Pharmaceutical Stewardship

Subcommittee Briefing and Discussion

March 2, 2016
Welcome and Meeting Purpose
Ad Hoc Subcommittee and Staff

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Today’s Agenda

✓ Discuss Key Policy Areas in Draft Pharmaceutical Stewardship Policy Outline, and identify issues for follow-up.

✓ Finalizing a Policy Outline for the public comment process

✓ Next Steps Policy Development and Public Comment Process

✓ Chair Wrap-up and Next Steps
Pharmaceutical Stewardship Policy

Adapting King Co’s model to Snohomish County
Discuss Draft Policy Outline

• Based on model of King Co Secure Medicine Return Regulations
• Lists some Policy Options for Snohomish County

Today’s Goal:
- policy discussion
- identify policy areas for further research & discussion
What’s in Stewardship Legislation

Responsibilities Defined for Producers & Other Stakeholders – “Level Playing Field”

Performance Requirements for Stewardship Plans
- products accepted
- collection convenience standard
- security requirements
- disposal methods
- promotion
- reporting
- costs producers responsible for

Deadlines for Plan Submission

Enforcement Mechanisms
1. Acceptance of Medicines Used in Homes and other Residential Settings ("covered drugs")

✓ Prescription medicines, including controlled substances
✓ Over-the-counter medicines

Not included:
- OTC medicines also regulated as cosmetics
- vitamins, supplements, herbal and homeopathic remedies
- medicines from business sources
- pet pesticide products (but otherwise pet meds included)
- drugs for which FDA requires a take-back program (REMS)
- biologic drugs where producer already provides take-back program
- medical devices

Policy Options:
- Include medicines collected during Medical Examiner’s investigation (regulatory considerations)
2. Convenient Collection System

Service convenience goal (multi-part):

General goal: reasonably convenient & equitable access for all residents.

Preferred collection method: drop boxes at pharmacies and police stations. Any that volunteer to host drop box must be included.

Geographic minimum standard: 1 drop box in every city with either a pharmacy or a law enforcement office, AND 1 additional drop box for every 30,000 residents in city or unincorporated area.

Alternative collection to fill in gaps: collection events or prepaid mailers.

For homebound or disabled residents: prepaid, preaddressed mailers on request.

Policy Options:
- Include any hospital with on-site pharmacy that volunteers as preferred collector.
- Include tribal police collection sites in county ordinance?
New Opportunities for Take-Back

DEA Rule on Disposal of Controlled Substances, Effective Oct. 2014

Secure Collection Receptacles at:
- Retail pharmacies
- Hospitals with on-site pharmacies
- Narcotic treatment centers
- Long-term care facilities (partnered with a retail pharmacy)

And new options for transporting or shipping medicines to disposal facilities.

Take-Back Events Run By Law Enforcement

Mail-back Programs
3. Secure & Confidential Protocols for Medicines and Packaging

Stewardship plans must:

• propose protocols/policies for safe and secure handling of medicines from collection through final disposal.

• comply with all federal/state laws & regulations, including DEA and the WA Pharmacy Quality Assurance Commission.

• protect confidential patient information on packaging.

Plans are encouraged to recycle packaging to the extent feasible.

Policy Options:
4. Environmentally Sound Disposal of Medicines

Collected medicines must be destroyed at a properly permitted hazardous waste facility (per EPA’s recommendation)

eg Clean Harbors in Utah or Veolia in Texas.

SHD may approve a petition for the following alternative disposal methods:

• Use of a large municipal waste combustion facility (e.g. Waste-to-Energy facility) because of cost or logistical barriers to using a hazardous waste facility.
  e.g. Spokane WTE or Covanta WTE in OR

• Use of alternative disposal technologies demonstrated to provide superior environmental and human health protection than high temperature incineration.
5./6. Education & Outreach Requirements

- Promote safe storage of medicines in the home, and
- Explain how to use the medicine take-back system to residents, pharmacists, retailers, health professionals, and others.
  - website & toll-free telephone number
  - materials to pharmacies, health-care facilities, and others
  - easily recognizable drop box design & clear instructions
  - plain language and images, understandable to all residents

- Conduct surveys of residents & practitioners on awareness & convenience after year 1 & at intervals
- Propose goals for public awareness, and county may define goals.
- In annual report, evaluate effectiveness of education.

Policy Options:
- Require that programs explain Snohomish code prohibiting disposal of pharmaceuticals in solid waste system.
- Require any medicine retailer that does not host a medicine drop box to display signage about drop box locations (per San Francisco ordinance).
- Other customized education requirements?
7. Annual Reporting

Medicine producers must report annually on program results, including:

• pounds of medicines collected, by each collection method;
• program operations and activities;
• annual evaluation of how goals were met and effectiveness of program promotion;
• results of required surveys of residents to measure awareness and program convenience; and
• total expenditures for the program.

Policy Options:
8. Producer Financing & Shared Stakeholder Responsibilities

Producers may not charge a specific fee to consumers at point-of-sale of medicines or at point-of-collection.

Medicine producers are responsible for costs of:
• Collection supplies for drop-off sites including drop boxes,
• Prepaid mailers and any collection events.
• Transportation and final destruction.
• Program promotion and evaluation.
• Administrative costs.
• Payment of fees to SHD to reimburse costs of agency oversight.

Roles for Other Stakeholders:
• Drug distributors provide list of producers.
• Collectors volunteer, and may/may not negotiate any compensation.
• Local agencies, cities, healthcare providers help with promotion.
8. Producer Financing & Shared Stakeholder Responsibilities

Policy Options:

• Submission of producer list by drug distributors could be changed from mandatory to “upon request by SHD”.
• Retailers selling medicines could be required to help promote the program if not hosting a drop box (per Education & Outreach section).
9./10. Producer Participation Requirements & Stewardship Organizations

Every producer selling “covered drugs” in/into county must participate.

• participate in the “standard” stewardship plan or
• a producer may propose an “independent” stewardship plan, either individually or jointly with others.

Every plan must meet all the requirements of the law.

Producer definition places responsibility on the manufacturer (per RCW). Does not include: retailer of store brand drug if manufacturer participating, compounding pharmacist, or wholesaler.

Policy Options:
• Consider options for how producers work together in stewardship org’s.
• Consider formation of a local stakeholder advisory committee to provide input to producers on plan development.
Defining How Producers May Work Together

**King Co. law**
Each producer must participate in the “standard” stewardship plan approved by the Director; however a producer or group of producers may participate in an independent stewardship plan if approved.

*Policy goal:* encourage all producers to work together, but allow flexibility

*In practice:*
- fostered competition - two plans submitted
- first plan meeting all requirements approved as standard plan

**CA county laws:**
Each producer must participate in a stewardship plan.

Producers may work *individually* or *jointly*.

*Policy goal:* allow producers flexibility; avoid county having to select which plan is the “standard” plan

*In practice:* so far in Alameda, only 1 plan submitted with minimal service
11. Implementation Deadlines After Effect Date

2 months: drug wholesalers must provide list of producers;
6 months: each producer must notify SHD of intent to participate in plan; retailers with store label drug must notify that their manufacturer intends to participate.
9 months: producers must notify SHD of their stewardship plan operator; and must notify all pharmacies and law enforcement of opportunity to be a collector.
1 year: proposed stewardship plan due;
3 months after approval: stewardship plan(s) must begin operations.
Every 4 years: stewardship plans must be updated.

SHD has discretion to approve extensions to these deadlines.

Policy Options:
• Consider shortening the implementation timeline.
• Consider options and impacts of a two-stage implementation.
Two-Stage Implementation Option

Benefit & Challenges

First stage:
Producers/stewardship organization(s) propose plan for financial support and logistical coordination for drop boxes at law enforcement agencies.

Second stage:
Next, producers/stewardship organization(s) propose a plan(s) to expand the program to additional collection sites (e.g., pharmacies, hospitals) to achieve the service convenience goal.
SHD responsibilities include:

- Notifying producers of compliance requirements;
- Assessing producer compliance and pursuing enforcement;
- Reviewing stewardship plan(s); SHD has authority to reject plans and/or impose changes on rejected plans;
- Monitoring stewardship plan operations; Investigating any complaints;
- Auditing and inspecting stewardship programs as needed;
- Reviewing any substantive changes to the approved plan(s);
- Reviewing any petitions for alternative disposal methods;
- Reviewing annual reports and working with producers on performance goals as needed.

SHD Enforcement Mechanisms

Policy Options:
- Consider reasonable adjustments to the stewardship plan review process to support more rapid implementation.
Stewardship Plan Review Process

- Producers/Stewardship Org Submit Proposed Plan
- Agency has 3 months to review
- If Plan is rejected, Producers must submit a Revised Plan within 2 months
- If Revised Plan is again rejected, Agency may request another revision or impose changes

*In King Co law:*
Standard Plan is allowed multiple Plan revisions.
But review of an Independent Plan allows for only one revision, if rejected, then those producers must work with Standard Plan.
Finalizing a Policy Outline for Public Comment Process
Proposed Process for Policy Development & Public Comment
## Proposed Policy Development Timeline

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| February  | Policy Discussions  
Development of Policy Outline for Public Comment |
| March     | Updates at BOH Meetings  
Public Comment Process on Policy Outline |
| April     | Small Stakeholder Meetings  
Develop Draft Ordinance |
| May 10    | 1st Reading & Public Hearing                                  |
| June 14   | 2nd Reading & Public Hearing                                  |

BOH Ad Hoc Steering Committee Meetings Every 2 weeks
Solicit public comment based on the Ad Hoc Committee’s pharmaceutical stewardship policy outline through:

**Option A**
- Press release – March 17
- Preliminary comment period March 18-April 8
  - Accepted via online survey, email, and mail
- Public comment at BOH meetings
  - May 10
  - June 14

**Option B**
- Press release – March 17
- Preliminary comment period March 18-April 8
  - Accepted via online survey, email, and mail
  - Public comment at Ad Hoc mtg
- Public comment at BOH meetings
  - May 10
  - June 14
Stakeholders

- Community members
- Pharmacies, WA Pharmacy Association
- Hospitals
- Law Enforcement
- Health/medical organizations & healthcare providers
- Substance abuse prevention groups
- Environmental groups
- City governments
- Pharmaceutical manufacturers & associations
- Pharmaceutical Stewardship Organizations: PPSWG and ReturnMeds
- Drug Distributors, Reverse Distributors, Waste Service Providers, Disposal Facilities
Chair Wrap-Up & Next Steps
Remaining slides are extras, in case needed
County Pharmaceutical Stewardship Laws Timeline

- **2012**: Alameda sued in Federal court by PhRMA, GPHA, BIO
- **2013**: King sued by PhRMA, GPHA, BIO, CHPA
- **2014**: San Francisco, Santa Clara, Marin
- **2015**: May 2015 - U.S. Supreme Court refuses to review Ninth Circuit ruling in favor of Alameda
- **2016**: Santa Cruz
• Lawsuit slowed but did not halt implementation of King County law.
• Stewardship plans submitted by 2 groups of pharma companies
• June 2016 program start anticipated
Every drug producer whose medicines are sold in or into King County must finance and provide a county-wide secure medicine return system.

- **Provide secure drop boxes** in pharmacies or law enforcement offices. Or periodic collection events or prepaid return mailers.
- **Accept prescription and over-the-counter medicines** from residential sources. Not clinical or business wastes. Cosmetics/personal care products excluded.
- **Promote program**; annual reporting; periodic public awareness surveys.
- **Utilize secure protocols** for collection, handling, transportation of drugs according to federal & state regulations and guidelines.
- **Drugs disposed at hazardous waste facility**. Or approval may be granted for use of a WTE incinerator.

King County provides oversight to ensure compliance and safety.
Status of Stewardship Plans Submitted to King County

King County MED-Project
Medication Education & Disposal

Formed by PPSWG (Pharmaceutical Product Stewardship Work Group)
> 330 Producers

Feb – Initial Plan Submitted for Review
April – REJECTED

June - Revised Plan Submitted
Oct. - REJECTED

Dec. - Re-Revised Plan Submitted
Under Review as Independent Plan
March 16th Accept/Reject Decision

If Rejected – the PPSWG producers must work with Standard Plan & cannot propose an Independent Plan for 6 months.

Subsidiary of Call2Recycle
8 Producers
(trying to recruit more)

Feb – Initial Plan Submitted
April - REJECTED

June - Revised Plan Submitted

June 10, 2016
Start Date for Standard Plan
and Independent Plan
(if approved)
Implementation of Stewardship Laws

- Producers Form/Hire Stewardship Organization
- Stewardship Org. Makes Agreements with Collectors, Transporters, Facilities, etc.
- Producers Submit Detailed Stewardship Plan
- Producers Revise Plan if Not Accepted
- Agency Reviews Plan
- Plan Accepted

- Law Takes Effect
- Program Starts
- Typically 1 Year Deadline