

First Regular Session
Sixty-eighth General Assembly
STATE OF COLORADO

INTRODUCED

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.

(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.

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

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

25-15-408. Home-generated sharps - collection and disposal plan - violation - exceptions. (1) (a) ON OR BEFORE JULY 1, 2012, ANY PHARMACEUTICAL MANUFACTURER THAT SELLS OR DISTRIBUTES A MEDICATION IN COLORADO THAT IS USUALLY INTENDED TO BE SELF-INJECTED IN A HOME THROUGH THE USE OF A HYPODERMIC NEEDLE, PEN NEEDLE, INTRAVENOUS NEEDLE, OR OTHER SIMILAR DEVICE, RESULTING IN THE GENERATION OF SHARPS, SHALL CREATE A PLAN DESCRIBING HOW THE MANUFACTURER SUPPORTS THE SAFE COLLECTION AND PROPER DISPOSAL OF SUCH HOME-GENERATED SHARPS. THE MANUFACTURER MUST UPDATE THE PLAN AT LEAST ANNUALLY.

(b) A MANUFACTURER SUBJECT TO THIS SECTION SHALL:

(I) ANNUALLY SUBMIT TO THE DEPARTMENT, IN AN ELECTRONIC FORMAT PRESCRIBED BY THE COMMISSION, THE PLAN REQUIRED UNDER PARAGRAPH (a) OF THIS SUBSECTION (1); AND

(II) POST TO ITS WEB SITE THE MOST CURRENT VERSION OF THE PLAN REQUIRED UNDER PARAGRAPH (a) OF THIS SUBSECTION (1). THE MANUFACTURER SHALL PROVIDE A LINK ON THE HOME PAGE OF ITS WEB SITE TO THE PLAN.

1 (c) THE DEPARTMENT SHALL POST TO ITS WEB SITE THE PLANS IT
2 RECEIVES PURSUANT TO PARAGRAPH (b) OF THIS SUBSECTION (1) AND A
3 TIME AND DATE STAMP OR OTHER INDICATOR OF WHEN EACH PLAN WAS
4 RECEIVED.

5 (2) THE PLAN REQUIRED BY SUBSECTION (1) OF THIS SECTION MUST
6 INCLUDE, AT A MINIMUM:

7 (a) IDENTIFICATION BY NAME OF THE MANUFACTURER'S
8 MEDICATIONS THAT ARE USUALLY INTENDED TO BE SELF-INJECTED IN A
9 HOME; AND

10 (b) A DESCRIPTION OF THE ACTIONS, IF ANY, TAKEN BY THE
11 MANUFACTURER TO:

12 (I) PROVIDE FOR THE SAFE COLLECTION AND PROPER DISPOSAL OF
13 SHARPS;

14 (II) EDUCATE CONSUMERS ABOUT SAFE MANAGEMENT OF SHARPS
15 AND COLLECTION OPPORTUNITIES;

16 (III) TRAIN THE FOLLOWING EMPLOYEES ON SAFE SHARPS DISPOSAL
17 METHODS AVAILABLE TO CONSUMERS IN COLORADO:

18 (A) MEDICAL PERSONNEL AND OTHER STAFF WHO ANSWER THE
19 MANUFACTURER'S TOLL-FREE NUMBER; AND

20 (B) MEDICAL STAFF MEMBERS WHO CONDUCT HOME VISITS WITH
21 NEW PATIENTS; AND

22 (IV) SUPPORT GROUPS WITH AN INTEREST IN PROTECTING PUBLIC
23 HEALTH AND SAFETY, INCLUDING RETAILERS, PHARMACEUTICAL
24 DISTRIBUTORS, GOVERNMENTAL ENTITIES, HEALTH CARE ORGANIZATIONS,
25 PUBLIC HEALTH OFFICERS, SOLID WASTE SERVICE PROVIDERS, AND
26 ORGANIZATIONS REPRESENTING PATIENTS WHO USE SHARPS, IN THE
27 GROUPS' EFFORTS TO PROMOTE PROPER AND SAFE SALE, COLLECTION, AND

1 DISPOSAL OF SHARPS.

2 (3) A MANUFACTURER THAT VIOLATES THIS SECTION IS SUBJECT TO
3 THE CIVIL PENALTIES SET FORTH UNDER SECTION 25-15-406 (1).

4 (4) THIS SECTION DOES NOT APPLY TO A PHARMACEUTICAL
5 MANUFACTURER THAT PROVIDES WRITTEN NOTIFICATION TO THE
6 DEPARTMENT ON OR BEFORE JULY 1, 2012, AND ANNUALLY THEREAFTER,
7 STATING THAT THE MANUFACTURER:

8 (a) PREVIOUSLY SUBMITTED A PLAN TO AN AGENCY OF A STATE
9 GOVERNMENT DOCUMENTING THAT THE MANUFACTURER HAS ARRANGED
10 TO PROVIDE TO CONSUMERS OF ITS SELF-INJECTED MEDICATIONS, AT NO
11 COST TO THE CONSUMERS, MAIL-BACK CONTAINERS APPROVED BY THE
12 UNITED STATES POSTAL SERVICE; AND

13 (b) CONTINUES TO PROVIDE SUCH MAIL-BACK SERVICES TO
14 RESIDENTS OF COLORADO.

15 **SECTION 2. Act subject to petition - effective date.** This act
16 shall take effect at 12:01 a.m. on the day following the expiration of the
17 ninety-day period after final adjournment of the general assembly (August
18 10, 2011, if adjournment sine die is on May 11, 2011); except that, if a
19 referendum petition is filed pursuant to section 1 (3) of article V of the
20 state constitution against this act or an item, section, or part of this act
21 within such period, then the act, item, section, or part shall not take effect
22 unless approved by the people at the general election to be held in
23 November 2012 and shall take effect on the date of the official
24 declaration of the vote thereon by the governor.