

Pharmaceuticals from Households: A Return Mechanism (PH:ARM)

A Washington State Pilot Program to Return Medications for Proper Disposal

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Washington State Board of Pharmacy



PH:ARM Team and Affiliates



- **Interagency Resources for Achieving Cooperation (IRAC)**
- **Washington State Department of Ecology**
- **Local Hazardous Waste Management Program in King County**
- **Washington Citizens for Resource Conservation**
- **Washington State Board of Pharmacy**
- **Northwest Product Stewardship Council**
- **Snohomish County Solid Waste Management Division**
- **Public Health – Seattle & King County**
- **Bartell Drugs**
- **Group Health Cooperative**
- **Pacific NW Pollution Prevention Resource Center (PPRC)**
- **DSHS, Aging and Disabilities Services**
- PS Industries
- Puget Sound Action Team
- Snohomish County Health Department
- Thurston County Department of Health and Environmental Services
- Kitsap County Health District
- Tacoma-Pierce County Health Department
- City of Tacoma Waste Water Management
- City of Seattle, Seattle Public Utilities
- Spokane Regional Solid Waste System (Waste to Energy Facility), Spokane, WA
- Environmental Protection Agency, Region X
- Washington Toxics Coalition
- Kitsap County School District
- Office of the Attorney, Agriculture and Health Division
- Washington Poison Control
- State Medical Association
- King County Board of Health
- State Medical Association
- Office of Financial Management, Governors Sustainability Office
- President of WA State Senior Citizens Lobby
- Residents Councils of Washington
- Executive Director of the Washington Association of Sheriffs and Police Chiefs
- Tacoma Fire Department
- Boarding Home Advisory Council
- People for Puget Sound
- City of Seattle, Office of Sustainability
- Seattle Chief of Police
- Washington State Pharmacists Association
- Washington State Nurses Association
- Residential Care Survey
- King County Industrial Pretreatment
- Mercer Island Police Department
- University of Washington



What are PH:ARM's Goals?

- Reduce the likelihood of excess or unused pharmaceuticals being:
 - Improperly disposed and negatively impacting the environment
 - Available for intentional/unintentional misuse
 - Available for accidental poisoning
- Serve all residents of Washington
- Create a model for other states
- Prevent waste in the first place
- Keep material out of the environment

Meeting the Public's Needs



- Shouldn't be any harder to dispose of medications than it is to purchase them
- Public comfort with solution is key
- January 2006 SoundStats Survey showed that:
 - *74% of respondents said that they would be willing or very willing to return medications to a pharmacy.*
 - *84% of respondents indicate a local pharmacy would be the most convenient location to dispose of unused or expired medicines.*
 - *4% said they would be willing to use sheriff or police office, 5% said special collection event, 2% said public hazardous waste facility.*

Basic Tenets of PH:ARM



- Secure system (secure collection, transport, destruction)
- Low-cost and financially sustainable
- Effective (volume recovered)
 - Accessible & user friendly
 - Ongoing
- Government is regulating and overseeing but not funding the program

Programs Addressing the Need for Medication Disposal

- Australia
- British Columbia
- Prince Edward Island
- Sweden
- Ottawa
- 11 European Union nations

- Northeast USA (incl. Maine)
- Florida
- Indiana
- California



Types of Existing Drug Return Programs

- Segregated collection at hazardous waste facilities
- Short-term drop off events
- Law enforcement-staffed collection events
- Hybrids
- Regularly available, ongoing, inclusive programs



Ongoing, national, government-financed* program: **Australia**

**Return unwanted
medicines to
your pharmacy**



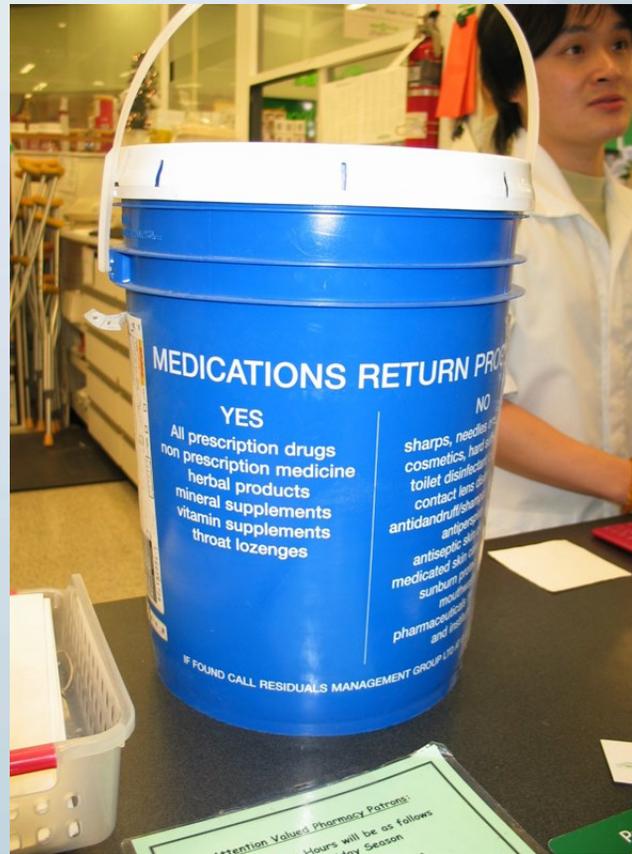
- Ongoing, permanent program since 1998
- Uses wholesaler for delivery of new container with liner and pick-up of old container
- Container behind pharmacist counter
- Schedule 8 (C.S) drugs are 'destroyed' through chemical mixing onsite and then placed in the container
- Wholesaler does not open container
- At incineration site, bucket is opened and liner is emptied into incinerator, bucket is cleaned and reused
- *Wholesaler discounts delivery and collection, government pays for disposal and advertising
- **Collected 696,241 lbs in 2005**
- **US \$737,000** million a year in costs
- Serves 21 million people

Ongoing, provincial, industry-financed program: **British Columbia**

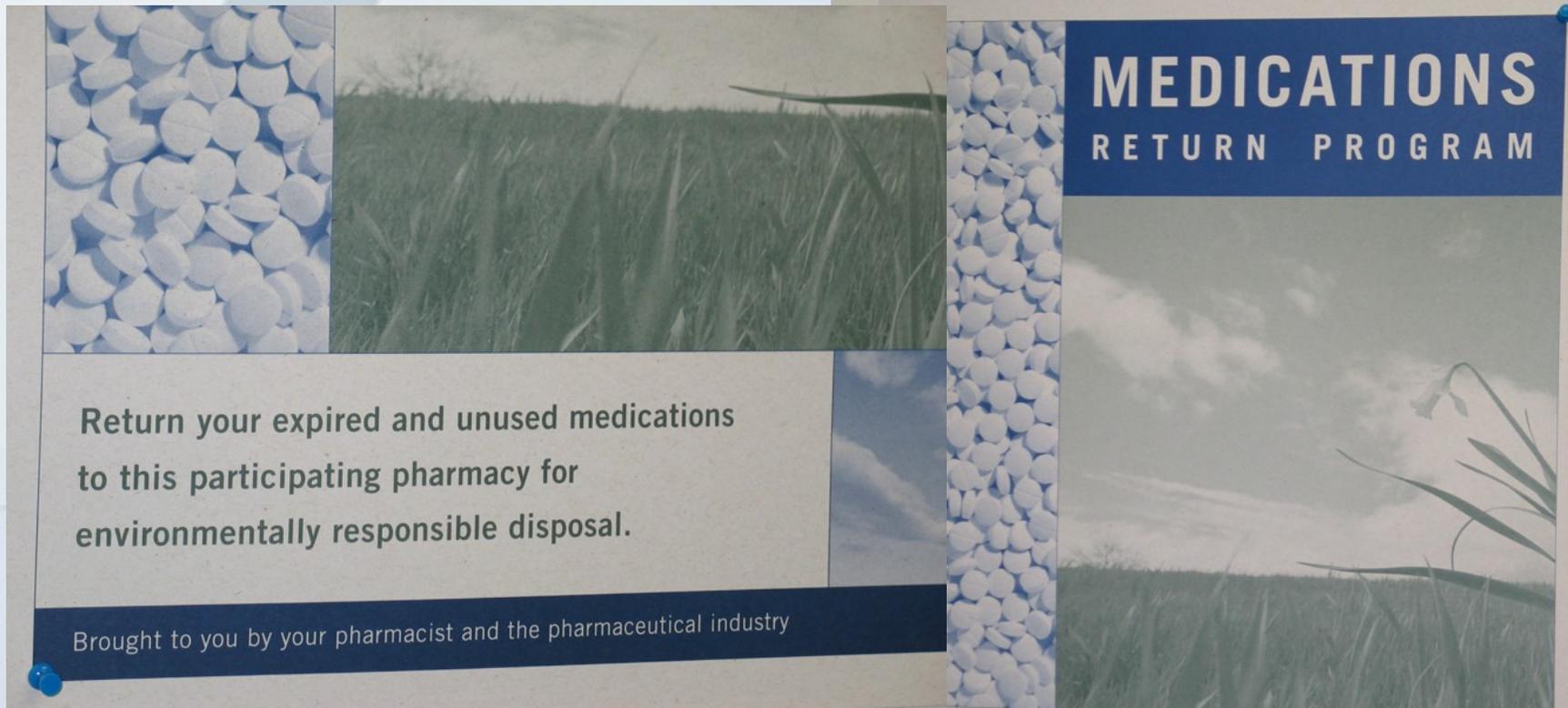
- Ongoing, permanent program since 1996
- Administrated by the Residuals Management Group Ltd., with funding by the Post Consumer Pharmaceutical Stewardship Association (industry association)
- User friendliness for pharmacy is key to their participation
 - Pick-up schedule easy and on-demand
 - Tracking through shipping labels
 - Transportation of unwanted medications was essential issue, largest cost
 - 90% participation rate from pharmacies
- Urban and rural pharmacies are participating
- Container is very inexpensive and practical
- Collected ~2,000 5-gal buckets, **totaling 52,800 lbs in 2004**
- Total cost is US **\$170,500** per year
- Serves 4 million people



British Columbia Program



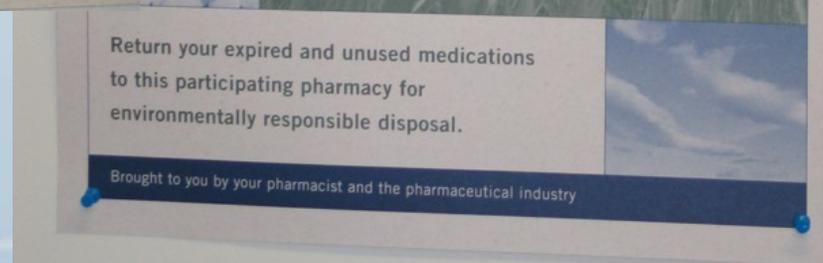
British Columbia Program

A flyer for the Medications Return Program. The top right corner features a dark blue banner with the text "MEDICATIONS RETURN PROGRAM" in white, bold, sans-serif font. The background is a collage of images: a close-up of white, round pills on the left, a field of tall green grass in the center, and a blue sky with white clouds on the right. A dark blue banner at the bottom contains the text "Brought to you by your pharmacist and the pharmaceutical industry" in white. The flyer is pinned to a light-colored surface with blue pushpins.

**MEDICATIONS
RETURN PROGRAM**

Return your expired and unused medications
to this participating pharmacy for
environmentally responsible disposal.

Brought to you by your pharmacist and the pharmaceutical industry

A smaller version of the Medications Return Program flyer, showing the same layout and text as the larger one above. It features the same collage of images and text, pinned to a light-colored surface with blue pushpins.

Return your expired and unused medications
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Hybrid Program

Clark County, WA



- Clark County is an ongoing, but segregated program
- Non-controlled substances go to pharmacies – not tracked
- Controlled Substances go to one sheriff's office
 - heat sealed in plastic bag
 - placed in locked container
 - sheriff's property officers pick up sealed bags
 - bags are open and items logged in by chemical name, dose and quantity
 - **sheriff's property officer picks up sealed bags**
 - incinerated

Comparison of Programs

	Clark County	Australia	British Columbia	Washington (Proposed)
Total		501,000 lbs (2005) 413 million pills	52,800 lbs (2004) 43 million pills	91,000 lbs, no packaging, w/ nursing homes 74 million pills
Noncontrolled	?	501,000 lbs (2005) 413 million pills	52,800 lbs (2004) 43 million pills	76,500 lbs 62 million pills 6,600 lbs from nursing homes 5.4 million pills from nursing homes
Controlled	19 lbs (2005) 15,367 pills	Included (‘schedule 8’ is destroyed before put in container)	Included	7,300 lbs 6 million pills 634 lbs from nursing homes 523,000 pills from nursing homes
Packaging	?	195,000 lbs (Included)	Not collected	35,000 lbs
Cost	Absorbed through public program & pharmacies	\$ 737,000 / year (government costs only) \$1.47 per lbs	\$170,500/ year \$3.25 per lbs	\$400,000? \$4.40 per lbs
Sites	47 pharmacies and one sheriff’s office	5,000 pharmacies	802 pharmacies	1,068 pharmacies, 900 nursing homes, etc.

Anticipated Outcomes - of the PH:ARM Approach



- Our statewide program could collect **83,000 lbs per year for proper disposal** plus **7,200 lbs from nursing homes**
 - *Data from British Columbia and Washington waste surveys*
- Decrease diversion of **7,900 lbs of controlled substances** from unsecured household cabinets, garbage cans, and sewer in Washington
- Potential service at **3,879 locations**: 1,068 pharmacies, 900 nursing homes, 1,361 small animal clinics, & 550 boarding homes

Removing Controlled Substances from Harm's Way

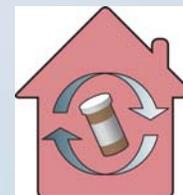


What could be expected from Washington's population?

285 lbs. - Using Return to Law Enforcement or Events with Law Enforcement Present (NE and Clark County)

(or)

7,300 lbs. – Using Return to Pharmacy like B.C. and Australia



PH:ARM Pilot

- Beginning in 2006, for approximately two years.
- Pilot three types of locations:
 - Retail Drug Pharmacies
 - Institutional Health Clinics
 - Nursing homes



PH:ARM Pilot – Pilot locations:

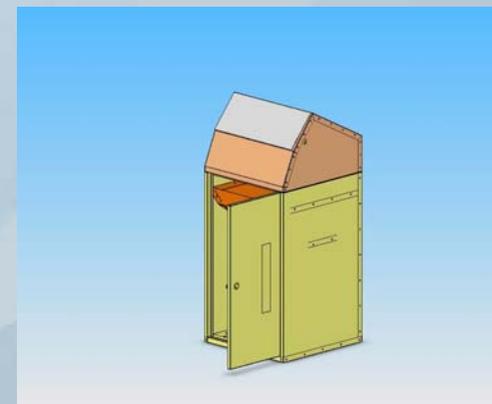
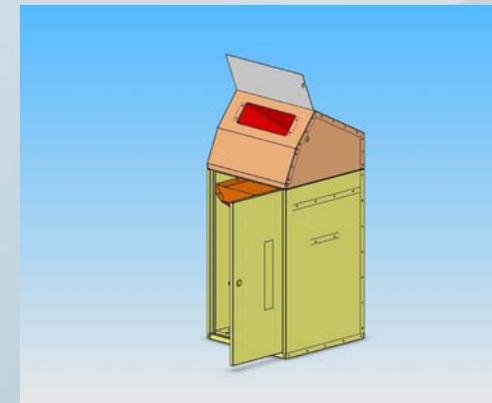
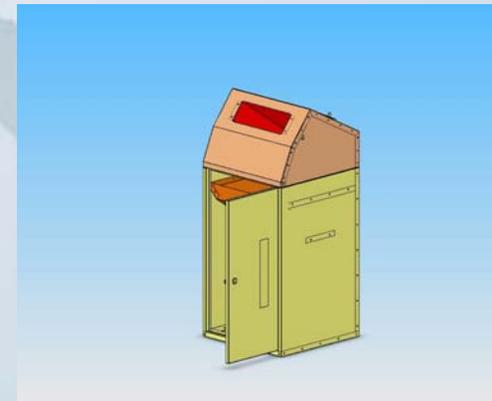
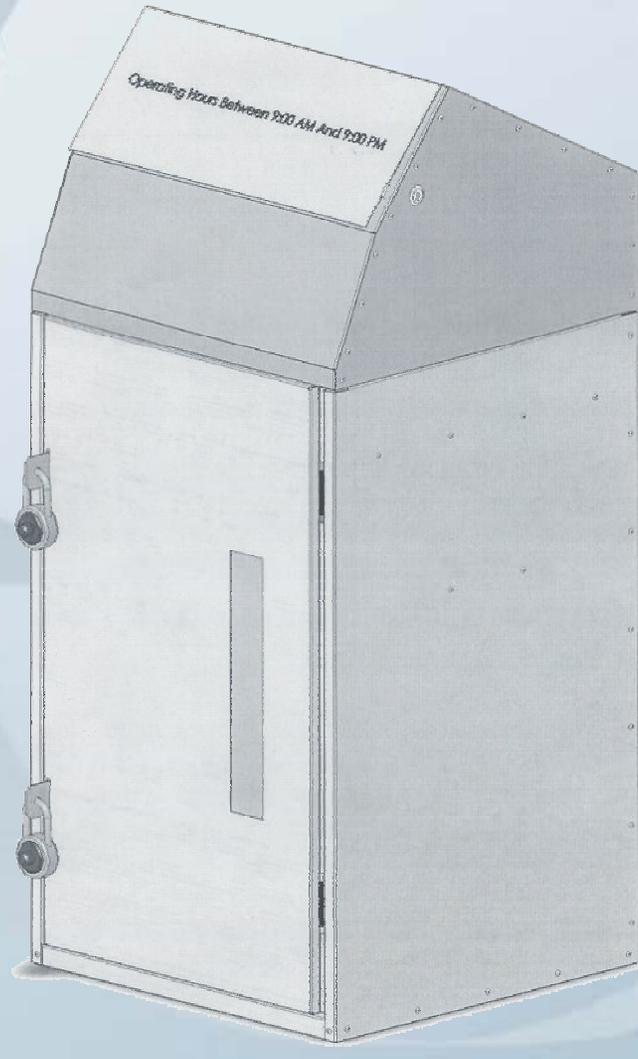
- 54 Bartell Drug chain Pharmacies
- 24 Group Health Clinic Pharmacies
- Approx 12 Nursing homes.



PH:ARM Pilot Models: Collection

- Behind the Counter and In-Front of Counter
- Self Serve or Pharmacist Receives Medications
 - Self serve metal security drop-box
 - \$650 each plus bucket cost
 - Heavy plastic security toter
 - \$180 each plus bag costs
 - B.C. bucket system behind counter
 - \$5 each

Steel Drop Box Design: dVault



Actual Metal Drop Box



Secure Plastic Toter



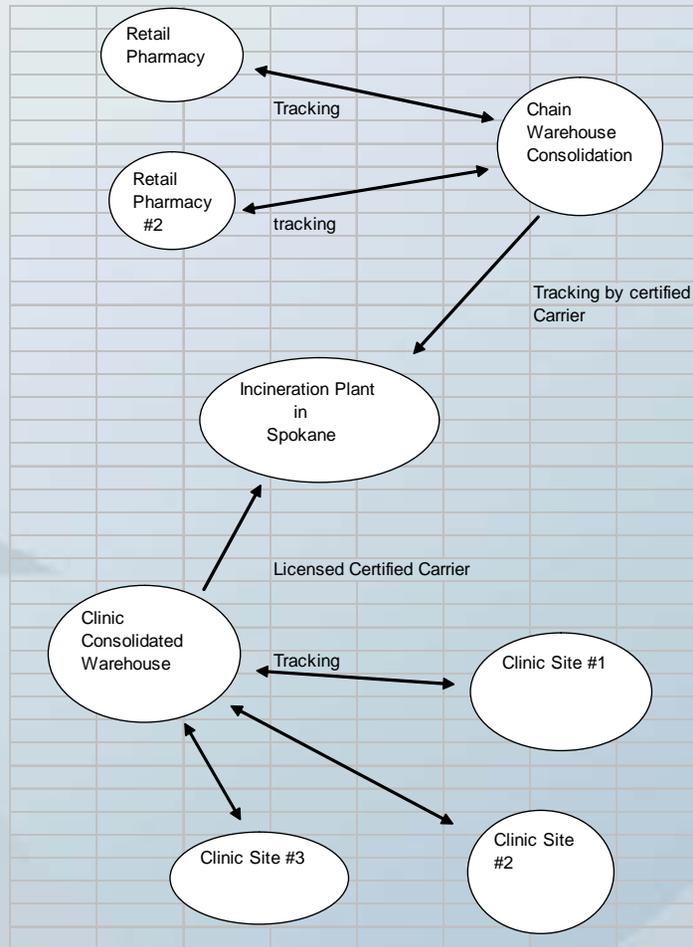
B.C. Bucket





PH:ARM Pilot: Transport

- Pharmaceutical bucket or bag sealed with security tape and double witness
- Each bucket or bag is tracked
- Reverse delivery back to warehouse for secure consolidation and storage using same staff and security that delivers pharmaceuticals to pharmacy
- Pharmaceuticals in bags maybe consolidated into fiber drums (depending on container type) in locked cage





PH:ARM Pilot: Destruction

- Consolidated Pharmaceuticals picked up and delivered to incinerator for witnessed destruction
- For pilot, Board of Pharmacy is providing investigator to accompany licensed reverse distributor for transport from consolidation to incinerator

Long Term Roles in the PH:ARM Program



“Shared responsibility for a secure program”

- **Government:** oversight and education
- **Pharmacies:** provide take-back infrastructure
- **Consumers:** change disposal practices and bring back medications
- **Distributors:** transport material for consolidation
- **Pharmaceutical industry:** future financing
- **Nursing homes and others:** provide take-back infrastructure and handling on behalf of residents

What Does the Board of Pharmacy Want?



- **Safe collection, transport & disposal**
 - Eliminates / reduces material diversion into the community
 - Promotes less abuse of available material
 - Assures the incineration / destruction of the material
- **Environmentally-sound**
- **Convenient**
 - For patients, customers, & healthcare professionals
- **Uses private funding**
- **Regulated**
 - Maintains high level of State over-site and control
- **Efficient**
 - Promotes a cost efficient and effective collection system

What STATES Need To Move Forward:



- Licensed approach:
 - State regulatory boards of pharmacies (or other pertinent law-enforcement and/or State agencies) can oversee program
- Enabling regulations:
 - A legal way to collect all medications utilizing one common system
 - AVOID conflicting regulations
- Alternatives to item pill inventory requirement and paperwork – When a secure collection system is utilized
 - Approximately **6.5 million controlled substance pills per year** are expected to be collected in Washington (how much waste generated is unknown)

What are the Regulatory Allowances Needed?



- Allow states to set up secure collection systems
- Allow end-users (non-DEA registrants) to return controlled substances to approved, state-licensed, and regulated programs
- Allow state-licensed and approved programs to collect controlled substances from end users (non-Registrants)

Regulatory Allowances Cont.



- Permit the collection of all C.S. classes with other legend drugs
- Do NOT require the item inventorying of material (utilizing a “secure Collection” system)
- Allow existing Wholesaler-Distributors to participate in the consolidation logistics of programs

Regulatory Allowances Needed



- Permit the participation of Reverse Distributors in these programs.
- Allow that documented waste disposal at Nursing Homes, Boarding Homes, or other Family Care Homes, into “Secure Collection” systems, would be then considered “destroyed”
- Continued encouragement for automated unit dose systems to minimize waste

Future Rule Coordination



- Coordinate with Medicare and Medicaid the use of automated dispensing devices for unit dose dispensing
- Coordinate with US EPA rule changes that allow the use Reverse Distributors in the take back of Household Pharmaceutical waste utilizing “secure collection” take-back systems
- Coordinate RCRA rules with DEA

Program Monitoring & Quality Assurance



- Program and personnel back ground checks and monitoring
- Requirements for complete material tracking
- Program audits
- Disciplinary Action
 - Personnel
 - Programs

DEA Regs: The 'Exception' Approach



- We do NOT want to change the basic character of the existing Federal Rules
- Want to allow an exception for a State Licensed and supervised program to operate Pharmaceutical take-back programs – utilizing “SECURE COLLECTION” SYSTEMS

Outcomes of the PH:ARM Approach



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- Decrease diversion of **7,900 lbs of controlled substances** from unsecured household cabinets, garbage cans, and sewer in Washington
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Why the Time is Ripe



- Diversity of government agencies and departments are increasingly concerned about this issue and seeking solutions
- Public is concerned about water and health
- Funding organizations offering grants

PH:ARM Works Within Bounds of Existing System



- PH:ARM can offer a practical solution to complicated issue
- Pharmacists want to offer solution
- Governments want to offer solution
- Opportunity for DEA to address diversion concerns and public concern by piggy-backing on a broadly supported program
- Utilize what is learned to propose model program legislation.

PH:ARM Support needed:



- Funding for a 2nd generation of secure container(s).
- Funding for secure container tracking.
 - Bar Coding
 - RFID
 - Other(must be easy, fairly inexpensive, sustainable)

Contact



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- **Northwest Product Stewardship Council and Pharmaceutical Project**
<http://www.productstewardship.net/>
- **Product Stewardship Institute Pharmaceutical Project**
<http://www.productstewardship.us/>
- **Washington Citizens for Resource Conservation**
<http://www.wastenotwashington.org>