Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Environment Committee

HB 1370

Brief Description: Creating a statewide program for the collection, transportation, and disposal of unwanted medicines.

Sponsors: Representatives Van De Wege, Hudgins, Jinkins, Anderson, Rolfes, Cody, Dunshee, Roberts, Goodman, Ormsby, Hunt, Dickerson, Appleton, Ryu, Upthegrove, Kagi, Kenney, Seaquist, Hasegawa, Orwall, Sells, Green, Jacks, Fitzgibbon and Tharinger.

Brief Summary of Bill

- Creates an association to finance and operate a product stewardship program, with the approval of the State Board of Pharmacy, for the collection and disposal of unwanted drugs from residential sources.
- Requires producers of drugs subject to the product stewardship program to participate in the program.

Hearing Date: 2/3/11

Staff: Courtney Barnes (786-7194).

Background:

Consumers have unused medicines in their homes for a variety of reasons. Consumers may dispose of drugs by throwing them in the garbage, flushing them down the toilet or sink, or returning them to their pharmacy. Guidance to consumers on how to properly dispose of unused medications varies.

In Washington, the State Board of Pharmacy (BOP) within the Department of Health (DOH), the U.S. Drug Enforcement Administration (DEA), and the Washington Department of Ecology (DOE) regulate pharmaceutical waste. The DOE and local governments implement solid waste disposal and hazardous waste disposal programs. The BOP licenses health care professionals who are authorized to prescribe and administer drugs.

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not a part of the legislation nor does it constitute a statement of legislative intent.

The federal Secure and Responsible Drug Disposal Act of 2010 amends the Controlled Substances Act [21 U.S.C. 822] to allow people who have prescriptions for controlled substances to deliver the drugs to another person for disposal without being registered by the DEA.

Summary of Bill:

Medicine Return Association.

The Medicine Return Association (Association) is established as a nonprofit product stewardship organization to finance and operate a product stewardship program for the collection, transportation, and disposal of unwanted covered drugs from residential sources. Covered drugs include all legend and non-legend drugs from residential sources, including brand name and generic drugs. Covered drugs do not include the following:

- herbal-based remedies and homeopathic products;
- personal care products that are regulated as both cosmetics and non-legend drugs under the federal Food, Drug, and Cosmetic Act;
- drugs for which producers provide a take-back program as part of a federal Food and Drug Administration managed risk evaluation and mitigation strategy;
- drugs that are biological products if the producer already provides a take-back program; and
- pet pesticide products contained in pet collars, powders, or shampoos.

Membership. Membership in the Association must be open to all producers of covered drugs sold in the state. All producers of covered drugs sold in the state must participate in the Association's product stewardship program.

Management. The Association is managed by a board of directors (board), initially appointed by the Secretary of the DOH. The board must be comprised of representatives of producers whose covered drugs are sold in the state. At a minimum, the board must include representatives of:

- two branded legend drug makers;
- two generic legend drug makers;
- two non-legend drug makers; and
- two biotechnology sector drug makers.

Duties. The Association must select a chair and adopt articles of association and bylaws. The Association must prepare and adopt a plan of operation including procedures for assessing costs and collecting funds from participating producers. The plan of operation must also include: (a) a dispute mechanism through which a producer selling covered drugs may challenge an assessment determination made by the board; and (b) a mechanism for the Association to notify a producer selling covered drugs in this state that is failing to participate in the Association and report such a producer to the BOP.

By January 1, 2013, the Association must submit a proposed product stewardship program to the BOP for review. The Association must operate a product stewardship program by January 1, 2014. By June 30, 2015, the Association must submit a report to the BOP describing the program's activities during the previous reporting period. This report must be submitted annually and made available to the public.

Funding. The Association must pay all administrative and operational costs related to the product stewardship program. Association costs must be financed by the producers who sell covered drugs in this state. The Association's board must determine a method for equitably apportioning costs among producers and determine the method and timing of assessment collection. Each producer selling covered drugs in this state must be assessed for its share of the Association's total costs. Administrative and operational costs related to the product stewardship program are defined.

The Association's board may offer incentives or payments to collectors if necessary to ensure the product stewardship program requirements for the minimum number of collection sites are met. Producers may not impose a visible fee on consumers when covered drugs are purchased or returned. The total annual cost responsibility of the Association, not including penalties or fines, may not exceed $2.5 million dollars per calendar year. The total annual cost responsibility of the Association must be adjusted annually for inflation starting in 2012. A producer may appeal an assessment of charges or apportionment of costs to the BOP.

Product Stewardship Program.

Prior to submitting the proposed product stewardship program to the BOP, the Association must provide opportunities for public comment and at least one public hearing. The Association must provide a product stewardship program without using state or local government funds. The product stewardship program must be approved and licensed by the BOP prior to collecting unwanted covered drugs. The Association's product stewardship program must provide:

- a description of the proposed collection system;
- a description of the handling and disposal system, including identifying and providing contact information for collectors, transporters, and waste disposal facilities;
- a description of how the Association will use existing providers of waste pharmaceutical services;
- a description of how covered drugs will be separated and how packaging will be recycled;
- the policies and procedures to be followed by persons in charge of unwanted covered drugs;
- a description of how the collected, unwanted covered drugs are tracked through final disposal;
- a description of how patient information on drug packaging will be kept secure;
- a description of the public education effort and communications strategy; and
- contact information for all drug producers participating in the Association.

The Association must promote the use of the product stewardship program. The Association must establish a toll-free telephone number and web site where collection options are publicized. The Association must prepare educational and outreach materials describing where and how to return unwanted covered drugs. These materials must be provided to pharmacies, health care facilities, and other interested parties.

Collection. The collection system for all unwanted covered drugs must be safe, secure, and protect patient information. The collection system must be convenient and adequately serve the needs of residents in both urban and rural areas. At a minimum, the collection systems must provide one drop-off collection site in all counties in the state and one drop-off collection site in

all cities with a population greater than 10,000. Collectors may include law enforcement, pharmacies, hospitals, and other relevant public or private entities. If a drop-off location cannot be arranged, prepaid mailing envelopes must be provided.

Drugs collected under the product stewardship program must be disposed of at a properly permitted hazardous waste facility. Unwanted covered drugs from residential sources retain all other generator exemptions for household hazardous waste. The Association may petition the DOE for a waiver from the requirement for use of hazardous waste disposal for all or some of the collected drugs. The alternative facility must be approved by the DOE and cannot be a solid waste landfill or an industrial furnace.

The Association must annually invite public comments on the services provided by the product stewardship program. This information must be provided to the BOP. At least every four years, the Association must update its product stewardship program and submit the updates to the BOP for review.

The State Board of Pharmacy.

The proposed product stewardship program developed by the Association must be submitted to and approved by the BOP. The BOP must consult with the DOE and the Washington Association of Sheriffs and Police Chiefs. Within 90 days of receiving the proposed product stewardship program, the BOP must either approve or reject the Association's proposal. If the Association's proposal is rejected, the Association must submit a revised plan or appeal the decision. The BOP must review product stewardship program updates submitted by the Association. Any change to the product stewardship program, including changes in collection locations, must have prior approval by the BOP.

The BOP may adopt rules necessary to implement the requirements of the bill. The BOP, in consultation with the DOE, may establish performance standards for the product stewardship program. The BOP may suspend the product stewardship program if necessary to protect the public from imminent danger. If the Association or a producer is not in compliance with the bill or the program standards, the BOP may assess penalties for noncompliance.

The BOP may audit the activities of the Association as necessary. By December 31, 2016, the BOP must report to the Legislature concerning the statutes of the product stewardship program and recommendations for changes.

Other.

The DOH, the DOE, and local governments must promote the use of the product stewardship program and the program's toll-free telephone number and web site through existing educational methods.

Beginning in 2012, each drug wholesaler that sells any covered drug in the state must provide a list of producers of covered drugs to the BOP. Wholesalers must update the list by January 15th of each year.

The Pharmaceutical Product Stewardship Program Account (Account) is created. All receipts from fees and penalties collected under the bill must be deposited into the Account. Expenditures from the account may be used only for administering the requirements of the bill. Only the Secretary of the DOH or the Secretary's designee may authorize expenditures from the account.

Appropriation: None.

Fiscal Note: Requested on 1/19/11.

Effective Date: The bill takes effect 90 days after adjournment of the session in which the bill is passed.