

(4) Medication-assisted treatment for substance use disorder; or

(5) Other circumstances determined in rule by the Department of Health and Human Services pursuant to Title 22, section 7254, subsection 2; and

B. When directly ordering or administering a benzodiazepine or opioid medication to a person in an emergency room setting, an inpatient hospital setting, a long-term care facility or a residential care facility.

As used in this paragraph, "administer" has the same meaning as in Title 22, section 7246, subsection 1-B.

3. Electronic prescribing. An individual licensed under this chapter whose scope of practice includes prescribing opioid medication and who has the capability to electronically prescribe shall prescribe all opioid medication electronically by July 1, 2017. An individual who does not have the capability to electronically prescribe must request a waiver from this requirement from the Commissioner of Health and Human Services stating the reasons for the lack of capability, the availability of broadband infrastructure and a plan for developing the ability to electronically prescribe opioid medication. The commissioner may grant a waiver for circumstances in which exceptions are appropriate, including prescribing outside of the individual's usual place of business and technological failures.

4. Continuing education. By December 31, 2017, an individual licensed under this chapter must successfully complete 3 hours of continuing education every 2 years on the prescription of opioid medication as a condition of prescribing opioid medication. The board shall adopt rules to implement this subsection. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

5. Penalties. An individual who violates this section commits a civil violation for which a fine of $250 per violation, not to exceed $5,000 per calendar year, may be adjudged. The Department of Health and Human Services is responsible for the enforcement of this section.

Sec. 14. 32 MRSA §2591-A, sub-§2, ¶M, as amended by PL 1997, c. 680, Pt. B, §6, is further amended to read:

M. Failure to comply with the requirements of Title 24, section 2905-A; ~~or~~

Sec. 15. 32 MRSA §2591-A, sub-§2, ¶N, as enacted by PL 1997, c. 680, Pt. B, §7, is amended to read:

N. Revocation, suspension or restriction of a license to practice medicine or other disciplinary action; denial of an application for a license; or surrender of a license to practice medicine following the institution of disciplinary action by another state or a

territory of the United States or a foreign country if the conduct resulting in the disciplinary or other action involving the license would, if committed in this State, constitute grounds for discipline under the laws or rules of this State.; or

Sec. 16. 32 MRSA §2591-A, sub-§2, ¶O is enacted to read:

O. Failure to comply with the requirements of Title 22, section 7253.

Sec. 17. 32 MRSA §2600-C is enacted to read:

§2600-C. Requirements regarding prescription of opioid medication

1. Limits on opioid medication prescribing. Except as provided in subsection 2, an individual licensed under this chapter whose scope of practice includes prescribing opioid medication may not prescribe:

A. To a patient any combination of opioid medication in an aggregate amount in excess of 100 morphine milligram equivalents of opioid medication per day;

B. To a patient who, on the effective date of this section, has an active prescription for opioid medication in excess of 100 morphine milligram equivalents of an opioid medication per day, an opioid medication in an amount that would cause that patient's total amount of opioid medication to exceed 300 morphine milligram equivalents of opioid medication per day; except that, on or after July 1, 2017, the aggregate amount of opioid medication prescribed may not be in excess of 100 morphine milligram equivalents of opioid medication per day;

C. On or after January 1, 2017, within a 30-day period, more than a 30-day supply of an opioid medication to a patient under treatment for chronic pain. For purposes of this paragraph, "chronic pain" has the same meaning as in Title 22, section 7246, subsection 1-C; or

D. On or after January 1, 2017, within a 7-day period, more than a 7-day supply of an opioid medication to a patient under treatment for acute pain. For purposes of this paragraph, "acute pain" has the same meaning as in Title 22, section 7246, subsection 1-A.

2. Exceptions. An individual licensed under this chapter whose scope of practice includes prescribing opioid medication is exempt from the limits on opioid medication prescribing established in subsection 1 only:

A. When prescribing opioid medication to a patient for:

(1) Pain associated with active and aftercare cancer treatment;

(2) Palliative care, as defined in Title 22, section 1726, subsection 1, paragraph A, in conjunction with a serious illness, as defined in Title 22, section 1726, subsection 1, paragraph B;

(3) End-of-life and hospice care;

(4) Medication-assisted treatment for substance use disorder; or

(5) Other circumstances determined in rule by the Department of Health and Human Services pursuant to Title 22, section 7254, subsection 2; and

B. When directly ordering or administering a benzodiazepine or opioid medication to a person in an emergency room setting, an inpatient hospital setting, a long-term care facility or a residential care facility.

As used in this paragraph, "administer" has the same meaning as in Title 22, section 7246, subsection 1-B.

3. Electronic prescribing. An individual licensed under this chapter whose scope of practice includes prescribing opioid medication and who has the capability to electronically prescribe shall prescribe all opioid medication electronically by July 1, 2017. An individual who does not have the capability to electronically prescribe must request a waiver from this requirement from the Commissioner of Health and Human Services stating the reasons for the lack of capability, the availability of broadband infrastructure and a plan for developing the ability to electronically prescribe opioid medication. The commissioner may grant a waiver for circumstances in which exceptions are appropriate, including prescribing outside of the individual's usual place of business and technological failures.

4. Continuing education. By December 31, 2017, an individual licensed under this chapter must successfully complete 3 hours of continuing education every 2 years on the prescription of opioid medication as a condition of prescribing opioid medication. The board shall adopt rules to implement this subsection. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

5. Penalties. An individual who violates this section commits a civil violation for which a fine of $250 per violation, not to exceed $5,000 per calendar year, may be adjudged. The Department of Health and Human Services is responsible for the enforcement of this section.

Sec. 18. 32 MRSA §3282-A, sub-§2, ¶¶Q and R, as enacted by PL 2013, c. 355, §12, are amended to read:

Q. Failure to produce upon request of the board any documents in the licensee's possession or under the licensee's control concerning a pending complaint or proceeding or any matter under investigation by the board, unless otherwise prohibited by state or federal law; ~~or~~

R. Failure to timely respond to a complaint notification sent by the board~~.~~; or

Sec. 19. 32 MRSA §3282-A, sub-§2, ¶S is enacted to read:

S. Failure to comply with the requirements of Title 22, section 7253.

Sec. 20. 32 MRSA §3300-F is enacted to read:

§3300-F. Requirements regarding prescription of opioid medication

1. Limits on opioid medication prescribing. Except as provided in subsection 2, an individual licensed under this chapter and whose scope of practice includes prescribing opioid medication may not prescribe:

A. To a patient any combination of opioid medication in an aggregate amount in excess of 100 morphine milligram equivalents of opioid medication per day;

B. To a patient who, on the effective date of this section, has an active prescription for opioid medication in excess of 100 morphine milligram equivalents of an opioid medication per day, an opioid medication in an amount that would cause that patient's total amount of opioid medication to exceed 300 morphine milligram equivalents of opioid medication per day; except that, on or after July 1, 2017, the aggregate amount of opioid medication prescribed may not be in excess of 100 morphine milligram equivalents of opioid medication per day;

C. On or after January 1, 2017, within a 30-day period, more than a 30-day supply of an opioid medication to a patient under treatment for chronic pain. "Chronic pain" has the same meaning as in Title 22, section 7246, subsection 1-C; or

D. On or after January 1, 2017, within a 7-day period, more than a 7-day supply of an opioid medication to a patient under treatment for acute pain. "Acute pain" has the same meaning as in Title 22, section 7246, subsection 1-A.

2. Exceptions. An individual licensed under this chapter whose scope of practice includes prescribing opioid medication is exempt from the limits on opioid medication prescribing established in subsection 1 only:

A. When prescribing opioid medication to a patient for:

(1) Pain associated with active and aftercare cancer treatment;

(2) Palliative care, as defined in Title 22, section 1726, subsection 1, paragraph A, in conjunction with a serious illness, as defined in Title 22, section 1726, subsection 1, paragraph B;

(3) End-of-life and hospice care;

(4) Medication-assisted treatment for substance use disorder; or

(5) Other circumstances determined in rule by the Department of Health and Human Services pursuant to Title 22, section 7254, subsection 2; and

B. When directly ordering or administering a benzodiazepine or opioid medication to a person in an emergency room setting, an inpatient hospital setting, a long-term care facility or a residential care facility.

As used in this paragraph, "administer" has the same meaning as in Title 22, section 7246, subsection 1-B.

3. Electronic prescribing. An individual licensed under this chapter and whose scope of practice includes prescribing opioid medication with the capability to electronically prescribe shall prescribe all opioid medication electronically by July 1, 2017. An individual who does not have the capability to electronically prescribe must request a waiver from this requirement from the Commissioner of Health and Human Services stating the reasons for the lack of capability, the availability of broadband infrastructure, and a plan for developing the ability to electronically prescribe opioid medication. The commissioner may grant a waiver including circumstances in which exceptions are appropriate, including prescribing outside of the individual's usual place of business and technological failures.

4. Continuing education. By December 31, 2017, an individual licensed under this chapter must successfully complete 3 hours of continuing education every 2 years on the prescription of opioid medication as a condition of prescribing opioid medication. The board shall adopt rules to implement this subsection. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

5. Penalties. An individual who violates this section commits a civil violation for which a fine of $250 per violation, not to exceed $5,000 per calendar year, may be adjudged. The Department of Health and Human Services is responsible for the enforcement of this section.

Sec. 21. 32 MRSA §3656, sub-§§3 and 4, as enacted by PL 2007, c. 402, Pt. P, §14, are amended to read:

3. False advertising. Engaging in false, misleading or deceptive advertising; ~~or~~

4. Unlawful prescription of controlled substance. Prescribing narcotic or hypnotic or other drugs listed as controlled substances by the federal Drug Enforcement Administration for other than accepted therapeutic purposes~~.~~; or

Sec. 22. 32 MRSA §3656, sub-§5 is enacted to read:

5. Controlled Substances Prescription Monitoring Program. Failure to comply with the requirements of Title 22, section 7253.

Sec. 23. 32 MRSA §3657 is enacted to read:

§3657. Requirements regarding prescription of opioid medication

1. Limits on opioid medication prescribing. Except as provided in subsection 2, an individual licensed under this chapter and whose scope of practice includes prescribing opioid medication may not prescribe:

A. To a patient any combination of opioid medication in an aggregate amount in excess of 100 morphine milligram equivalents of opioid medication per day;

B. To a patient who, on the effective date of this section, has an active prescription for opioid medication in excess of 100 morphine milligram equivalents of an opioid medication per day, an opioid medication in an amount that would cause that patient's total amount of opioid medication to exceed 300 morphine milligram equivalents of opioid medication per day; except that, on or after July 1, 2017, the aggregate amount of opioid medication prescribed may not be in excess of 100 morphine milligram equivalents of opioid medication per day;

C. On or after January 1, 2017, within a 30-day period, more than a 30-day supply of an opioid medication to a patient under treatment for chronic pain. "Chronic pain" has the same meaning as in Title 22, section 7246, subsection 1-C; or

D. On or after January 1, 2017, within a 7-day period, more than a 7-day supply of an opioid medication to a patient under treatment for acute pain. "Acute pain" has the same meaning as in Title 22, section 7246, subsection 1-A.

2. Exceptions. An individual licensed under this chapter whose scope of practice includes prescribing opioid medication is exempt from the limits on opioid medication prescribing established in subsection 1 only:

A. When prescribing opioid medication to a patient for:

(1) Pain associated with active and aftercare cancer treatment;

(2) Palliative care, as defined in Title 22, section 1726, subsection 1, paragraph A, in conjunction with a serious illness, as defined in Title 22, section 1726, subsection 1, paragraph B;

(3) End-of-life and hospice care;

(4) Medication-assisted treatment for substance use disorder; or

(5) Other circumstances determined in rule by the Department of Health and Human Services pursuant to Title 22, section 7254, subsection 2; and

B. When directly ordering or administering a benzodiazepine or opioid medication to a person in an emergency room setting, an inpatient hospital setting, a long-term care facility or a residential care facility.

As used in this paragraph, "administer" has the same meaning as in Title 22, section 7246, subsection 1-B.

3. Electronic prescribing. An individual licensed under this chapter and whose scope of practice includes prescribing opioid medication with the capability to electronically prescribe shall prescribe all opioid medication electronically by July 1, 2017. An individual who does not have the capability to electronically prescribe must request a waiver from this requirement from the Commissioner of Health and Human Services stating the reasons for the lack of capability, the availability of broadband infrastructure, and a plan for developing the ability to electronically prescribe opioid medication. The commissioner may grant a waiver including circumstances in which exceptions are appropriate, including prescribing outside of the individual's usual place of business and technological failures.

4. Continuing education. By December 31, 2017, an individual licensed under this chapter must successfully complete 3 hours of continuing education every 2 years on the prescription of opioid medication as a condition of prescribing opioid medication. The board shall adopt rules to implement this subsection. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

5. Penalties. An individual who violates this section commits a civil violation for which a fine of $250 per violation, not to exceed $5,000 per calendar year, may be adjudged. The Department of Health and Human Services is responsible for the enforcement of this section.

Sec. 24. 32 MRSA §4864, sub-§12, ¶D, as amended by PL 2007, c. 402, Pt. R, §8, is further amended to read:

D. The continuance of a veterinarian directly or indirectly in the employ of or in association with any veterinarian after knowledge that such veterinarian is engaged in the violation of the provisions of this chapter; ~~or~~

Sec. 25. 32 MRSA §4864, sub-§13, as amended by PL 2007, c. 402, Pt. R, §8, is further amended to read:

13. Lack of sanitation. Failure to maintain veterinary premises and equipment in a clean and sanitary condition as defined by the board in accordance with the sanitation provisions included in Title 7, section 3936.; or

Sec. 26. 32 MRSA §4864, sub-§15 is enacted to read:

15. Controlled Substances Prescription Monitoring Program. Failure to comply with the requirements of Title 22, section 7253.

Sec. 27. 32 MRSA §4878 is enacted to read:

§4878. Requirements regarding prescription of opioid medication

1. Limits on opioid medication prescribing. A veterinarian licensed under this chapter whose scope of practice includes prescribing opioid medication to an animal is subject to the requirements of the Controlled Substances Prescription Monitoring Program established under Title 22, chapter 1603, except that Title 22, section 7254 does not apply.

2. Electronic prescribing. A veterinarian licensed under this chapter whose scope of practice includes prescribing opioid medication and who has the capability to electronically prescribe shall prescribe all opioid medication electronically by July 1, 2017. A veterinarian who does not have the capability to electronically prescribe must request a waiver from this requirement from the Commissioner of Health and Human Services stating the reasons for the lack of capability, the availability of broadband infrastructure and a plan for developing the ability to electronically prescribe opioid medication. The commissioner may grant a waiver for circumstances in which exceptions are appropriate, including prescribing outside of the individual's usual place of business and technological failures.

3. Continuing education. By December 31, 2017, a veterinarian who prescribes opioid medication must successfully complete 3 hours of continuing education every 2 years on the prescription of opioid medication as a condition of prescribing opioid medication. The board shall adopt rules to implement this subsection. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

4. Penalties. A veterinarian who violates this section commits a civil violation for which a fine of $250 per violation, not to exceed $5,000 per calendar year, may be adjudged. The Department of Health and Human Services is responsible for the enforcement of this section.

Sec. 28. 32 MRSA §13702-A, sub-§20-A is enacted to read:

20-A. Opioid medication. "Opioid medication" means a controlled substance containing an opioid included in schedule II of 21 United States Code, Section 812 or 21 Code of Federal Regulations, Part 1308.

Sec. 29. 32 MRSA §13756 is enacted to read:

§13756. Electronic prescribing of opioid medication

By July 1, 2017, a pharmacy must have the capability to process electronic prescriptions from prescribers for an opioid medication or request a waiver from the Commissioner of Health and Human Services stating the reasons for the waiver including but not limited to a lack of capability, the availability of broadband infrastructure and a plan for developing the ability to receive electronically prescribed opioid medication. The commissioner may grant a waiver for circumstances in which exceptions are appropriate, including technological failures.

Sec. 30. 32 MRSA §13786-B is enacted to read:

§13786-B. Partial dispensing of prescription for opioid medication

1. Partial dispensing authorized. Notwithstanding any law or rule to the contrary, a pharmacist may partially dispense a prescription for an opioid medication in a lesser quantity than the recommended full quantity indicated on the prescription if requested by the patient for whom the prescription is written. The remaining quantity of the prescription in excess of the recommended full quantity is void and may not be dispensed without a new prescription.

2. Notice to practitioner. If a pharmacist partially dispenses a prescription for an opioid medication as permitted under this section, the pharmacist or the pharmacist's designee shall, within a reasonable time following the partial dispensing but not more than 7 days, notify the practitioner of the quantity of the opioid medication actually dispensed. The notice may be conveyed by a notation on the patient's electronic health record or by electronic transmission, by facsimile or by telephone to the practitioner.

Sec. 31. 32 MRSA §13786-C is enacted to read:

§13786-C. Dispensing of prescription of opioid medication; immunity

A pharmacist who dispenses opioid medication in good faith is immune from any civil liability that might otherwise result from dispensing medication in excess of the limit established in section 2210, subsection 1, paragraphs A and B; section 2600-C, subsection 1, paragraphs A and B; section 3300-F, subsection 1, paragraphs A and B; section 3657, subsection 1, paragraphs A and B; or section 18308, subsection 1, paragraphs A and B, if the medication was dispensed in accordance with a prescription issued by a practitioner. In a proceeding regarding immunity from liability, there is a rebuttable presumption of good faith.

Sec. 32. 32 MRSA §18308 is enacted to read:

§18308. Requirements regarding prescription of opioid medication

1. Limits on opioid medication prescribing. Except as provided in subsection 2, an individual licensed under this chapter whose scope of practice includes prescribing opioid medication may not prescribe:

A. To a patient any combination of opioid medication in an aggregate amount in excess of 100 morphine milligram equivalents of opioid medication per day;

B. To a patient who, on the effective date of this section, has an active prescription for opioid medication in excess of 100 morphine milligram equivalents of an opioid medication per day, an opioid medication in an amount that would cause that patient's total amount of opioid medication to exceed 300 morphine milligram equivalents of opioid medication per day; except that, on or after July 1, 2017, the aggregate amount of opioid medication prescribed may not be in excess of 100 morphine milligram equivalents of opioid medication per day;

C. On or after January 1, 2017, within a 30-day period, more than a 30-day supply of an opioid medication to a patient under treatment for chronic pain. For purposes of this paragraph, "chronic pain" has the same meaning as in Title 22, section 7246, subsection 1-C; or

D. On or after January 1, 2017, within a 7-day period, more than a 7-day supply of an opioid medication to a patient under treatment for acute pain. For purposes of this paragraph, "acute pain" has the same meaning as in Title 22, section 7246, subsection 1-A.

2. Exceptions. An individual licensed under this chapter whose scope of practice includes prescribing opioid medication is exempt from the limits on opioid medication prescribing established in subsection 1 only:

A. When prescribing opioid medication to a patient for:

(1) Pain associated with active and aftercare cancer treatment;

(2) Palliative care, as defined in Title 22, section 1726, subsection 1, paragraph A, in conjunction with a serious illness, as defined in Title 22, section 1726, subsection 1, paragraph B;

(3) End-of-life and hospice care;

(4) Medication-assisted treatment for substance use disorder; or

(5) Other circumstances determined in rule by the Department of Health and Human Services pursuant to Title 22, section 7254, subsection 2; and

B. When directly ordering or administering a benzodiazepine or opioid medication to a person in an emergency room setting, an inpatient hospital setting, a long-term care facility or a residential care facility.

As used in this paragraph, "administer" has the same meaning as in Title 22, section 7246, subsection 1-B.

3. Electronic prescribing. An individual licensed under this chapter whose scope of practice includes prescribing opioid medication and who has the capability to electronically prescribe shall prescribe all opioid medication electronically by July 1, 2017. An individual who does not have the capability to electronically prescribe must request a waiver from this requirement from the Commissioner of Health and Human Services stating the reasons for the lack of capability, the availability of broadband infrastructure and a plan for developing the ability to electronically prescribe opioid medication. The commissioner may grant a waiver for circumstances in which

exceptions are appropriate, including prescribing outside of the individual's usual place of business and technological failures.

4. Continuing education. By December 31, 2017, an individual licensed under this chapter must successfully complete 3 hours of continuing education every 2 years on the prescription of opioid medication as a condition of prescribing opioid medication. The board shall adopt rules to implement this subsection. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

5. Penalties. An individual who violates this section commits a civil violation for which a fine of $250 per violation, not to exceed $5,000 per calendar year, may be adjudged. The Department of Health and Human Services is responsible for the enforcement of this section.

Sec. 33. 32 MRSA §18325, sub-§1, ¶¶N and O, as enacted by PL 2015, c. 429, §21, are amended to read:

N. Any violation of a requirement imposed pursuant to section 18352; ~~and~~

O. A violation of this chapter or a rule adopted by the board~~.~~; and

Sec. 34. 32 MRSA §18325, sub-§1, ¶P is enacted to read:

P. Failure to comply with the requirements of Title 22, section 7253.

Sec. 35. Department of Health and Human Services to amend rules to require registration of pharmacists; automatic enrollment. The Department of Health and Human Services shall amend its rules governing the Controlled Substances Prescription Monitoring Program under the Maine Revised Statutes, Title 22, chapter 1603 no later than January 1, 2017 to require pharmacists to register as data requesters. The enrollment mechanism for pharmacists who are registering with the program or renewing registration must be automatic when applying for or renewing a professional license in the same manner as it is for prescribers who are health care professionals with authority to prescribe controlled substances.

Sec. 36. Department of Health and Human Services to amend rules to require registration of veterinarians; automatic enrollment. The Department of Health and Human Services shall amend its rules governing the Controlled Substances Prescription Monitoring Program under the Maine Revised Statutes, Title 22, chapter 1603 no later than January 1, 2017 to require veterinarians to register as data requesters. The enrollment mechanism for veterinarians who are registering with the program or renewing registration must be automatic when applying for or renewing a professional license in the same manner as it is for prescribers who are health care professionals with authority to prescribe controlled substances.

Sec. 37. Enhancements to the Controlled Substances Prescription Monitoring Program. The Department of Health and Human Services shall include in its request for proposals process under the Maine Revised Statutes, Title 22, section 7248, subsection 2 the following enhancements to the Controlled Substances Prescription Monitoring Program under Title 22, chapter 1603:

1. A mechanism or calculator for converting dosages to and from morphine milligram equivalents;

2. A mechanism to automatically transmit de-identified peer data on an annual basis to prescribers of opioid medication;

3. Allowance for a broader authorization for staff members of prescribers to access the program including a single annual authorization for staff members at a licensed hospital and a pharmacy;

4. Improvements in communication regarding the ability of a prescriber to authorize staff members to access the program on behalf of the prescriber;

5. Improvements in communication regarding the ability of a pharmacist to authorize staff members to access the program on behalf of the pharmacist;

6. Improvements in the speed of the program for prescribers and pharmacists required to submit information and check the program, and the ability for prescribers and pharmacists to tailor the functions of the program to fit into the workflow of the prescribers and pharmacists required to access the program; and

7. The establishment of a data modifier for information from a veterinarian prescribing opioid medication to an animal that differentiates the recipient of the opioid prescription from people.

Notwithstanding the Title 32, section 2210, subsection 5; section 2600-C, subsection 5; section 3300-F, subsection 5; section 3657, subsection 5; and section 18308, subsection 5, a penalty may not be imposed for a violation of the limits on opioid prescribing in Title 32, section 2210, subsection 1; section 2600-C, subsection 1; section 3300-F, subsection 1; section 3657, subsection 1; or section 18308, subsection 1 until the enhancement to the Controlled Substances Prescription Monitoring Program described in subsection 1 is implemented.

Sec. 38. Effect on out-of-pocket costs. The Bureau of Insurance within the Department of Professional and Financial Regulation shall evaluate the effect of the limits on prescriptions for opioid medication established by this Act on the claims paid by health insurance carriers and the out-of-pocket costs, including copayments, coinsurance and deductibles, paid by individual and group health insurance policyholders. On or before January 1, 2018, the bureau shall submit a report on the evaluation, along with any recommended policy and regulatory options that will ensure costs for patients are not increased as a result of new prescribing limitations on the amounts of opioid medications, to the joint standing committees of the Legislature having jurisdiction over health and human services matters and over insurance and financial services matters. The joint standing committee of the Legislature having jurisdiction over health and human services matters and the joint standing committee of the Legislature having jurisdiction over insurance and financial services matters may report out legislation related to the evaluation to the Second Regular Session of the 128th Legislature.

Sec. 39. Department of Health and Human Services implementation report. The Department of Health and Human Services shall report to the joint standing committees of the Legislature having jurisdiction over health and human services matters and over occupational and professional regulation matters, no later than January 31, 2018, with progress on implementing the provisions of this Act. The report must contain information on the following:

1. Registration of prescribers and dispensers in the Controlled Substances Prescription Monitoring Program under the Maine Revised Statutes, Title 22, chapter 1603;

2. Data regarding the checking and using of the Controlled Substances Prescription Monitoring Program by data requesters;

3. Data from professional boards regarding the implementation of continuing education requirements for prescribers of opioid medication;

4. Effects on the prescriber workforce;

5. Changes in the numbers of patients taking more than 100 morphine milligram equivalents of opioid medication per day;

6. Data regarding the total number of opioid medication pills prescribed;

7. Progress on electronic prescribing of opioid medication; and

8. Improvements to the Controlled Substances Prescription Monitoring Program through the request for proposals process including feedback from prescribers and dispensers on those improvements.'

SUMMARY

This amendment, which is the majority report of the committee, makes the following changes to the laws governing the Controlled Substances Prescription Monitoring Program and the prescribing and dispensing of opioid medication and other drugs.

1. It provides to the prescriber immunity from liability for disclosure of information to the Controlled Substances Prescription Monitoring Program.

2. It allows the Department of Health and Human Services to provide prescription monitoring information to and receive prescription monitoring information from a Canadian province.

3. It clarifies that staff in hospitals and pharmacies are authorized to access the Controlled Substances Prescription Monitoring Program insofar as the access relates to a patient's prescription.

4. It establishes a fine for dispensers who fail to submit prescription monitoring information to the Controlled Substances Prescription Monitoring Program of $250 per incident, not to exceed $5,000 per calendar year.

5. It provides that upon the initial prescription of a benzodiazepine or an opioid medication to a person and every 90 days for as long as the prescription is renewed, a prescriber must check prescription monitoring information maintained by the Controlled Substances Prescription Monitoring Program for records related to that person. A prescriber who violates this provision is subject to a fine of $250 per incident, not to exceed $5,000 per calendar year.

6. It requires dispensers to check the prescription monitoring information for out-of-state individuals, for out-of-state prescribers, for individuals paying cash and if an individual has not had a prescription for an opioid medication in the previous 12 months.

A dispenser who violates this provision is subject to a fine of $250 per incident, not to exceed $5,000 per calendar year.

7. It provides that the failure of a health care provider who is a prescriber or dispenser to check the prescription monitoring information or to submit prescription monitoring information to the Department of Health and Human Services as required by law is grounds for discipline of that health care provider.

8. It requires that a health care provider who is a prescriber of opioid medication or a veterinarian who is a prescriber of opioid medication must complete 3 hours every 2 years of continuing education related to opioid medication prescribing practices.

9. It sets limits on the supply of opioid medication that may be prescribed to a patient to 7 days for acute pain and 30 days for chronic pain beginning January 1, 2017.

10. It sets limits on the amount of opioid medication that may be prescribed to no more than 100 morphine milligram equivalents for new prescriptions beginning on the effective date of this legislation. For patients who have prescriptions that total over 100 morphine milligram equivalents on the effective date of this legislation, the prescribing limit is 300 morphine milligram equivalents; those patients must be tapered to a level of no more than 100 morphine milligram equivalents by July 1, 2017.

11. It establishes statutory exceptions to opioid medication limits and requires the Department of Health and Human Services to adopt rules for other exceptions. The rules must be adopted by January 1, 2017.

12. It clarifies that opioid medication limits do not apply to health care professionals directly administering medication to a patient in an emergency room setting, inpatient hospital setting, long-term care setting or residential care setting.

13. It provides immunity for pharmacists who dispense opioid medication over 100 morphine milligram equivalents in accordance with a prescription.

14. It requires prescribers to electronically prescribe opioid medication if the capability exists. A prescriber who does not have the capability for electronic prescribing must seek a waiver from the Commissioner of Health and Human Services listing the reasons why the prescriber is unable to electronically prescribe. Pharmacists must be able to receive electronic prescriptions of opioid medication or seek a waiver.

15. It requires pharmacists and veterinarians who prescribe opioid medication to register with the Controlled Substances Prescription Monitoring Program.

16. It authorizes pharmacists to partially fill prescriptions of schedule II controlled substances upon request from the patient.

17. It requires the Department of Professional and Financial Regulation, Bureau of Insurance to evaluate the effect of prescription limits on out-of-pocket costs and report on options to the joint standing committee of the Legislature having jurisdiction over health and human services matters and the joint standing committee of the Legislature having jurisdiction over insurance and financial services matters.

18. It requires the Department of Health and Human Services to make enhancements to the Controlled Substances Prescription Monitoring Program through its request for proposals process for the maintenance of the program. It provides that a penalty may not

be imposed for a violation of the limits on opioid medication prescribing until the enhancement to the Controlled Substances Prescription Monitoring Program that will enable the conversion of dosages to and from morphine milligram equivalents is implemented.

19. It requires the Department of Health and Human Services to report to the joint standing committees of the Legislature having jurisdiction over health and human services matters and occupational and professional regulation matters on the implementation of the registration and use of the Controlled Substances Prescription Monitoring Program, improvements to the program, the effect of opioid medication prescribing limits on the prescriber workforce, the implementation of continuing education requirements and progress on the electronic prescribing of opioid medication.

FISCAL NOTE REQUIRED

(See attached)

Approved: 04/12/16 mac

127th MAINE LEGISLATURE

LD 1646 **LR 2717(02)**

An Act To Prevent Opiate Abuse by Strengthening the Controlled Substances Prescription Monitoring Program

Fiscal Note for Bill as Amended by Committee Amendment "A" (S-531)
Committee: Health and Human Services
Fiscal Note Required: Yes

Fiscal Note

Minor cost increase – General Fund
Minor revenue increase - General Fund

Correctional and Judicial Impact Statements

Establishes new civil violations.

The collection of additional fines may also increase General Fund revenue by minor amounts.

Fiscal Detail and Notes

Any additional costs to the Department of Health and Human Services, the Bureau of Insurance within the Department of Professional and Financial Regulation (DPFR) and certain other boards affiliated and within DPFR from the provisions of this bill are expected to be minor and can be absorbed within existing budgeted resources.