

**FIRST ENGROSSMENT  
with Conference Committee Amendments****ENGROSSED HOUSE BILL NO. 1256**

Introduced by

Representatives Weisz, Pollert, Thoreson

Senators Christmann, J. Lee, Robinson

1 A BILL for an Act to create and enact chapter 43-15.2 of the North Dakota Century Code,  
2 relating to the creation of a legend prescription drug and device donation and repository  
3 program; and to provide an appropriation.

4 **BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:**

5 **SECTION 1.** Chapter 43-15.2 of the North Dakota Century Code is created and  
6 enacted as follows:

7 **43-15.2-01. Definitions.** In addition to the definitions under section 43-15-01, in this  
8 chapter unless the context otherwise requires:

- 9 1. "Donor" means a person that donates to the program legend drugs, devices, or  
10 supplies needed to administer such drugs.
- 11 2. "Participant" means a practitioner or pharmacy that has elected to participate in the  
12 program and accepts legend drugs, devices, and supplies from donors for the  
13 program.
- 14 3. "Program" means the legend drug donation and repository program established  
15 under this chapter.
- 16 4. "Supplies" means any supplies used in the administration of a legend drug.

17 **43-15.2-02. Administration.**

- 18 1. The state board of pharmacy shall establish and contract with a third party to  
19 administer a legend drug donation and repository program.
- 20 2. The board may develop and maintain a participant registry for the program. A  
21 participant registry created under this subsection must include the name, address,  
22 and telephone number of the participants. A participant registry created under this  
23 subsection must be available through the board or on the board's web site.

- 1           3.   The board may cooperate with nongovernmental organizations to maintain a  
2                   web-based list of legend drugs, devices, or supplies that have been donated and  
3                   are available through the program and the participants from which the donated  
4                   items may be available.

5           **43-15.2-03. Conditions for participation.**

- 6           1.   A donor may donate legend drugs, devices, or supplies to the program through a  
7                   practitioner or pharmacy that meets the criteria established for such participation.  
8                   Legend drugs, devices, or supplies may not be donated directly to a specific  
9                   patient and donated items may not be resold.
- 10          2.   The items donated to the program may be prescribed for use by an individual by a  
11                   practitioner who is authorized by law to prescribe and only a participant may  
12                   dispense donated items.

13          **43-15.2-04. Conditions for acceptance of a donation.**

- 14          1.   A drug donated, prescribed, or dispensed under the program must be in the  
15                   original, unopened, sealed, and tamper-evident unit dose packaging, except a drug  
16                   packaged in single-unit doses may be accepted and dispensed if the outside  
17                   packaging has been opened and the single-unit-dose package is unopened.
- 18          2.   A drug may not be accepted or dispensed under the program if the drug has  
19                   reached its expiration date or if the drug is adulterated or misbranded as  
20                   determined under subsection 3.
- 21          3.   Before being dispensed to an eligible individual, the legend drugs, devices, and  
22                   supplies donated under the program must be inspected by a pharmacist to  
23                   determine that the legend drugs, devices, and supplies are not adulterated or  
24                   misbranded.

25          **43-15.2-05. Storage, distribution, and dispensing.**

- 26          1.   A participant that accepts donated legend drugs, devices, or supplies under the  
27                   program shall comply with all applicable provisions of state and federal law relating  
28                   to the storage, distribution, and dispensing of the donated legend drugs, devices,  
29                   or supplies.

- 1           2. A participant may charge an individual a handling fee that does not exceed two  
2                   hundred fifty percent of the medicaid prescription dispensing fee for dispensing  
3                   donated legend drugs, devices, or supplies under the program.
- 4           3. A dispenser of donated legend drugs, devices, or supplies may not submit a claim  
5                   or otherwise seek reimbursement from any public or private third-party payer for  
6                   the cost of donated legend drugs, devices, or supplies dispensed to any eligible  
7                   individual under the program. A public or private third-party payer is not required  
8                   to provide reimbursement to a dispenser for the cost of donated legend drugs,  
9                   devices, or supplies dispensed to any eligible individual under the program.

10           **43-15.2-06. Liability.**

- 11           1. A donor of legend drugs, devices, or supplies, or any participant in the program,  
12                   that exercises reasonable care in donating, accepting, distributing, prescribing, and  
13                   dispensing legend drugs, devices, or supplies under the program and the rules  
14                   adopted to implement this chapter is immune from civil or criminal liability and from  
15                   professional disciplinary action of any kind for any injury, death, or loss to personal  
16                   property relating to such activities.
- 17           2. In the absence of intentional misconduct, a pharmaceutical manufacturer is  
18                   immune from civil or criminal liability for any claim, injury, death, or loss to person  
19                   or property arising from transfer, donation, dispensing, or acceptance of any  
20                   legend drugs, devices, or supplies under this chapter, including liability for failure  
21                   to transfer or communicate product or consumer information regarding the  
22                   transferred legend drugs, devices, or supplies as well as the expiration date of the  
23                   legend drugs, devices, or supplies under the program.

24           **43-15.2-07. Recordkeeping.**

- 25           1. A participant shall retain separate records detailing the receipt, distribution, and  
26                   dispensing of legend drugs, devices, and supplies under this program.
- 27           2. The records of receipt must include:
- 28                   a. The name and address of the donor;
- 29                   b. The drug name and strength;
- 30                   c. The manufacturer of the legend drugs, devices, or supplies;
- 31                   d. The manufacturer lot number;

- 1 e. The drug expiration date;
- 2 f. The date received; and
- 3 g. The quantity received.
- 4 3. Records of distribution and dispensing must include:
- 5 a. The name and address of the participant;
- 6 b. The drug or device name;
- 7 c. The drug strength;
- 8 d. The quantity distributed;
- 9 e. The identity of the manufacturer of the legend drugs, devices, or supplies;
- 10 f. The manufacturer lot number;
- 11 g. The expiration date;
- 12 h. The date of distribution or dispensing; and
- 13 i. The name and address of the individual to whom the donated item was
- 14 distributed.
- 15 4. Records of dispensing must include:
- 16 a. The requirements for a prescription label; and
- 17 b. The manufacturer's lot number.

18 **SECTION 2. APPROPRIATION.** There is appropriated out of any moneys in the  
19 general fund in the state treasury, not otherwise appropriated, the sum of \$22,000, or so much  
20 of the sum as may be necessary, to the state department of health for the purpose of providing  
21 a grant of \$22,000 to the state board of pharmacy for establishing and administering a legend  
22 prescription drug and device donation and repository program, for the biennium beginning  
23 July 1, 2007, and ending June 30, 2009. The state department of health may not impose a fee  
24 for providing the grant nor impose any condition on the issuance of the grant other than that the  
25 state board of pharmacy is required to use the funds to establish and administer a legend  
26 prescription drug and device donation and repository program in accordance with section 1 of  
27 this Act.