

First Regular Session
Sixty-eighth General Assembly
STATE OF COLORADO

REENGROSSED

*This Version Includes All Amendments
Adopted in the House of Introduction*

LLS NO. 11-0330.01 Kate Meyer

SENATE BILL 11-043

SENATE SPONSORSHIP

Steadman,

HOUSE SPONSORSHIP

(None),

Senate Committees
Health and Human Services

House Committees

A BILL FOR AN ACT

101 **CONCERNING A REQUIREMENT THAT PHARMACEUTICAL**
102 **MANUFACTURERS DEVELOP PLANS FOR THE SAFE DISPOSAL 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

Shading denotes HOUSE amendment. Double underlining denotes SENATE amendment.
Capital letters indicate new material to be added to existing statute.
Dashes through the words indicate deletions from existing statute.

SENATE
3rd Reading Unamended
February 21, 2011

SENATE
Amended 2nd Reading
February 18, 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) FOR A PHARMACEUTICAL MANUFACTURER, IDENTIFICATION 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 CONSUMERS IN COLORADO; AND

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 PUBLIC HEALTH OFFICERS, SOLID WASTE SERVICE PROVIDERS, AND
20 ORGANIZATIONS REPRESENTING PATIENTS WHO USE SHARPS, IN THE
21 GROUPS' EFFORTS TO PROMOTE PROPER AND SAFE SALE, COLLECTION, AND
22 DISPOSAL OF SHARPS.

23 (3) A MANUFACTURER SHALL NOT PASS ON TO CONSUMERS OR
24 RETAILERS THE COSTS OF CREATING OR POSTING THE PLAN REQUIRED
25 UNDER THIS SECTION.

26 (4) THIS SECTION DOES NOT APPLY TO A PHARMACEUTICAL OR
27 DEVICE MANUFACTURER THAT PROVIDES WRITTEN NOTIFICATION TO THE

1 DEPARTMENT ON OR BEFORE JULY 1, 2012, AND ANNUALLY THEREAFTER,
2 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 MEDICATIONS OR ITS
6 DEVICES, 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 (5) (a) THE GENERAL ASSEMBLY HEREBY AUTHORIZES AND
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 WEB SITE TO THE PLANS POSTED BY MANUFACTURERS PURSUANT TO
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.