

**First Regular Session  
Sixty-eighth General Assembly  
STATE OF COLORADO**

**PREAMENDED**

*This Unofficial Version Includes Committee  
Amendments Not Yet Adopted on Second Reading*

LLS NO. 11-0330.01 Kate Meyer

**SENATE BILL 11-043**

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**SENATE SPONSORSHIP**

**Steadman,**

**HOUSE SPONSORSHIP**

**(None),**

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**Senate Committees**

Health and Human Services

**House Committees**

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**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.**

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**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.

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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:

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

22 (II) POST TO ITS WEB SITE THE MOST CURRENT VERSION OF THE

1 PLAN REQUIRED UNDER PARAGRAPH (a) OF THIS SUBSECTION (1). THE  
2 MANUFACTURER SHALL PROVIDE A LINK ON   ITS WEB SITE TO THE PLAN.

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

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

9 (a) FOR A PHARMACEUTICAL MANUFACTURER, IDENTIFICATION BY  
10 NAME OF THE MANUFACTURER'S MEDICATIONS THAT ARE USUALLY  
11 INTENDED TO BE SELF-INJECTED IN A HOME; AND

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

14 (I) PROVIDE FOR THE SAFE COLLECTION AND PROPER DISPOSAL OF  
15 SHARPS;

16 (II) EDUCATE CONSUMERS ABOUT SAFE MANAGEMENT OF SHARPS  
17 AND COLLECTION OPPORTUNITIES;

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

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

22 (B) MEDICAL STAFF MEMBERS WHO CONDUCT HOME VISITS WITH  
23 NEW PATIENTS; AND

24 (IV) SUPPORT GROUPS WITH AN INTEREST IN PROTECTING PUBLIC  
25 HEALTH AND SAFETY, INCLUDING RETAILERS, PHARMACEUTICAL  
26 DISTRIBUTORS, GOVERNMENTAL ENTITIES, HEALTH CARE ORGANIZATIONS,  
27 PUBLIC HEALTH OFFICERS, SOLID WASTE SERVICE PROVIDERS, AND

1 ORGANIZATIONS REPRESENTING PATIENTS WHO USE SHARPS, IN THE  
2 GROUPS' EFFORTS TO PROMOTE PROPER AND SAFE SALE, COLLECTION, AND  
3 DISPOSAL OF SHARPS.

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

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

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

16 (4) THE GENERAL ASSEMBLY HEREBY AUTHORIZES AND  
17 ENCOURAGES THE DEPARTMENT TO CONVENE A TASK FORCE OR WORKING  
18 GROUP, OR OTHERWISE CONSULT WITH PERSONS WHO ARE INTERESTED IN  
19 OR AFFECTED BY HOME-GENERATED SHARPS PLANS, FOR THE PURPOSE OF  
20 EVALUATING THE EFFECTIVENESS OF THIS SECTION. ANY SUCH  
21 CONSULTATION OR EVALUATION MUST BE DONE WITHIN EXISTING  
22 APPROPRIATIONS.

23 **SECTION 2. Act subject to petition - effective date.** This act  
24 shall take effect at 12:01 a.m. on the day following the expiration of the  
25 ninety-day period after final adjournment of the general assembly (August  
26 10, 2011, if adjournment sine die is on May 11, 2011); except that, if a  
27 referendum petition is filed pursuant to section 1 (3) of article V of the

1 state constitution against this act or an item, section, or part of this act  
2 within such period, then the act, item, section, or part shall not take effect  
3 unless approved by the people at the general election to be held in  
4 November 2012 and shall take effect on the date of the official  
5 declaration of the vote thereon by the governor.