OFFICE OF POLICY AND LEGAL ANALYSIS

Date: March 25, 2021
To: Joint Standing Committee on Health & Human Services
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LD 330 An Act To Prevent Accidental Overdoses by Establishing a Protocol for Prescription Drug Recovery

SUMMARY: This bill seeks to reduce accidental overdose deaths caused by access to unused controlled substances.

1. It requires an agency, facility or individual who offers or plans to offer any in-home or community support services or institutionally based long-term care services and who administers a controlled substance to an adult with long-term care needs as part of those services, referred to in the bill as "an administering provider," to document any controlled substance prescribed and obtained for the adult with long-term care needs, referred to in the bill as "the client-patient," and to participate in the Controlled Substances Prescription Monitoring Program under the Maine Revised Statutes, Title 22, chapter 1603, with certain exceptions.

2. It requires that all controlled substances be kept in a locked container to which only the administering provider, the client-patient and, if there is one, a designated caregiver have access.

3. It requires the administering provider, upon the death of the client-patient, to collect any unused controlled substances that were prescribed and obtained for that client-patient and dispose of them properly after documenting the National Drug Code, quantity and strength. The administering provider is required to submit this documentation, including the manner of disposal of the controlled substances collected from the deceased client-patient, to the Department of Health and Human Services using the reporting system established in the Controlled Substances Prescription Monitoring Program under the Maine Revised Statutes, Title 22, chapter 1603

ISSUES FROM TESTIMONY

- Sponsor looking for a method to track and dispose medications after the person that the medications were prescribed to has died.

- Concerns from opponents: Intrusive and/or risky for nurses to visit after death to collect medications; processes already exist to manage controlled substances; lockboxes could result in lost keys and confusion (already used sometimes); medications are property of patient and in patient's home; list of medications and plans of care already sent to the home and ask families to dispose of medications after death.
- Need for continuing education on med management and disposal and be required in every patient's home. Increase use of Rx disposal.
- DHHS: PMP is structured for clinicians and pharmacists; this would require a new user role. Would allow some unlicensed in home and community support workers without training access to all of the PMP. Adding users would result in fiscal note for HIPAA compliance and PMP training; would take 6-12 months to complete before going live. Alternative solution would be a fillable form on the PMP/OBH website for administering providers regarding controlled substances reclaimed and disposed, which is then uploaded into the PMP. Also: concerns about the lockbox. Need to define client-patient locations to avoid conflict with existing LTC settings and those regulations.

DRAFTING ISSUES:

- PMP is checked by the prescribers and dispensers; unclear why establishing a new class of user is necessary for disposal. Can the "administering provider" provide the PMP information when working in the home?
- Proposed §7351 applies to "an adult with long-term care needs" – broader than hospice. Applies to institutional and any home and community based care and other direct care workers qualified to administer medications? Is the term "client-patient" used elsewhere in statutes? Should there be a different process for institutions and home care?
- Administering provider is defined to include an employee or contractor of a provider. Sub-§5 requires each administering provider to develop a written policy – is this each person? For each patient? Or an employer?

ADDITIONAL INFORMATION REQUESTED BY COMMITTEE:

- Requested from DHHS: What is required by DLC for licensing hospice agencies (at home and institutional) with respect to policies on medication? Is there a standard or typical policy around the following:
  - Providing health care plans and/or medication lists to families (at home).
  - Providing information about disposal of medications including after the death of the patient (at home).
  - Is there a standard form that family members have to sign about medications and disposal (at home).
  - Requirements around disposal of medications after the death of the patient (institutional).

- Federal regulations and regulations:
  - Existing DEA rules were clarified to state that hospices were prohibited from disposing or assisting in the disposal of controlled substances for hospice patients unless there was a state law granting authority to do so; the rules encouraged education.
  - In 2018 the SUPPORT for Patients and Communities Act (Pub. L. 115-271) was signed which included the Safe Disposal of Unused Medication Act. That Act allowed, but did not require, certain home hospice staff in qualified hospices to dispose of controlled substances as long as it was lawfully dispensed and destroyed on site. Apparently, there is no effective date or guidance on the Safe Disposal law. It is on pp 55-57 here: https://www.congress.gov/115/plaws/publ271/PLAW-115publ271.pdf
  - The 2018 Safe Disposal law also required a GAO study on requirements and challenges of disposal of controlled substances in a home hospice setting. The GAO report issued in August 2020, is found here: https://www.gao.gov/assets/gao-20-378.pdf
  - CFR §418.106(e) CMS regulations require written policies and discussions on disposal with family members.

42 CFR § 418.106 - Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment

(e) ***Standard: Labeling, disposing, and storing of drugs and biologicals*** -

(1) ***Labeling.*** Drugs and biologicals must be labeled in accordance with currently accepted professional practice and must include appropriate usage and cautionary instructions, as well as an expiration date (if applicable).

(2) ***Disposing.***

(i) Safe use and disposal of controlled drugs in the patient's home. The hospice must have written policies and procedures for the management and disposal of controlled drugs in the patient's home. At the time when controlled drugs are first ordered the hospice must:

(A) Provide a copy of the hospice written policies and procedures on the management and disposal of controlled drugs to the patient or patient representative and family;

(B) Discuss the hospice policies and procedures for managing the safe use and disposal of controlled drugs with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe use and disposal of controlled drugs; and

(C) Document in the patient's clinical record that the written policies and procedures for managing controlled drugs was provided and discussed.

(ii) Disposal of controlled drugs in hospices that provide inpatient care directly. The hospice that provides inpatient care directly in its own facility must dispose of controlled drugs in compliance with the hospice policy and in accordance with State and Federal requirements. The hospice must maintain current and accurate records of the receipt and disposition of all controlled drugs.

(3) ***Storing.*** The hospice that provides inpatient care directly in its own facility must comply with the following additional requirements -

(i) All drugs and biologicals must be stored in secure areas. All controlled drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1976 must be stored in locked compartments within such secure storage areas. Only personnel authorized to administer controlled drugs as noted in paragraph (d)(2) of this section may have access to the locked compartments; and

(ii) Discrepancies in the acquisition, storage, dispensing, administration, disposal, or return of controlled drugs must be investigated immediately by the pharmacist and hospice administrator and where required reported to the appropriate State authority. A written account of the investigation must be made available to State and Federal officials if required by law or regulation.

- LD 8 in ENR requires certain drug manufacturers to operate drug take back programs. Still in committee; voted 10-3 OTP-A.
- Other states? NCSL provided a list of state laws regarding the disposal of unused prescription drugs, as of 2019.
  - NJ, PA and MD have laws that allow hospice providers to dispose of unused medications but the law requires surrender of the medications. (MD law is attached and NJ law is below)
  - Several other states have drug take back laws similar to LD 8.

FISCAL IMPACT:

OFPR preliminary fiscal impact statement: DHHS will require a GF appropriation of $105,000 in FY 22-23 and $30,000 GF on going in future years. $75,000 is for one-time technology upgrades and then $30,000 on going technology costs.

NJ law:

26:2H-81.1 Definitions relative to hospice care, disposal of unused prescription medications.

1. a. As used in this section:

"Family member" means a hospice care patient's spouse, parent, adult sibling, adult child, or adult grandchild.

"Health care representative" means a person, including a member of the patient's family, who is authorized to make health care decisions on behalf of a hospice care patient.

"Hospice care patient" means a person currently receiving hospice care services in a private home or an assisted living facility through a licensed hospice care program.

"Third party caregiver" means a person who:

(1) is 18 years of age or older;

(2) provides care or assistance to a hospice care patient; and

(3) is not the patient's health care representative, a family member of the patient, or employed by the patient's hospice care program.

b. A hospice care program licensed pursuant to P.L.1997, c.78 (C.26:2H-79 et seq.) may choose, but shall not be required, to accept for disposal, at such time as a hospice care patient ceases to use the drug or medication or ceases to receive hospice care services through the program, the hospice care patient's unused prescription drugs and medications. A hospice care program that chooses to accept unused prescription drugs and medications for disposal pursuant to this section shall:

(1) Establish a written policy setting forth procedures for accepting and disposing of unused prescription drugs and medications;

(2) Furnish a copy of the written policy to each patient, and to the patient's health care representative, at the time the patient is enrolled in the hospice care program, and designate a program representative who shall discuss the procedures and requirements for surrendering unused prescription drugs and medications with the patient and the patient's health care representative;

(3) Accept drugs and medications prescribed and dispensed to the patient pursuant to the patient's hospice care plan, as well as any other prescription drugs and medications that the patient, or the patient's health care representative, chooses to surrender to the program;

(4) Not accept any drug or medication for surrender except at such time as the patient ceases to use the drug or medication or ceases to receive hospice care services through the program;

(5) Obtain any certifications, authorizations, or waivers as may be required under State or federal law in order to accept and dispose of unused prescription drugs and medications pursuant to this section; and

(6) (a) at the time the patient is enrolled in the hospice care program, at such time as any change is made to the patient's course of treatment that results in a change in the drugs or medications prescribed for the patient, or in the patient discontinuing the use of a prescription drug or medication, and at such time as the patient ceases to receive hospice care services through the program, provide the patient or the patient's health care representative with oral instructions and written informational materials advising that when unused, unwanted, or expired drugs and medications are not properly, safely, and promptly disposed of:

(i) there is a risk that the drug or medication can be stolen, diverted, abused, misused, or accidentally ingested, which can pose a risk to the health and safety of the patient and other members of the patient's household;

(ii) children are particularly at risk of accidentally ingesting unused, unwanted, and expired medications that have not been properly, safely, and promptly disposed of;

(iii) when drugs or medications are disposed of in the household trash or flushed down the drain, the drugs and medications can leak into the ecosystem, which can have a potentially adverse or harmful effect on the environment; and

(iv) when drugs or medications are disposed of in the household trash without the drug or medication having been rendered deactivated, inaccessible, or otherwise unusable, the drug or medication may be stolen by individuals seeking to divert, abuse, or misuse the drug or medication;

(b) make available on-site, for purchase or at no cost to the patient, at least one consumer method for individuals to dispose of unwanted or expired prescription drugs, including, but not limited to over-the-counter at-home or site-of-use solutions or secured medication collection kiosks or boxes; and

(c) provide the patient with oral and written instructions on how to properly, safely, and promptly dispose of unused, unwanted, or expired drugs and medications, which may include, but shall not be limited to, providing instructions concerning the use of an over-the-counter at-home or site-of-use solution furnished to the patient pursuant to subparagraph (b) of this paragraph, and advising the patient of

the availability of secure prescription medication drop-off receptacles and prescription medication take back programs.

c. At the time a hospice care patient ceases to receive hospice care services, a program representative shall provide a written request for surrender of unused drugs and medications to the patient or the patient's health care representative, which shall:

(1) request that the patient or the patient's health care representative surrender any unused prescription drugs or medications that were prescribed and dispensed to the patient pursuant to the patient's hospice care plan;

(2) offer to accept and dispose of any other prescription drug or medication which the patient will not use; and

(3) urge that the patient or the patient's health care representative dispose of any unused prescription drug or medication that is not surrendered to the program in a safe and legal manner, so as to avoid the risk of theft, diversion, or accidental ingestion.

d. No hospice care program may accept and dispose of an unused prescription drug or medication pursuant to this section unless the patient or the patient's health care representative authorizes, in writing, the surrender of the unused prescription drug or medication to the program; except that, if the patient is unable to provide written authorization and the patient does not have a health care representative, a third party caregiver may provide written authorization for the surrender. A hospice care program shall not accept an unused prescription drug or medication unless the drug or medication is identified for inclusion in the authorization for surrender.

e. (1) Unused prescription drugs and medications surrendered to a hospice care program pursuant to this section shall be surrendered to a registered professional nurse or a licensed practical nurse employed by the program.

(2) A nurse accepting the surrender of unused prescription drugs or medications pursuant to this section shall dispose of the drugs or medications at the site where hospice care was provided; in no case shall the nurse transport the unused prescription medications off-site for disposal or for any other purpose. The nurse may dispose of the unused drugs or medications using an over-the-counter at-home or site-of-use solution that meets the requirements of paragraph (2) of subsection a. of section 1 of P.L.2019, c.509 (C.45:14-67.6).

(3) A nurse who accepts and disposes of an unused prescription drug or medication pursuant to this section shall document:

(a) the name and quantity of each drug or medication surrendered;

(b) the name of the person authorizing the surrender, and the relationship of the person to the patient;

(c) the date and method of disposal; and

(d) the quantity and type of any unused prescription drug or medication, of which the nurse is aware, that was prescribed and dispensed to the patient pursuant to the patient's hospice care plan, but was not surrendered to the program or otherwise disposed of by another person in the nurse's presence.

(4) The person authorizing the surrender of a drug or medication shall be provided with the opportunity to review, verify, and sign the documentation required under paragraph (3) of this subsection.

f. Nothing in this section shall prohibit any person from disposing of an unused prescription drug or medication by any means authorized by law, including, but not limited to, disposing of the drug or medication pursuant to subparagraph (b) of paragraph (6) of subsection b. of this section or surrendering the medication at a secure prescription medication drop-off receptacle.

g. No person shall be subject to civil or criminal liability or professional disciplinary action for any act or omission undertaken in good faith consistent with the requirements of this section.

L.2017, c.135, s.1; amended 2019, c.509, s.2.