SENATE PUBLIC AFFAIRS COMMITTEE SUBSTITUTE FOR SENATE BILL 37

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

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

- (2) "donor" means an individual who donates unused prescription drugs to a clinic or a participating practitioner for the purpose of redistribution to established patients of that clinic or practitioner;
- (3) "participating practitioner" means a licensed practitioner who is authorized to prescribe drugs and who registers with the board, and is subject to rules promulgated by the board, to participate in the collection of donated drugs, prescribed for use by established patients of that practitioner and donated for the purpose of redistribution to established patients of that practitioner;
- (4) "recipient" means an individual who voluntarily receives donated prescription drugs; and
- (5) "tamper-evident" means a device or process that makes unauthorized access to protected pharmaceutical packaging easily detected.
- B. Unused prescription drugs may be donated to a clinic or a participating practitioner and a clinic or a participating practitioner may accept and redistribute the donated prescription drugs in accordance with rules promulgated by the board.
 - C. The board shall promulgate rules to establish:
 - (1) procedures to allow the donation and

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redistribution	of	certain	${\tt prescription}$	drugs,	including
refrigerated di	1105	s. that:			

- (a) ensure that the redistribution process is consistent with public health and safety standards; and
 - (b) exclude controlled substances.
- (2) standards and procedures for accepting, storing, labeling and redistributing donated prescription drugs;
- (3) standards and procedures for inspecting donated prescription drugs to determine that the packaging is tamper-evident and that the donated prescription drugs are unadulterated, safe and suitable for redistribution;
- (4) a form to be signed by the recipient
 specifying:
- (a) knowledge that the donor is not a pharmacist and took reasonable care of the donated prescription drug;
- (b) knowledge that the donor is known to the clinic or the participating practitioner and that there is no reason to believe that the donated prescription drug was improperly handled or stored;
- (c) that any person who exercises reasonable care in donating, accepting or redistributing pursuant to this section shall be immune from civil or criminal .184540.1

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the prescription drug;

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liability or professional disciplinary action of any kind for
any related injury, death or loss; and
(d) that the immunity provided by this
section shall not decrease or increase the civil or criminal
liability of a drug manufacturer, distributor or dispenser that
would have existed but for the donation;
(5) a form to be signed by the donor verifying
that:
(a) the donor is the owner of the
donated prescription drug;
(b) the donated prescription drug has
been properly stored and the container has not been opened or
tampered with;
(c) the donated prescription drug has
not been adulterated or misbranded; and
(d) the donor is voluntarily donating
(d) the donor is voluntarily donating

- (6) a handling fee not to exceed twenty dollars (\$20.00) that may be charged to the recipient by the clinic or the participating practitioner to cover the costs of inspecting, storing, labeling and redistributing the donated prescription drug; and
- (7) any other standards deemed necessary by the board.
- D. The board shall maintain and publish a current .184540.1

listing of clinics and participating practitioners.

- E. Before redistributing donated prescription drugs, the clinic or the participating practitioner shall:
- (1) comply with all applicable federal laws and the laws of the state that deal with the inspection, storage, labeling and redistribution of donated prescription drugs; and
- (2) examine the donated prescription drug to determine that it has not been adulterated or misbranded and certify that the drug has been stored in compliance with the requirements of the product label.
- F. Any person who exercises reasonable care in donating, accepting or redistributing prescription drugs pursuant to this section shall be immune from civil or criminal liability or professional disciplinary action of any kind for any related injury, death or loss.
- G. The immunity provided by this section shall not decrease or increase the civil or criminal liability of a drug manufacturer, distributor or dispenser that would have existed but for the donation.
- H. A manufacturer shall not be liable for failure to transfer or communicate product consumer information or the expiration date of the donated prescription drug pursuant to this section.
- I. This section does not restrict the authority of .184540.1

an appropriate governmental agency to regulate or ban the use of any prescription drugs."

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