SENATE, No. 64

STATE OF NEW JERSEY

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SYNOPSIS

"Charlie's Law"; requires pharmacy practice sites and hospice programs to furnish patients with information and means to safely dispose of unused prescription drugs and medications.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel.

AN ACT concerning prescription medications, supplementing Title 45 of the Revised Statutes, and amending P.L.2017, c.135.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. (New section) a. A pharmacy practice site that dispenses prescription drugs, other than a long-term care pharmacy, shall, when dispensing to an individual located in this State a prescription drug or medication which is a controlled dangerous substance, and when dispensing any other prescription drug or medication as may be designated by the Commissioner of Health by regulation:

(1) provide the patient with written informational materials advising that when unused, unwanted, or expired drugs and medications are not properly, safely, and promptly disposed of:

(a) 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;

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

(c) 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

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

(2) 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, subject to the following requirements:

(a) as defined by the "EPA household waste exclusion" at 40 C.F.R. 261.4(b)(1), pharmaceuticals are not regulated federally as hazardous wastes and are handled and are handled through municipal solid waste regulations thus are not subject to the federal RCRA hazardous waste regulations. All At-Home and Site-of-Use drug disposal products shall follow the "alternative or innovative technology" guidelines set forth in N.J.A.C.7:26-3A1, including altering the characteristics of the prescription drug through

EXPLANATION – Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined <u>thus</u> is new matter.

chemical, biological, or physical means to as to have a beneficial and long-term effect on the environment. In addition, At-Home and Site-of-Use drug disposal products shall, pursuant to municipal waste regulations, consist of a non-toxic composition, blend, solution, or formulation that renders the active ingredients in the prescription medication, as defined in 21 C.F.R. 210.3(b)(7) unavailable and unusable for misuse and abuse;

(b) Secured medication collection kiosks or boxes shall follow federal Drug Enforcement Administration (DEA) requirements for collected pharmaceuticals, pursuant to part 1317 of Title 21 of the Code of Federal Regulations, and shall be marked and identified by prominent signage;

(c) any manufacturer of a non-toxic At-home or Site-of-Use composition for consumer drug disposal shall provide a method that renders the active ingredients in the prescription medication, as defined in 21 C.F.R. 210.3(b)(7), unusable so that the active ingredients cannot be transformed to a physical or chemical condition or transformed to the state of a controlled substance or controlled substance analog, as per 21 C.F.R. s.1317;

(d) the manufacturer of an At-home or Site-of-Use composition or a secured medicine collection kiosk or box made available by a pharmacy pursuant to this paragraph shall represent to the pharmacy, upon request by the pharmacy, that none of the components or methods of disposal individually or as a blend or as a solution or as treatment and destruction facility are toxic, and that the composition or medicine collection kiosk or box follows waste regulations outlined by the federal Environmental Protection Agency (EPA) for municipal house hold waste disposal; and

(e) the manufacturer, supplier, or servicing agent of a commercial collection program that uses secured medication collection kiosks or boxes shall follow the DEA requirements for collected pharmaceuticals, pursuant to part 1317 of Title 21 the Code of Federal Regulations, and shall ensure that methods of incineration follow the permitted hazardous waste combustor recommendations outlined by the federal Environmental Protection Agency (EPA) Recourse Conservation and Recovery Act (RCRA) regulations for incineration of hazardous waste; and

(3) provide the patient with written informational materials concerning how to properly, safely, and promptly dispose of unused, unwanted, or expired drugs and medications, which may include, but shall not be limited to, information concerning drug disposal options available pursuant to paragraph (2) of this subsection. The individual dispensing the prescription drug, or an appropriate designee, shall answer any questions the patient may have upon receiving the written informational materials pursuant to this paragraph.

b. The requirements of subsection a. of this section shall apply regardless of whether the prescription is an initial prescription or a

renewal or refill of an existing prescription, and regardless of whether the patient is a new or returning customer at the pharmacy practice site.

c. Any time a pharmacy practice site that dispenses prescription drugs, other than a long-term care pharmacy, sells or dispenses a hypodermic syringe or needle, regardless of whether the hypodermic syringe or needle is sold or dispensed pursuant to a prescription, the pharmacy practice site shall provide the patient with the written informational materials prepared by the Division of Consumer Affairs in the Department of Law and Public Safety pursuant to section 3 of this act concerning the safe disposal of used hypodermic syringes and needles so as to prevent against the potential transmission of bloodborne pathogens that can occur when used hypodermic syringes and needles are reused or when they result in accidental injury. The individual selling or dispensing the hypodermic syringe or needle, or an appropriate designee, shall answer any questions the patient may have upon receiving the written informational materials pursuant to this subsection.

2. Section 1 of P.L.2017, c.135 (C.26:2H-81.1) is amended to read as follows:

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 <u>drug or</u> medication or ceases to receive hospice care services through the program, the hospice care patient's unused prescription <u>drugs and</u> medications. A hospice care program that chooses to accept unused prescription <u>drugs and</u> medications for disposal pursuant to this section shall:

(1) Establish a written policy setting forth procedures for accepting and disposing of unused prescription <u>drugs and</u> 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; **[**and**]**

(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 unpalatable, the drug or medication may be stolen by individuals seeking to divert, abuse, or misuse the drug or medication;

(b) (2) make available for purchase or at no cost 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. , c. (C.) (pending before the Legislature as this bill); 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 **[**medication**]** 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 **[**medication**]** 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. , c. (C.) (pending before the Legislature as this bill).

(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.

(cf: P.L.2017, c.135, s.1)

3. (New section) The Division of Consumer Affairs in the Department of Law and Public Safety shall prepare written informational materials for distribution to patients by hospice care programs and pharmacy practice sites concerning the safe disposal of used hypodermic syringes and needles so as to prevent against the potential transmission of bloodborne pathogens that can occur when used hypodermic syringes and needles are reused or when they result in accidental injury. The written informational materials shall be made available through the division’s Internet website and shall be distributed to hospice care programs and pharmacy practice sites upon request.

4. This act shall take effect 90 days after the date of enactment.

STATEMENT

This bill requires each pharmacy practice site that dispenses prescription drugs, other than a long-term care pharmacy, to, when dispensing to an individual located in this State a prescription drug or medication which is a controlled dangerous substance, and when dispensing any other prescription drug or medication as may be designated by the Commissioner of Health by regulation: (1) provide the patient with written informational materials advising that there are risks when unused, unwanted, or expired drugs and medications are not properly, safely, and promptly disposed of; (2)

have 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 drug disposal solutions for use at home and secured medication collection kiosks or boxes; and (3) provide the patient with written informational materials concerning how to properly, safely, and promptly dispose of unused, unwanted, or expired drugs and medications. The individual dispensing the prescription drug, or an appropriate designee, is to answer any questions the patient may have upon receiving the written informational materials pursuant to this paragraph.

The bill identifies certain aspects of federal law that may relate to the requirements of the bill and indicate that the household drug disposal solutions to be made available under the bill are to meet certain Department of Environmental Protection requirements concerning alternate disposal methodologies for medical waste that currently apply to the medical industry. Medication collection kiosks or boxes are to be marked or identified by prominent signage.

The bill requires that, any time a pharmacy practice site that dispenses prescription drugs, other than a long-term care pharmacy, sells or dispenses a hypodermic syringe or needle, regardless of whether the hypodermic syringe or needle is sold or dispensed pursuant to a prescription, the pharmacy practice site is to provide the patient with the written informational materials prepared by the Division pursuant to the bill's provisions.

Under the bill, if a patient is enrolled in the hospice care program, and if 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, the hospice care program is to: (1) provide the patient or the patient's health care representative with oral instructions and written informational materials advising that there are risks when unused, unwanted, or expired drugs and medications are not properly, safely, and promptly disposed of; (2) make available for purchase or at no cost to the patient an At-Home or Site-of-Use prescription medication disposal product, and (3) provide the patient with written informational materials concerning how to properly, safely, and promptly dispose of unused, unwanted, or expired drugs and medications.

A nurse in the hospice care program may dispose of unused drugs or medications using an At-Home or Site-of-Use drug disposal solution.

The bill provides that the Division is to prepare written informational materials for distribution to patients by hospice care programs and pharmacy practice sites concerning the safe disposal of used hypodermic syringes and needles so as to prevent against the potential transmission of bloodborne pathogens that can occur when used hypodermic syringes and needles are reused or when

they result in accidental injury. The written informational materials are to be made available through the Division's Internet website and are to be distributed to hospice care programs and pharmacy practice sites upon request.

This bill is named "Charlie's Law" after Charlie Van Tassel, a young man who struggled with addiction for many years before finally succumbing in 2013, at the age of 33. Charlie was an athlete and family prankster who loved music and dancing, had a terrific sense of humor, and was a beloved brother and son. It is the sponsor's intent to help reduce the risk that young people like Charlie will develop a substance use disorder, as well as to reduce the potential harms caused by the improper disposal of used hypodermic syringes and needles.