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DELAWARE STATE SENATE

143rd GENERAL ASSEMBLY

SENATE BILL NO. 77

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO CREATION OF A PRESCRIPTION DRUG REPOSITORY PROGRAM.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

1 Section 1. Amend Title 16 of the Delaware Code by adding a new Chapter 30D to read as follows:

2 "Chapter 30D: Prescription Drug Repository Program.

3 §3001D. Definitions.

4 As used in this chapter:

5 (a) 'Health Care Facility' means:

6 1. A hospital,

7 2. A hospice care program,

8 3. A nursing home,

9 4. A home health agency,

10 5. An intermediate care facility for the mentally retarded,

11 6. A facility that provides treatment or other services for individuals who have mental disorders, or

12 7. An assisted living program.

13 (b) 'Health Care Practitioner' means an individual licensed or certified under Title 24 to provide health care.

14 (c) 'Nonprofit clinic' means a public or private nonprofit organization that provides primary or specialty outpatient health care
15 services to indigent and uninsured individuals for free or at reduced cost.

16 (d) 'Prescription Drug' has the meaning stated in §3003B of this Title.

17 (e) 'Program' means the Prescription Drug Repository Program.

18 (f) 'Board' means the State Board of Pharmacy.

19 §3002D. Prescription drug repository program.

20 The Board shall establish a prescription drug repository program to accept and dispense prescription drugs donated for the purpose
21 of dispensing to individuals who are residents of the State and meet eligibility requirements established by the Board.

22 §3003D. Packaging of drugs.

23 Except as provided in subsection (b) of this section, the Program may only accept and dispense drugs in their original unopened,
24 sealed, and tamper-evident unit dose packaging.

25 (a) The Program may accept and dispense drugs packaged in single unit doses when the outside packaging is opened if the
26 single unit dose packaging is undisturbed.

27 (b) The Program may not accept or dispense drugs:

- 28 1. Bearing an expiration date that is less than 6 months from the date the drug is donated; or
29 2. That may be deemed adulterated according to the standards of §3303 of this Title.

30 §3004D. Donation of drugs.

31 (a) Any person, including an individual, a drug manufacturer, or a health care facility, may donate prescription drugs to the
32 Program.

33 (b) Drugs may only be donated at a pharmacy, hospital, or nonprofit clinic that participates in the Program.

34 §3005D. Dispensing of drugs.

35 (a) A pharmacy, hospital, or nonprofit clinic that participates in the Program may only dispense drugs donated through the
36 Program:

37 (1) To individuals who are residents of the State and meet the eligibility standards established by the Board; or

38 (2) To government entities and nonprofit private entities to be dispensed to individuals who are residents of the State
39 and meet the eligibility standards established by the Board.

40 (b) A drug donated through the Program may only be dispensed on a prescription issued by an authorized prescriber.

41 (c) A pharmacy, hospital, or nonprofit clinic that accepts donated drugs shall:

42 (1) Comply with all applicable Federal laws and laws of this State pertaining to storage and distribution of
43 prescription drugs; and

44 (2) Inspect all drugs before dispensing to determine that the drugs are not adulterated.

45 (d) The pharmacy, hospital, or nonprofit clinic may charge individuals receiving donated drugs a handling fee established in
46 accordance with regulations adopted by the Board.

47 (e) Drugs donated to the Program may not be resold.

48 §3006D. Liability.

49 (a) This Section applies to:

50 (1) The Board;

51 (2) The Secretary of the Department of Health and Social Services;

52 (3) Any person that donates drugs to the Program;

53 (4) Any pharmacy, hospital, nonprofit clinic, or health care practitioner that accepts or dispenses drugs under the
54 Program; and

55 (5) Any pharmacy, hospital, or nonprofit clinic that employs a health care practitioner who accepts or dispenses drugs
56 under the Program.

57 (b) For matters related to donating, accepting, or dispensing drugs under the Program, a person described in subsection (a) of
58 this Section who acts in good faith may not be subject to:

59 (1) Criminal prosecution;

60 (2) Liability in tort or other civil action for injury, death, or loss to person or property; or

61 (3) Disciplinary action by a professional licensing board.

62 (c) A drug manufacturer acting in good faith may not be subject to criminal prosecution or liability in tort or other civil action
63 for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a drug
64 manufactured by the drug manufacturer that is donated by any person under the Program, including liability for failure to
65 transfer or communicate product or consumer information or the expiration date of the donated drug.

66 §3007D. Promulgation of Rules and Regulations.

67 (a) On or before October 1, 2005, and in consultation with the Secretary, the Board shall adopt regulations governing the
68 Program.

69 (b) The regulations shall establish:

70 (1) Participation requirements for pharmacies, hospitals, and nonprofit clinics to accept and dispense donated drugs
71 under the Program;

72 (2) Standards and procedures for accepting, safely storing, and dispensing donated drugs;

73 (3) Standards and procedures for inspecting donated drugs to determine that:

74 i. The original unit dose packaging is sealed and tamper-evident; and

75 ii. The drugs are unadulterated, safe, and suitable for dispensing;

- 76 (4) Eligibility standards based on economic need for individuals to receive drugs;
- 77 (5) A means, such as an identification card, by which an individual who is eligible to receive donated drugs may
- 78 demonstrate eligibility to the pharmacy, hospital, or nonprofit clinic dispensing the drugs;
- 79 (6) A form that an individual receiving a drug from the Program must sign before receiving the drug to confirm that
- 80 the individual understands the immunity provisions of the Program;
- 81 (7) A formula to determine the amount of a handling fee that pharmacies, hospitals, and nonprofit clinics may charge
- 82 to drug recipients to cover restocking and dispensing costs;
- 83 (8) A list of drugs that the repository will accept;
- 84 (9) A list of drugs that the repository will not accept, including a statement as to why the drug is ineligible for
- 85 donation;
- 86 (10) For an individual donor, a form each donor must sign stating that the donor is the owner of the drugs and intends
- 87 to voluntarily donate them to the Program; and
- 88 (11) Any other standards and procedures the Board considers appropriate.”

89 Section 2. This Act shall take effect October 1, 2005.

SYNOPSIS

This bill creates a Prescription Drug Repository Program for the purpose of safely accepting and dispensing donated, unused, unopened prescription drugs. This Program would be available to eligible residents of the State with a valid prescription from an authorized prescriber. The Program would bring critical medications to eligible Delawareans for no charge or at a very minimal cost, which they otherwise might not be able to afford.

Author: Senator Blevins