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

Massey,

Senate Committees
Health and Human Services

House Committees

A BILL FOR AN ACT

CONCERNING A REQUIREMENT THAT PHARMACEUTICAL MANUFACTURERS DEVELOP PLANS FOR THE SAFE DISPOSAL OF 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 Unamended
February 21, 2011

SENATE
Amended 2nd Reading
February 18, 2011

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 - consultation with interested parties.

(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, AND ANY MANUFACTURER OF HYPODERMIC NEEDLES, PEN NEEDLES, INTRAVENOUS NEEDLES, AND OTHER SIMILAR DEVICES THAT SELLS OR DISTRIBUTES SUCH DEVICES IN THE STATE, 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 POST TO ITS WEB SITE THE MOST CURRENT VERSION OF THE PLAN REQUIRED UNDER PARAGRAPH (a) OF THIS SUBSECTION (1).

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

INCLUDE, AT A MINIMUM:

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

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

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

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

(III) EDUCATE MEDICAL PERSONNEL AND OTHER STAFF MEMBERS WHO ANSWER THE MANUFACTURER'S TOLL-FREE NUMBER, AND HEALTH CARE PROFESSIONALS WHO INTERACT WITH PATIENTS WHO USE SHARPS AT HOME, REGARDING SAFE SHARPS DISPOSAL METHODS AVAILABLE TO CONSUMERS IN COLORADO; AND

(IV) SUPPORT GROUPS WITH AN INTEREST IN PROTECTING PUBLIC HEALTH AND SAFETY, INCLUDING RETAILERS, PHARMACEUTICAL DISTRIBUTORS, GOVERNMENTAL ENTITIES, HEALTH CARE ORGANIZATIONS, PUBLIC HEALTH OFFICERS, SOLID WASTE SERVICE PROVIDERS, AND 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 UNDER THIS SECTION.

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

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

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

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

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

(b) THE DEPARTMENT IS ENCOURAGED TO PROVIDE LINKS ON ITS WEB SITE TO THE PLANS POSTED BY MANUFACTURERS PURSUANT TO PARAGRAPH (b) OF SUBSECTION (1) OF THIS SECTION.

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

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