Areas of Key Policy Development

• **U.S. Drug Enforcement Administration regulations**
  – By default, require law enforcement to be present when certain prescription drugs are collected (under Controlled Substances Act)

• “**Producer responsibility**” for pharmaceuticals

• **A Vision for the Great Lakes**
Secure and Responsible Drug Disposal Act 2010

What the law **does** do
- DEA to develop regulations for take-back of CS (besides law enforcement officer)
  - Variety of methods of collection
  - Ease of program cost/implementation
- Authorize long-term care facilities to dispose of CS for patients

What the law **does not** do
- Create take-back programs
- Fund take-back programs

Awaiting draft regulations – **fall 2012?**
- DEA public hearing in January 2011
- Convenience, collecting all drugs together, cost (pharmacies)
Extended Producer Responsibility (EPR):

- Mandatory

- Requires product producer to be responsible post-consumer management of products and packaging.
  
  - Shifts financial and management responsibility, with government oversight, upstream to the producer and away from the public sector
  
  - Providing incentives to producers to incorporate environmental considerations into the design of products and packaging
U.S. State EPR legislation for pharmaceuticals (2009 - 2012)

Source: Product Stewardship Institute, Inc. (2011)
Even Congress is getting in on the action

- **Pharmaceutical Stewardship Act (HR 2939)**
  - Introduced by Congresswoman Louise Slaughter (D-NY)
  - EPR; draws on convenience standards, other elements from WA legislation
  - Statement of need/attention; not a reason to slow actions at local, state level
Local level ordinances

- Alameda County (CA) ordinance – awaiting 2\textsuperscript{nd} vote (July)

- San Francisco (CA) ordinance – passed once; now pilot program
Endorsements

• 31 Organizations/agencies endorsing to date

Key Elements of Pharmaceutical Collection and Disposal Programs:
A Vision for the Great Lakes Region

Significant progress has been made to establish safe and secure medicine collection and disposal programs in the Great Lakes Region. These programs include collections through retail pharmacies, clinics, law enforcement agencies, and municipal facilities, as well as through mail-back programs. Due primarily to funding constraints, programs are unable to fully meet the needs of residents throughout the region. The following key elements of a model program were developed by local and state agencies, organizations, and other stakeholders, with the goal to expand effective pharmaceutical collection and disposal programs throughout the region.

• Programs should protect public health and the environment by maximizing prompt collection and proper disposal of unused pharmaceuticals, including controlled substances. To this end, programs should be:
  • Ongoing. Residents should have year-round access to safe disposal opportunities for pharmaceutical drugs, reducing the need for home storage.
  • Convenient throughout the Great Lakes region. Programs should be available to all residents throughout the Great Lakes region. Eventually, there should be ongoing collection sites in every county, and every town or city of a population of 5,000 or greater. Mail-in services can help to fill gaps.
  • Set up to collect all types of pharmaceutical drugs. To the extent feasible under state and federal regulations, programs should accept all types of pharmaceuticals from households.
  • Secure. All programs must be operated in a secure manner, and in compliance with all state and federal regulations. Security is critical to minimizing the risk of illegal diversion.
  • Free at the point of delivery for disposal. There should be no charge to the public when they deliver unwanted pharmaceutical drugs via a collection location or mail-in service.
  • Widely promoted. A high level of public awareness must be created about the importance of safely storing and promptly disposing unused medications through the program. Public education should be a shared responsibility of all key stakeholders including those who prescribe, dispense, and manufacture pharmaceuticals.

• Programs should minimize the impact on the environment by ensuring that collected medicines are destroyed in compliance with federal, state, and local regulations. When possible, all material collected should be destroyed through high temperature incineration, or with the best available technology, to minimize the risk of environmental contamination. To the extent possible, transportation of wastes should be minimized.

• Programs should be sustainably and adequately funded to ensure continued service and widespread public outreach. Those who benefit from the manufacture, sale, and use of pharmaceutical drugs have the greatest responsibility for ensuring program success. Pharmaceutical companies should fund the expansion of existing programs and/or the development of new ones. Other stakeholders, including state and local governments, pharmacies, and prescribers should partner with pharmaceutical companies to educate the public, provide collection services, and/or implement other activities consistent with their capabilities and mission.

• Programs should also identify and address the underlying drivers that contribute to pharmaceutical waste. Reducing the quantity of drugs that become waste not only reduces environmental and public health risks, it also has the potential to improve medical care and reduce medical costs for individuals and taxpayers through Medicare and Medicaid programs. It may also reduce costs for manufacturers, distributors and retail establishments.