Pharmaceutical Stewardship
Subcommittee Briefing and Discussion

Welcome and Meeting Purpose
Ad Hoc Subcommittee and Staff

Brian Sullivan  Snohomish County Council  
Adrienne Fraley-Monillas  Edmonds City Council  
Kurt Hilt  Lake Stevens City Council  
Patric Slack  Snohomish Regional Drug & Gang Task Force  

Dr. Gary Goldbaum,  Health Officer  
Pete Mayer,  Deputy Director  
Heather Thomas,  Communications & Public Affairs  
Jeff Ketchel,  Environmental Health Director  
Andrea Pelham,  Environmental Health & Safety  

Margaret Shield,  Consultant  
Steve Uberti,  Counsel  

Today’s Agenda

✓ Medicine Take-back Programs  
✓ Pharmaceutical Stewardship Policies  
✓ Proposed Process for Policy Development and Public Comment  
✓ Chair Wrap-up and Next Steps
Medicine Take-Back Programs

A. Goals & Operations of Medicine Take-back Programs

B. Current Medicine Take-back Options

Snohomish County Partnership for Secure Medicine Disposal

Safely Dispose of Unwanted Medicine

Unused medications pose a risk to our families, communities and the environment. Don’t store them, flush them or throw them in the trash. Safely dispose of your unused medications for free at most law enforcement locations in Snohomish County or at participating pharmacies.

See details, locations and hours at www.snoco.org, search "pharmaceuticals" or call 425-388-3199.
Community Health Concerns

Prevent Poisonings and Deaths

#1 cause of unintentional injury deaths in Snohomish County

Common cause of poisonings/ER visits, especially for kids and seniors

Reduce Availability for Misuse

73% of teens say it’s easy to get prescription drugs from parents’ medicine cabinets

Many teens think prescription drugs are safer to use than street drugs

Epidemic of Opioid & Heroin Abuse

_SHD data:_ 91% of people injecting heroin had abused prescription drugs first. Opioids or Amphetamines.

_National data:_ 45% of heroin users are also addicted to prescription opioid painkillers.
National Drug Control Strategy: Prescription Drug Abuse

- Educate health providers and the public
- Expand prescription monitoring programs
- **Provide safe drug disposal – increase return/take-back and disposal programs**
- Focus on enforcement to address “pill mills” and “doctor shopping”

Environmental Health Concerns

- Improper disposal contributes to pollution
- Medicines are dangerous/hazardous waste
- No treatment by septic/wastewater systems
- Trash cans are not secure
- Pharmaceuticals not accepted in solid waste code
About 1/3 of Medicines Sold to Households Go Unused

For many reasons:
- Overprescribing.
- Overpurchasing.
- Patient doesn’t finish.
- "Use As Needed" medicines expire before used.
- Changes in medications.
- Lots of medicines needed during serious illness, and patient recovers.
- Lots of medicines, including strong pain relievers, needed for end-of-life care.

How the Snohomish Partnership Program Works

- Tamper-proof drop boxes at 28 law enforcement sites
- Medicines Accepted: Prescription (controlled & non-controlled) Over-the-counter Vitamins
- Secure storage & tracking of sealed boxes
- Disposal by high temperature incineration
New Opportunities for Take-Back
DEA Rule on Disposal of Controlled Substances, 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 Law Enforcement Drop Boxes as before

**Take-Back Events Run By Law Enforcement**
**Mail-back Programs**

And new options for transporting or shipping medicines to disposal facilities.
Convenient Pharmacies Collect More Medicines
San Francisco Pilot 2012-2015

Pharmacy Take-Back Programs

Bartell Drugs cannot currently accept controlled prescription drugs, but takes all other medicines.

To Accept Controlled Substances, Pharmacies in WA State Must:
- Submit take-back protocol meeting DEA requirements to the WA State Pharmacy Quality Assurance Commission.
- Get authorized by DEA (quick online form).

Secure Collection Receptacle Bolted to Countertop or Floor, Monitored by Pharmacy Staff

Secure Tracking & Storage

Safe Disposal by High Temperature Incineration
Current Medicine Take-back Options in Snohomish County

Law Enforcement Efforts:
- 28 law enforcement drop boxes,
- Twice-a-year DEA Prescription Drug Take-back Days (spring/fall, Saturdays)

Pharmacy Efforts:
- 11 Pharmacy drop boxes
  - 10 Bartell Drugs (no controlleds)
  - Pharm-A-Save in Granite Falls (controlleds?)
- Pay-per-use return mailers at some pharmacies - some accept controlleds.
- Coming in future – Walgreens drop boxes

Current Snohomish Partnership Medicine Take-back Model Not Sustainable

- **Staffing burden** on the Health District and local law enforcement
- **No resources** to spend on program promotion and education
- **No resources** to increase collection sites to pharmacies and hospitals
- **No capacity** to collect more uncaptured drug waste
Pharmaceutical Stewardship Policies

A. Overview of Product Stewardship
B. Summary of County Laws
C. Status of Industry Challenges & Compliance
D. Adapting King Co’s model to Snohomish Co

What is Product Stewardship?

- Minimizing the health, safety, environmental, and social impacts of a product throughout all lifecycle stages
- Producer of the product has the greatest responsibility
- Other stakeholders also have roles, including suppliers, retailers, and consumers.

Also known as Extended Producer Responsibility (EPR)
Extended Producer Responsibility Policies

Producers finance and operate a system for take-back and recycling or disposal of their products, as part of doing business.

- Not a tax
- Not funded through garbage fees/rates
- Not a government-run program

90% epr laws in 33 states
(including carpet, cell phones, agricultural pesticide containers, refrigerants + one “framework” law)

- 7
- 3
- 4
- 9
- 11
- 13
- 15
- 24

*not including 10 container deposit laws
WA Product Stewardship Laws

Electronic Products Recycling (started 2009)
Mercury Lights Recycling (started 2015)

Voluntary Rechargeable Battery Stewardship

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
Overview of King County Board of Health’s Secure Medicine Return Regulation

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.
- 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.

Implementation of Stewardship Laws

1. **Law Takes Effect**
   - Producers Form/Hire Stewardship Organization
2. **Program Starts**
   - Stewardship Org. Makes Agreements with Collectors, Transporters, Facilities, etc.
3. **Plan Accepted**
   - Producers Submit Detailed Stewardship Plan
4. **Agency Reviews Plan**
   - Typically 1 Year Deadline
5. **Plan Not Accepted**
   - Producers Revise Plan if Not Accepted
6. **Plan Accepted**
   - Revise Plan if Not Accepted
7. **Agency Reviews Plan**
   - Typically 1 Year Deadline
8. **Plan Accepted**
   - Program Starts
County Pharmaceutical Stewardship Laws Timeline

- Alameda
- King
- San Francisco
- Santa Clara
- Marin
- Santa Cruz

2012
- Alameda sued in Federal court by PhRMA, GPHA, BIO

2013
- King sued by PhRMA, GPHA, BIO, CHPA

2014
- Alameda
- May 2015 - U.S. Supreme Court refuses to review Ninth Circuit ruling in favor of Alameda

2015
- Alameda

2016

Pharmaceutical Associations Position, Lawsuits & Compliance

- Strongly opposed:
  - Patients should finish all their medicines
  - In-home disposal better = hiding medicines in trash
  - Medicine take-back is not effective or is unworkable, for various reasons
  - Medicine take-back should not be their responsibility

- Associations tried to block all county laws with federal lawsuits against Alameda & King

- Companies are complying, but Associations fighting further legislation

- Associations counterproposal: education campaign about trash disposal
• 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

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)
Discuss Draft Policy Outline

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

Today’s Goal:
– begin policy discussion
– identify policy areas to discuss in more detail at next meeting

Proposed Process for Policy Development & Public Comment
Proposed Policy Development Timeline

<table>
<thead>
<tr>
<th>Month</th>
<th>Activities</th>
</tr>
</thead>
</table>
| 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 | 1st Reading & Public Hearing |
| June | 2nd Reading & Public Hearing |

BOH Ad Hoc Steering Committee Meetings Every 2 weeks

Public Comment Process

Use Pharmaceutical Stewardship Policy Outline as defined by this Ad Hoc Steering Committee to solicit public comment prior to formal BOH readings/hearings:

- Accept comments via online form, email, mail, telephone
- Accept testimony at public meeting (mid-March?)
- Media releases to notify about process
**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**