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Date: (Filing No. S-)

HEALTH AND HUMAN SERVICES

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**STATE OF MAINE
SENATE
128TH LEGISLATURE
FIRST REGULAR SESSION**

COMMITTEE AMENDMENT “ ” to S.P. 338, L.D. 1031, Bill, “An Act To Establish Reasonable and Clinically Appropriate Exceptions to Opioid Medication Prescribing Limits”

Amend the bill by striking out the title and substituting the following:

'An Act To Clarify the Opioid Medication Prescribing Limits Laws'

Amend the bill by striking out everything after the title and before the emergency clause and inserting the following:

Emergency preamble. Whereas, acts and resolves of the Legislature do not become effective until 90 days after adjournment unless enacted as emergencies; and

Whereas, Public Law 2015, chapter 488 enacted a number of changes to the laws governing the Controlled Substances Prescription Monitoring Program and the prescribing and dispensing of opioid medication and other drugs; and

Whereas, health care providers need clarification of palliative care and serious illness exemptions to the opioid limit of 100 morphine milligram equivalents per day; and

Whereas, surgical procedures routinely require higher dosages than the current opioid limit laws allow and clarification to the law is necessary immediately; and

Whereas, in the judgment of the Legislature, these facts create an emergency within the meaning of the Constitution of Maine and require the following legislation as immediately necessary for the preservation of the public peace, health and safety; now, therefore,

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §1726, sub-§1, ¶¶A and B, as enacted by PL 2015, c. 203, §2, are amended to read:

A. "Palliative care" means patient-centered and family-focused medical care that optimizes quality of life by anticipating, preventing and treating suffering caused by a

COMMITTEE AMENDMENT

1 medical illness or a physical injury or condition that substantially affects a patient's
2 quality of life, including, but not limited to, addressing physical, emotional, social
3 and spiritual needs; facilitating patient autonomy and choice of care; providing access
4 to information; discussing the patient's goals for treatment and treatment options,
5 including, when appropriate, hospice care; and managing pain and symptoms
6 comprehensively. Palliative care does not always include a requirement for hospice
7 care or attention to spiritual needs.

8 B. "Serious illness" means a medical illness or physical injury or condition that
9 substantially affects quality of life for more than a short period of time. "Serious
10 illness" includes, but is not limited to, Alzheimer's disease and related dementias,
11 lung disease, cancer ~~and~~, heart, renal or liver failure and chronic, unremitting or
12 intractable pain such as neuropathic pain.

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

15 **2. Dispenser.** "Dispenser" means a pharmacist who is licensed or registered under
16 Title 32 ~~or a licensed health care professional with authority to dispense or administer~~
17 ~~prescription drugs.~~

18 **Sec. 3. 22 MRSA §7249, sub-§1**, as amended by PL 2011, c. 657, Pt. AA, §68, is
19 further amended to read:

20 **1. Information required.** ~~Each~~ Except as provided in subsection 1-A, each
21 dispenser shall submit to the department, by electronic means or other format specified in
22 a waiver granted by the department, specific items of information regarding dispensed
23 controlled substances determined by the office from the following list:

- 24 A. The dispenser identification number;
- 25 B. The date the prescription was filled;
- 26 C. The prescription number;
- 27 D. Whether the prescription is new or is a refill;
- 28 E. The National Drug Code (NDC) for the drug dispensed;
- 29 F. The quantity dispensed;
- 30 G. The dosage;
- 31 H. The patient identification number;
- 32 I. The patient name;
- 33 J. The patient address;
- 34 K. The patient date of birth;
- 35 L. The prescriber identification number;
- 36 M. The date the prescription was issued by the prescriber; and
- 37 N. The department-issued serial number if the department chooses to establish a
38 serial prescription system.

1 **Sec. 4. 22 MRSA §7249, sub-§1-A** is enacted to read:

2 **1-A. Small quantity dispensing.** If a controlled substance is dispensed by a hospital
3 emergency department to a person receiving care in the emergency department for use by
4 that person during a period of 48 hours or less after the controlled substance is dispensed,
5 the dispenser is not required to comply with subsection 1.

6 **Sec. 5. 22 MRSA §7250, sub-§4, ¶¶I and J,** as amended by PL 2017, c. 87, §1,
7 are further amended to read:

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

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

15 **Sec. 6. 22 MRSA §7250, sub-§4, ¶K,** as enacted by PL 2017, c. 87, §2, is
16 amended to read:

17 K. The chief medical officer, medical director or other administrative prescriber
18 employed by a licensed hospital, insofar as the information relates to prescriptions
19 written by prescribers employed by that licensed hospital; and

20 **Sec. 7. 22 MRSA §7250, sub-§4, ¶L** is enacted to read:

21 L. Staff members of a group practice of prescribers who are authorized by a
22 designated group practice leader, insofar as the information relates to a patient
23 receiving care from that group practice.

24 **Sec. 8. 22 MRSA §7253, sub-§2,** as enacted by PL 2015, c. 488, §9, is amended
25 to read:

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

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

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

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

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

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

38 **Sec. 9. 22 MRSA §7253, sub-§3,** as repealed and replaced by PL 2017, c. 122,
39 §1, is amended to read:

1 **3. Exceptions.** The requirements to check prescription monitoring information
2 established in this section do not apply:

3 A. When a licensed or certified health care professional directly orders or
4 administers a benzodiazepine or opioid medication to a person in an emergency room
5 setting, an inpatient hospital setting, a long-term care facility or a residential care
6 facility or in connection with a surgical procedure; or

7 B. When a licensed or certified health care professional directly orders, prescribes or
8 administers a benzodiazepine or opioid medication to a person suffering from pain
9 associated with end-of-life or hospice care.

10 **Sec. 10. 22 MRSA §7253, sub-§5**, as enacted by PL 2015, c. 488, §9, is repealed.

11 **Sec. 11. 22 MRSA §7254, sub-§2**, as enacted by PL 2015, c. 488, §9, is amended
12 to read:

13 **2. Rulemaking.** Notwithstanding section 7252, no later than January 1, 2017, the
14 department shall adopt routine technical rules as defined in Title 5, chapter 375,
15 subchapter 2-A to establish reasonable exceptions to prescriber limits in Title 32, sections
16 2210, 2600-C, 3300-F, 3657 and 18308, including for chronic pain and acute pain. The
17 rules must take into account clinically appropriate exceptions and include prescribers in
18 the rule-making process including the drafting of draft rules and changes after the public
19 hearing process to the extent permitted by Title 5, chapter 375. After July 1, 2017, any
20 rules adopted by the department pursuant to this section are governed by section 7252.

21 **Sec. 12. 32 MRSA §2210, sub-§1, ¶D**, as enacted by PL 2015, c. 488, §13, is
22 amended to read:

23 D. On or after January 1, 2017, within a 7-day period, more than a 7-day supply of
24 an opioid medication to a patient under treatment for acute pain unless the opioid
25 product is labeled by the federal Food and Drug Administration to be dispensed only
26 in a stock bottle that exceeds a 7-day supply as prescribed, in which case the amount
27 dispensed may not exceed a 14-day supply. "Acute pain" has the same meaning as in
28 Title 22, section 7246, subsection 1-A.

29 **Sec. 13. 32 MRSA §2210, sub-§2, ¶B**, as enacted by PL 2015, c. 488, §13, is
30 amended to read:

31 B. When directly ordering or administering a benzodiazepine or opioid medication to
32 a person in an emergency room setting, an inpatient hospital setting, a long-term care
33 facility or a residential care facility or in connection with a surgical procedure.

34 As used in this paragraph, "administer" has the same meaning as in Title 22, section
35 7246, subsection 1-B.

36 **Sec. 14. 32 MRSA §2600-C, sub-§1, ¶D**, as enacted by PL 2015, c. 488, §17, is
37 amended to read:

38 D. On or after January 1, 2017, within a 7-day period, more than a 7-day supply of
39 an opioid medication to a patient under treatment for acute pain unless the opioid
40 product is labeled by the federal Food and Drug Administration to be dispensed only
41 in a stock bottle that exceeds a 7-day supply as prescribed, in which case the amount

1 dispensed may not exceed a 14-day supply. For purposes of this paragraph, "acute
2 pain" has the same meaning as in Title 22, section 7246, subsection 1-A.

3 **Sec. 15. 32 MRSA §2600-C, sub-§2, ¶B,** as enacted by PL 2015, c. 488, §17, is
4 amended to read:

5 B. When directly ordering or administering a benzodiazepine or opioid medication to
6 a person in an emergency room setting, an inpatient hospital setting, a long-term care
7 facility or a residential care facility or in connection with a surgical procedure.

8 As used in this paragraph, "administer" has the same meaning as in Title 22, section
9 7246, subsection 1-B.

10 **Sec. 16. 32 MRSA §3300-F, sub-§1, ¶D,** as enacted by PL 2015, c. 488, §20, is
11 amended to read:

12 D. On or after January 1, 2017, within a 7-day period, more than a 7-day supply of
13 an opioid medication to a patient under treatment for acute pain unless the opioid
14 product is labeled by the federal Food and Drug Administration to be dispensed only
15 in a stock bottle that exceeds a 7-day supply as prescribed, in which case the amount
16 dispensed may not exceed a 14-day supply. "Acute pain" has the same meaning as in
17 Title 22, section 7246, subsection 1-A.

18 **Sec. 17. 32 MRSA §3300-F, sub-§2, ¶B,** as enacted by PL 2015, c. 488, §20, is
19 amended to read:

20 B. When directly ordering or administering a benzodiazepine or opioid medication to
21 a person in an emergency room setting, an inpatient hospital setting, a long-term care
22 facility or a residential care facility or in connection with a surgical procedure.

23 As used in this paragraph, "administer" has the same meaning as in Title 22, section
24 7246, subsection 1-B.

25 **Sec. 18. 32 MRSA §3657, sub-§1, ¶D,** as enacted by PL 2015, c. 488, §23, is
26 amended to read:

27 D. On or after January 1, 2017, within a 7-day period, more than a 7-day supply of
28 an opioid medication to a patient under treatment for acute pain unless the opioid
29 product is labeled by the federal Food and Drug Administration to be dispensed only
30 in a stock bottle that exceeds a 7-day supply as prescribed, in which case the amount
31 dispensed may not exceed a 14-day supply. "Acute pain" has the same meaning as in
32 Title 22, section 7246, subsection 1-A.

33 **Sec. 19. 32 MRSA §3657, sub-§2, ¶B,** as enacted by PL 2015, c. 488, §23, is
34 amended to read:

35 B. When directly ordering or administering a benzodiazepine or opioid medication to
36 a person in an emergency room setting, an inpatient hospital setting, a long-term care
37 facility or a residential care facility or in connection with a surgical procedure.

38 As used in this paragraph, "administer" has the same meaning as in Title 22, section
39 7246, subsection 1-B.

1 5. It removes the requirement for a dispenser to notify the Controlled Substances
2 Prescription Monitoring Program if the dispenser has reason to believe that a prescription
3 is fraudulent or duplicative, maintaining the requirement that the dispenser contact the
4 prescriber.

5 6. It clarifies that the requirement to check the Controlled Substances Prescription
6 Monitoring Program does not apply for surgical procedures, rather than only inpatient
7 surgery.

8 7. It clarifies that dispensing in connection with surgical procedures is exempt from
9 the 100 morphine milligram equivalents limitation on opioids.

10 8. It clarifies that an opioid product that is labeled by the federal Food and Drug
11 Administration to be dispensed only in a stock bottle that exceeds a 7-day supply may be
12 prescribed as long as the amount dispensed does not exceed a 14-day supply.

13 9. It makes all rules related to the Controlled Substances Prescription Monitoring
14 Program major substantive rules except that the Department of Health and Human
15 Services is directed to adopt routine technical rules to conform to the changes in the
16 definition of "dispenser" and the removal of the requirement of a pharmacist to notify the
17 program when a prescription appears fraudulent or duplicative.