First Regular Session Sixty-eighth General Assembly STATE OF COLORADO

REENGROSSED

This Version Includes All Amendments Adopted in the House of Introduction SENATE BILL 11-043

LLS NO. 11-0330.01 Kate Meyer

SENATE SPONSORSHIP

Steadman,

(None),

HOUSE SPONSORSHIP

Senate Committees Health and Human Services **House Committees**

A BILL FOR AN ACT

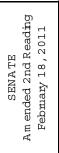
101	CONCERNING	А	REQUIREMENT	THAT	PHARMACI	EUTICAL
102	MANUFA	CTU	RERS DEVELOP PLA	NS FOR 1	THE SAFE DISH	POSAL OF

 103
 SHARPS INTENDED FOR HOME USE.

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at http://www.leg.state.co.us/billsummaries.)

The bill requires a pharmaceutical manufacturer that sells or distributes a medication in Colorado that is usually intended to be self-injected in a home to create a plan describing how the manufacturer supports the safe collection and proper disposal of home-generated sharps SENATE 3rd Reading Unam ended February 21, 2011



(plan).

The bill requires a plan to be annually submitted to the department of public health and environment and posted to the manufacturer's web site, and describes the minimum information that a manufacturer must include in the plan. Manufacturers providing free mail-back containers to consumers of its self-injected medications are exempted from the plan requirements.

1 Be it enacted by the General Assembly of the State of Colorado:

2 SECTION 1. Part 4 of article 15 of title 25, Colorado Revised
3 Statutes, is amended BY THE ADDITION OF A NEW SECTION to
4 read:

5 **25-15-408.** Home-generated sharps - collection and disposal 6 plan - violation - exceptions - consultation with interested parties. 7 (1) (a) ON OR BEFORE JULY 1, 2012, ANY PHARMACEUTICAL 8 MANUFACTURER THAT SELLS OR DISTRIBUTES A MEDICATION IN 9 COLORADO THAT IS USUALLY INTENDED TO BE SELF-INJECTED IN A HOME 10 THROUGH THE USE OF A HYPODERMIC NEEDLE, PEN NEEDLE, INTRAVENOUS 11 NEEDLE, OR OTHER SIMILAR DEVICE, RESULTING IN THE GENERATION OF 12 SHARPS, AND ANY MANUFACTURER OF HYPODERMIC NEEDLES, PEN 13 NEEDLES, INTRAVENOUS NEEDLES, AND OTHER SIMILAR DEVICES THAT 14 SELLS OR DISTRIBUTES SUCH DEVICES IN THE STATE, SHALL CREATE A PLAN 15 DESCRIBING HOW THE MANUFACTURER SUPPORTS THE SAFE COLLECTION 16 AND PROPER DISPOSAL OF SUCH HOME-GENERATED SHARPS. THE 17 MANUFACTURER MUST UPDATE THE PLAN AT LEAST ANNUALLY.

- 18 (b) A MANUFACTURER SUBJECT TO THIS SECTION SHALL POST TO
 19 ITS WEB SITE THE MOST CURRENT VERSION OF THE PLAN REQUIRED UNDER
- 20 PARAGRAPH (a) OF THIS SUBSECTION (1).
- 21

22 (2) THE PLAN REQUIRED BY SUBSECTION (1) OF THIS SECTION MUST

1 INCLUDE, AT A MINIMUM:

2	(a) <u>FOR A PHARMACEUTICAL MANUFACTURER, IDENTIFICATION</u> BY
3	NAME OF THE MANUFACTURER'S MEDICATIONS THAT ARE USUALLY
4	INTENDED TO BE SELF-INJECTED IN A HOME; AND
5	(b) A DESCRIPTION OF THE ACTIONS, IF ANY, TAKEN BY THE
6	MANUFACTURER TO:
7	(I) PROVIDE FOR THE SAFE COLLECTION AND PROPER DISPOSAL OF
8	SHARPS;
9	(II) EDUCATE CONSUMERS ABOUT SAFE MANAGEMENT OF SHARPS
10	AND COLLECTION OPPORTUNITIES;
11	(III) EDUCATE MEDICAL PERSONNEL AND OTHER STAFF MEMBERS
12	WHO ANSWER THE MANUFACTURER'S TOLL-FREE NUMBER, AND HEALTH
13	CARE PROFESSIONALS WHO INTERACT WITH PATIENTS WHO USE SHARPS AT
14	HOME, REGARDING SAFE SHARPS DISPOSAL METHODS AVAILABLE TO
15	<u>CONSUMERS IN COLORADO; AND</u>
16	(IV) Support groups with an interest in protecting public
17	HEALTH AND SAFETY, INCLUDING RETAILERS, PHARMACEUTICAL
18	DISTRIBUTORS, GOVERNMENTAL ENTITIES, HEALTH CARE ORGANIZATIONS,
19	
20	PUBLIC HEALTH OFFICERS, SOLID WASTE SERVICE PROVIDERS, AND
20	ORGANIZATIONS REPRESENTING PATIENTS WHO USE SHARPS, IN THE
20	
	ORGANIZATIONS REPRESENTING PATIENTS WHO USE SHARPS, IN THE
21	ORGANIZATIONS REPRESENTING PATIENTS WHO USE SHARPS, IN THE GROUPS' EFFORTS TO PROMOTE PROPER AND SAFE SALE, COLLECTION, AND
21 22	ORGANIZATIONS REPRESENTING PATIENTS WHO USE SHARPS, IN THE GROUPS' EFFORTS TO PROMOTE PROPER AND SAFE SALE, COLLECTION, AND DISPOSAL OF SHARPS.
21 22 23	ORGANIZATIONS REPRESENTING PATIENTS WHO USE SHARPS, IN THE GROUPS' EFFORTS TO PROMOTE PROPER AND SAFE SALE, COLLECTION, AND DISPOSAL OF SHARPS. (3) A MANUFACTURER SHALL NOT PASS ON TO CONSUMERS OR
21 22 23 24	ORGANIZATIONS REPRESENTING PATIENTS WHO USE SHARPS, IN THE GROUPS'EFFORTS TO PROMOTE PROPER AND SAFE SALE, COLLECTION, AND DISPOSAL OF SHARPS. (3) A MANUFACTURER SHALL NOT PASS ON TO CONSUMERS OR RETAILERS THE COSTS OF CREATING OR POSTING THE PLAN REQUIRED

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DEPARTMENT ON OR BEFORE JULY 1, 2012, AND ANNUALLY THEREAFTER,
 STATING THAT THE MANUFACTURER:

3 (a) PREVIOUSLY SUBMITTED A PLAN TO AN AGENCY OF A STATE
4 GOVERNMENT DOCUMENTING THAT THE MANUFACTURER HAS ARRANGED
5 TO PROVIDE TO CONSUMERS OF ITS SELF-INJECTED <u>MEDICATIONS OR ITS</u>
6 <u>DEVICES</u>, AT NO COST TO THE CONSUMERS, MAIL-BACK CONTAINERS
7 APPROVED BY THE UNITED STATES POSTAL SERVICE; AND

8 (b) CONTINUES TO PROVIDE SUCH MAIL-BACK SERVICES TO
9 RESIDENTS OF COLORADO.

10 THE GENERAL ASSEMBLY HEREBY AUTHORIZES AND (5) (a) 11 ENCOURAGES THE DEPARTMENT TO CONVENE A TASK FORCE OR WORKING 12 GROUP, OR OTHERWISE CONSULT WITH PERSONS WHO ARE INTERESTED IN 13 OR AFFECTED BY HOME-GENERATED SHARPS PLANS, FOR THE PURPOSE OF 14 EVALUATING THE EFFECTIVENESS OF THIS SECTION. ANY SUCH 15 CONSULTATION OR EVALUATION MUST BE DONE WITHIN EXISTING 16 APPROPRIATIONS. 17 (b) THE DEPARTMENT IS ENCOURAGED TO PROVIDE LINKS ON ITS

18 <u>WEB SITE TO THE PLANS POSTED BY MANUFACTURERS PURSUANT TO</u>
 19 PARAGRAPH (b) OF SUBSECTION (1) OF THIS SECTION.

20 **SECTION 2.** Act subject to petition - effective date. This act 21 shall take effect at 12:01 a.m. on the day following the expiration of the 22 ninety-day period after final adjournment of the general assembly (August 23 10, 2011, if adjournment sine die is on May 11, 2011); except that, if a 24 referendum petition is filed pursuant to section 1 (3) of article V of the 25 state constitution against this act or an item, section, or part of this act 26 within such period, then the act, item, section, or part shall not take effect 27 unless approved by the people at the general election to be held in

- 1 November 2012 and shall take effect on the date of the official
- 2 declaration of the vote thereon by the governor.