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SENATE BILL 37

50TH LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2011

INTRODUCED BY

Dede Feldman

AN ACT

RELATING TO PRESCRIPTION DRUGS; PROVIDING FOR PRESCRIPTION DRUG DONATION; ENACTING A NEW SECTION OF THE NEW MEXICO DRUG, DEVICE AND COSMETIC ACT.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

SECTION 1. A new section of the New Mexico Drug, Device and Cosmetic Act is enacted to read:

"[NEW MATERIAL] PRESCRIPTION DRUG DONATION.--

A. As used in this section:

(1) "clinic" means a facility licensed pursuant to Section 61-11-14 NMSA 1978 in which one or more licensed practitioners diagnose and treat patients and in which drugs are stored, dispensed or administered for the diagnosis and treatment of the facility's patients; provided that "clinic" does not include the privately owned practice of a

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1 licensed practitioner or group of licensed practitioners exempt
2 under Section 61-11-22 NMSA 1978;

3 (2) "donor" means an individual who donates
4 unused prescription drugs to a clinic or a participating
5 practitioner for the purpose of redistribution to established
6 patients of that clinic or practitioner;

7 (3) "participating practitioner" means a
8 licensed practitioner who is authorized to prescribe drugs and
9 who registers with the board, and is subject to rules
10 promulgated by the board, to participate in the collection of
11 donated drugs, prescribed for use by established patients of
12 that practitioner and donated for the purpose of redistribution
13 to established patients of that practitioner;

14 (4) "recipient" means an individual who
15 voluntarily receives donated prescription drugs; and

16 (5) "tamper-evident" means a device or process
17 that makes unauthorized access to protected pharmaceutical
18 packaging easily detected.

19 B. Unused prescription drugs may be donated to a
20 clinic or a participating practitioner and a clinic or a
21 participating practitioner may accept and redistribute the
22 donated prescription drugs in accordance with rules promulgated
23 by the board.

24 C. The board shall establish procedures to allow
25 the donation and redistribution of certain prescription drugs,

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1 including refrigerated drugs, that:

2 (1) ensure that the redistribution process is
3 consistent with public health and safety standards; and

4 (2) exclude controlled substances and drugs
5 required by the United States food and drug administration to
6 have a risk evaluation and mitigation strategy.

7 D. The board shall promulgate rules to include:

8 (1) standards and procedures for accepting,
9 storing, labeling and redistributing donated prescription
10 drugs;

11 (2) standards and procedures for inspecting
12 donated prescription drugs to determine that the packaging is
13 tamper-evident and that the donated prescription drugs are
14 unadulterated, safe and suitable for redistribution;

15 (3) a form to be signed by the recipient
16 specifying:

17 (a) knowledge that the donor is not a
18 pharmacist and took ordinary care of the donated prescription
19 drug;

20 (b) knowledge that the donor is known to
21 the clinic or the participating practitioner and that there is
22 no reason to believe that the donated prescription drug was
23 improperly handled or stored;

24 (c) that by accepting the donated
25 prescription drug, the recipient accepts any risks that an

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1 accidental mishandling could create;

2 (d) the release of the donor and the
3 clinic or participating practitioner from liability; and

4 (e) the release of the pharmaceutical
5 manufacturer for any claim or injury arising from the transfer
6 of any prescription drug of that manufacturer pursuant to this
7 section;

8 (4) a form to be signed by the donor verifying
9 that:

10 (a) the donor is the owner of the
11 donated prescription drug;

12 (b) the donated prescription drug has
13 been properly stored and the container has not been opened or
14 tampered with;

15 (c) the donated prescription drug has
16 not been adulterated or misbranded; and

17 (d) the donor is voluntarily donating
18 the prescription drug;

19 (5) a handling fee not to exceed twenty
20 dollars (\$20.00) that may be charged to the recipient by the
21 clinic or the participating practitioner to cover the costs of
22 inspecting, storing, labeling and redistributing the donated
23 prescription drug; and

24 (6) any other standards deemed necessary by
25 the board.

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1 E. The board shall maintain and publish a current
2 listing of clinics and participating practitioners.

3 F. Before redistributing donated prescription
4 drugs, the clinic or the participating practitioner shall:

5 (1) comply with all applicable federal laws
6 and the laws of the state that deal with the inspection,
7 storage, labeling and redistribution of donated prescription
8 drugs; and

9 (2) examine the donated prescription drug to
10 determine that it has not been adulterated or misbranded and
11 certify that the drug has been stored in compliance with the
12 requirements of the product label.

13 G. A donor acting in good faith shall not be
14 subject to any penalty pursuant to Section 26-1-26 NMSA 1978.

15 H. A clinic or participating practitioner that, in
16 good faith, receives a donated prescription drug and
17 redistributes it at no charge, other than a handling fee, shall
18 not be subject to any penalty pursuant to Section 26-1-26 NMSA
19 1978 resulting from the condition of the donated drug unless an
20 injury arising from the donated drug is caused by the gross
21 negligence, recklessness or intentional conduct of the clinic
22 or participating practitioner.

23 I. This section does not restrict the authority of
24 an appropriate governmental agency to regulate or ban the use
25 of any prescription drugs."

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