

# Oregon Pharmaceutical Product Stewardship Program Outline for Legislation

**D R A F T - 7/31/08**

## **Program Goals**

Work collaboratively with the pharmaceutical producers that serve Oregon to institute a take back program for unused and unwanted pharmaceuticals, based on a product stewardship model. The program must be easy to understand and convenient to all Oregonians, serve consumers including households, residents of long-term care facilities and persons enrolled in hospice, palliative care and home health programs. The program should be provided at no additional collection or disposal cost to those participating.

## **Section A - Program Outline**

1. Requires a pharmaceutical take back program be instituted by those companies that sell pharmaceuticals in Oregon (patented, generic, over-the-counter).
2. Pharmaceutical producers that serve Oregon must prepare a plan for collecting unwanted and unused medications by July 1, 2010 (12 months after the legislation passes).
3. Pharmaceutical producers must operate the program by July 1, 2011.
4. Each producer can institute their own take back program or can collaborate with other producers to institute a program.
5. Program will:
  - 5.1. Collect unwanted controlled and uncontrolled drugs from consumers, including households, residents of long-term care facilities and persons enrolled in hospice, palliative care, and home health programs.
  - 5.2. Take all pharmaceutical products sold in Oregon regardless of producer.
  - 5.3. Be designed to be as convenient as possible for the public. It should not be designed around one-day or even routine collection events.
  - 5.4. Be provided at no additional collection or disposal cost to consumers, long term care facilities, or hospice and home health care providers.
  - 5.5. Serve urban and rural Oregon.
  - 5.6. Not add additional duties to the routine responsibilities of Oregon's law enforcement agencies.
  - 5.7. Incorporate a strong public education program to inform Oregonians of the benefits of proper disposal of unwanted and unused pharmaceuticals.
  - 5.8. Collect unwanted and unused pharmaceuticals for proper destruction of the collected medicines by incineration or hazardous waste disposal. Solid waste landfilling of collected pharmaceuticals is not an acceptable long-term option.
6. The program plan will be submitted to the Oregon Public Health Division Director for evaluation and approval.
  - 6.1. Plan will include:
    - 6.1.1. Public education and outreach
      - 6.1.1.1. The education and outreach program shall focus on consumers and patients and shall include at a minimum, outreach to retail pharmacies,

- doctor's offices, county health departments, hospitals, hospice care providers, and long term care providers.
- 6.1.2. Evaluation and improvement.
  - 6.1.3. Recovery rate, date for achieving that rate, and action plan if the rate is not met.
  - 6.1.4. Proposed destruction method for collected drugs
    - 6.1.4.1. The proposed destruction method will be forwarded to the Oregon Department of Environmental Quality for review and approval.
  - 6.1.5. How plans will coordinate if there is more than one to minimize consumer confusion.
  - 6.2. Annual reports to the Oregon Legislature and the Oregon Human Services Director on the program accomplishments and areas for improvement planned for the next year including pounds of pharmaceuticals collected will be required starting June 30, 2012.
  - 6.3. If the plan does not meet the criteria, the plan would be returned for revisions and resubmitted for approval within 60 days or less.
  - 6.4. After July 1, 2011, all pharmaceutical producers that serve Oregon shall have an approved plan.
    - 6.4.1. If there is no a legal method to return both controlled and uncontrolled drugs, affected manufacturers can apply to the Oregon Public Health Division for a time extension for submitting an approved plan. The time extension request should be for one year or less. The request should be made in writing to the Oregon Public Health Division Director.
  - 6.5. All retail pharmacy outlets are required to post a sign, developed by the Public Health Division and posted on the Internet, which discusses how pharmaceuticals can be safely returned. At a minimum, the sign shall be posted at the pharmacy counter.
  - 6.6. The Oregon Public Health Division will appoint a diverse advisory committee of 11 members serving 3 year terms to provide advice to the Public Health Division on the Oregon Drug Take Back program. The Advisory Committee will meet four times annually.

### **Section B - Funding**

1. All the costs of the state to oversee the program will be paid by the manufacturers by a fee added to the existing Board of Pharmacy fees.
  - 1.1. Board of Pharmacy will collect the dollars and forward the collected dollars to the Oregon Public Health Division exclusively for the Oregon Pharmaceuticals take back program implementation costs.
  - 1.2. Board of Pharmacy can retain a percentage of the collected fees to cover their billing and collection costs.
2. One full time position will be funded within the Oregon Public Health Division to oversee the program. The position will be funded by a surcharge on the Board of Pharmacy manufacturer fees.
  - 2.1. Funding for this position will be effective July 1, 2009.
3. The bill declares an emergency and is in effect immediately.

**Section C – Enforcement – additional details to be added when bill is drafted**

1. After July 1, 2011, appropriate enforcement mechanisms will be initiated against manufacturers without an approved plan and those not implementing their approved plan.
2. If the program is not being operated in accordance with the plan approved by Oregon Public Health Division, the agency may suspend or cancel approval of plan.
  - a. The appropriate procedures of the Oregon Administrative Procedures Act will be followed.

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