Pharmaceutical-Related Legislation Passed or Proposed

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Legislation, Regulation, Enforcement, and Guidance Documents

All play different roles in changing behavior

RCRA (Resource Conservation & Recovery Act):

Legislation established the legal basis for the definition and management of solid waste and hazardous waste

Regulation defined the specific categories of hazardous waste and management requirements

Enforcement ensures that the regulations are followed by the regulated community
Legislation: Enabling vs Enforcement

Legislation can enable best practices to occur

Amendment to the CSA

Minnesota legislation enabling additional parties to have possession of prescription drugs for the purpose of disposal

Legislation can also break new ground

Illinois law prohibiting drain disposal of solid dosage forms of drugs

Enforcement can provide a strong argument for compliance
Rx Waste: Businesses vs Consumers

Businesses (hospital, clinics, surgery center, etc.):
- Already regulated under RCRA
- Enforcement highly variable depending on EPA region and state
- Early Leaders: MN, FL, EPA Regions 1 and 2

Consumers:
- Not regulated
- EPA and TCEQ exempt consumer-generated Rx hazardous waste from regulation
- Lack of DEA regulation forms a barrier

Long term care facilities, other residential treatment centers: business or household?

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Legislation/Regulation/Guidance/Enforcement Affecting Healthcare Businesses

Water Quality Investment Act
Water Protection & Reinvestment Act
Potential regulation of pharms in drinking water
2010 Effluent Guidelines
Addition of hazardous pharmaceutical waste to the Universal Waste Rule
Increased state and EPA enforcement of RCRA
Current Water Protection Legislative Initiatives

Water Quality Investment Act of 2009 (Oberstar) HR 1262

Task Force on proper disposal of Unused Pharmaceuticals
“(B) provide for limiting the disposal of unused pharmaceuticals through treatment works in accordance with the Federal Water Pollution Control Act”
http://thomas.loc.gov/cgi-bin/query/F?c111:4::/temp/~c111DxK77b:e63062:

Water Protection and Reinvestment Act of 2009 (Blumenauer) HR 3202

(1) an excise tax on the sale of containers of water-based beverages, water disposal products, and pharmaceutical products
(3) take back and dispose of prescription and over-the-counter drugs in an environmentally sound manner
http://www.govtrack.us/congress/bill.xpd?bill=h111-3202&tab=summary
EPA May Regulate Pharms in Drinking Water

104 chemicals being considered for possible regulation under the Safe Drinking Water Act
Pharmaceuticals considered for the first time
Several estrogens included:
estradiol, estrone, ethinyl estradiol, mestranol
Also erythromycin (antibiotic) & nitroglycerin (cardiac)
Collection and evaluation will take years (2013) but could result in drinking water standards for drugs

http://www.pharmecology.com/pedd/jsp/static/a6_news_alert.jsp
EPA Solicited Comments: Preliminary 2010 Effluent Guidelines Program Plan

Presented summary of current efforts since 2008 to solicit information regarding drug disposal, primarily within the healthcare sector

Offered opportunity to provide a variety of input comments on page 68614, section B.

Comment period closed February 26, 2010

Access at

“EPA estimates that it has gathered sufficient data from its site visits and outreach to **begin the development of best practices for unused pharmaceutical management at health care facilities.** During the next year EPA will continue to work with a variety of stakeholders in the development of these best practices and the means for their dissemination and adoption. EPA expects to have a draft of the development of these best practices for the final 2010 Plan.”

EPA Region 1, Janet Bowen, Hospital Email, Sept. 3, 2009
State of Illinois Bans Drain Disposal of Drugs

Safe Pharmaceutical Disposal Act, Aug. 10, 2009
Prohibits the disposal of solid dosage forms into wastewater systems by any healthcare provider, including hospitals, long term care, hospice, and home health organization
IVs are excluded; no mention of oral liquids
Provides for an exclusion for Schedule II drugs for long term care facilities
Took effect January 1, 2010
http://www.pharmecology.com/pedd/jsp/static/a6_news_20090826.jsp
NY Fines Send Shock Waves

New York Office of Attorney General cites 2 hospitals, 3 nursing homes for inappropriate disposal of drugs. Including flushing and hazardous waste violations

More inspections on the horizon

Precedent-setting action draws national attention to pharmaceutical waste management practices

EPA Proposal to Add Pharmaceuticals to Universal Waste Rule

Federal Register publication Dec 2, 2008 – Comments were due March 4, 2009

Information:
http://www.epa.gov/epawaste/hazard/wastetypes/universal/pharm.htm

Proposed UWR only applies to drug waste that meets the definition of RCRA hazardous waste

Only intended for healthcare-type generators, not manufacturers

Intent to streamline pharmaceutical waste management and encourage consumer take-back programs

Estimated Summer, 2011 for federal enactment; states may or may not adopt
RCRA and Universal Waste

“Universal Waste” is a subset of RCRA hazardous waste.

Federal RCRA Hazardous Waste (includes some pharmaceuticals)

Federal EPA: Batteries, Pesticides, Mercury-containing devices, Lamps (bulbs)

FL, MI: RCRA Pharmaceuticals

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Impact of Universal Waste Regulations

Applies ONLY to 4% of drugs in the marketplace that are RCRA hazardous waste… does not address other 96% of drugs.

Brings attention to the industry regarding the proper disposal of pharmaceutical waste.
Specific Benefits of Adding Pharmaceuticals to UWR

Hazardous pharmaceutical waste would no longer contribute to the generator size.

Storage time limits would increase to one year total, allowing more time in storage accumulation area.
Economic Impact

Suggested practice of managing all Rx waste as universal waste

Fee differential as large as 5x to 10x between medical incineration and RCRA hazardous waste incinerator

RMW: $.19/lb - $.50/lb
RCRA: $.95/lb - $4.95/lb
FDA Guidance:

Options include rendering non-recoverable and disposing in kitty litter
Controversial “flush list” for highly toxic controlled substances

Pending Legislation to Amend the Controlled Substances Act

Safe Drug Disposal Act of 2009

Introduced into the House on February 25, 2009: HR 1191
Introduced into the Senate on June 24, 2009: S 1336

To amend the Controlled Substances Act to provide for the disposal of controlled substances by ultimate users and care takers through State take-back disposal programs

To amend the Federal Food, Drug and Cosmetic Act to prohibit recommendations on drug labels for the disposal by flushing

Secure & Responsible Drug Disposal Act of 2009

Introduced into the House on March 5, 2009: HR 1359
Introduced into the Senate on June 18, 2009: S. 1292

To amend the Controlled Substances Act to direct DEA to issue federal rules governing consumer take-back programs

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Minnesota Bill Passed to Broaden Legal Possession of Non-DEA Rx Drugs for Disposal

HF 1217 – passed House and Senate April 2010

A bill for an act

1.2 relating to health; expanding categories of persons allowed to possess legend and nonprescription drugs to include those disposing of them

Enables counties and their designees to be in possession of legend and OTC drugs for the purpose of disposal

Must still comply with DEA regulations
State of New York

Don’t Flush Your Drugs Campaign
August 8, 2008: http://www.dec.ny.gov/chemical/
October 20 -24, 2009: Numerous pharm waste collection events around the state

An Act to amend the environmental conservation law, in relation to the management and disposal of drugs
Became law September 25th, 2008
Requires public information, displayed in every pharmacy

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Summary: Healthcare Facilities

Regulations already exist requiring proper identification, segregation and disposal of RCRA hazardous pharmaceutical waste.

Enforcement has not been consistent at the state or EPA regional level.

Decision needed regarding long term care and other residential treatment facilities (business or household).

Guidance in process on disposal of non-RCRA drug waste.
Summary: Consumer Take-back Scenarios

Continue to be hampered by DEA regulations
Need amendment of Controlled Substances Act
Some confusion in recent press releases regarding ability to include controlled substances
Need to work with State Board of Pharmacy, others, to insure that state enables possession of “legend” drugs (Rx only) by relatives, waste vendors, and other involved parties.
Need consistent funding – Product Stewardship Legislation?

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Proposed Product Stewardship Bills

Florida: HR 1357, SB 2650 (previous session)
Maine: HP0557, LD 821 – passed House, died in Senate 3/26/10
Maryland: HB 648 – unfavorable report, 3/22/10
Minnesota: HF 1217, SF 1568 – heavily modified
Oregon: SB 598 (previous session)
Washington State: SHB 1165, SB 5279 re-introduced 3/15/10

None have passed to date – only a matter of time
What’s Needed: Product Stewardship Model Language

States are clearly adopting language from each other
Washington State, Maine, Minnesota very influential

Suggested Action Item:
- Draft model language that retains much of the acceptable common elements
- Involve industry in dialog
- Move the discussion to federal legislation with some state flexibility

Use federal act to move hazardous pharmaceuticals into Universal Waste Rule (UWR) in tandem with EPA

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Questions?

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Alternative Methods of Disposal or Management of Unused Pharmaceuticals – Healthcare Industry

TCEQ
April 22, 2010
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Differentiating Between Products and Waste

Expired products often eligible for credit through reverse distribution

Virtually 100% of hospitals and most retail pharmacies use reverse distributors for outdated drugs

Samples and items purchased on a “no return” basis not eligible (most flu vax)

Not available to clinics, surgery centers, long term care facilities, dental offices, veterinary practices

Do not use the same wholesale drug network, volumes too low to
Expired Drugs Eligible for Reverse Distribution

Expired drugs in manufacturers’ original packages
May be eligible for credit, managed as “products,” not waste
Sent through a reverse distributor
Licensed by state board of pharmacy
DEA registrant
Large quantity hazardous waste generator (not TSDF)
Complete inventory returned to pharmacy
Process Overview

Rx Industry Distribution and Reverse Distribution Model

Manufacturers

Reverse Distributors

Wholesalers

Creditable Product

Direct accounts only

Wholesaler returns

Debit memo information

Pharmacy Returns

Reporting

Waste

Incinerators

Retail/Institutional Pharmacies, LTC, Other indirect customer, etc.
When is an Outdated Drug a Waste?

At the time and place the decision is made to discard it

Two EPA guidance letters to the industry:
- Merck & Co., 1981
- BFI Pharmaceutical, 1991

Enables shipping of potentially creditable outdates to a reverse distributor as product

PROHIBITS the shipping of waste-like items, such as unused IVs, partial vials, expired repacks, samples

Hospital is liable for using due diligence in selecting a vendor
Non-returnable Waste

Returnable Expired Product
Where is Pharmaceutical Waste Generated in a Hospital?

Pharmacy/Satellites
Patient Care Units
ER/OR
ICU/CCU/NICU
Oncology/Hematology, Ambulatory OR, and other outpatient clinics
Radiology
Satellite Medical Clinics
Long Term Care Facilities
RCRA: Risk Management & Liability

Civil and criminal liability
   Civil: State/USEPA enforcement
   Criminal: FBI, Attorney General, Grand Jury

Corporate fines: $37,500/violation/day

Personal liability: Fines and/or imprisonment

No statute of limitations

Managers up through CEO liable

Potential Liability for Rx Hazardous Waste Management
Which Discarded Drugs Become Hazardous Waste?

P-listed chemicals (acutely hazardous)
  Sole active ingredient; unused; empty containers

U-listed chemicals (toxic)
  Sole active ingredient; unused

Characteristic of hazardous waste
  Ignitability
  Toxicity
  Corrosivity
  Reactivity
Listed Hazardous Pharmaceutical Waste

P-listed Chemicals
Sole active ingredient
Examples:

- Arsenic trioxide  P012
- Nicotine  P075
- Warfarin  (conc. greater 0.3%)  P001

U-listed Chemicals
Sole active ingredient
Examples:

- Chloral Hydrate (CIV)  U034
- Cyclophosphamide  U058
- Lindane  U129
Characteristic Hazardous Waste

Ignitability: ≥ 24% alcohol, oxidizers, flammable propellants

Corrosivity: pH ≥ 12.5 or ≤ 2

Toxicity: Heavy metals and other chemicals specifically listed with individual leaching concentrations prohibited. Mercury, barium, selenium, chromium, etc.

Reactivity: Nitroglycerin in finished dosage forms excluded federally and in Texas
Examples of Pharmaceuticals Exhibiting the Characteristic of Toxicity

Preservatives: thimerosal & m-cresol

Heavy metals: selenium, chromium and silver
## Common Pharmaceutical Waste Stream Management

<table>
<thead>
<tr>
<th>Type of Waste Container</th>
<th>Color code</th>
<th>Contents</th>
<th>Treatment Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red bag (non-pathology)</td>
<td>Red</td>
<td>Biohazardous (RMW) + Rx</td>
<td>Autoclave/ Landfill</td>
</tr>
<tr>
<td>Red sharps/ needlebox</td>
<td>Red</td>
<td>Biohazardous; needles, etc. + Rx</td>
<td>Autoclave/ Landfill</td>
</tr>
<tr>
<td>Trace chemo Rx</td>
<td>Yellow</td>
<td>Bulk &amp; Trace Chemo, needles, tubing</td>
<td>RMW Incineration</td>
</tr>
<tr>
<td>Sewer</td>
<td></td>
<td>Unused IVs, tablets, etc.</td>
<td>Wastewater Treatment Plant</td>
</tr>
<tr>
<td>Municipal Trash</td>
<td></td>
<td>Unused ointments, etc.</td>
<td>Landfill</td>
</tr>
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### Management Recommendations For Pharmaceutical Waste

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<td>Autoclave/ Landfill</td>
</tr>
<tr>
<td>Trace chemo Rx</td>
<td>Yellow</td>
<td>Biohazardous &amp; Trace Chemo</td>
<td>RMW Incineration</td>
</tr>
<tr>
<td>RCRA Toxic/Ignitable Hazardous Rx</td>
<td>Black</td>
<td>RCRA &amp; BMP Hazardous Rx</td>
<td>RCRA TSDF</td>
</tr>
<tr>
<td>Non-hazardous Rx</td>
<td>White/Blue</td>
<td>Non-hazardous Rx</td>
<td>RMW Incineration</td>
</tr>
</tbody>
</table>
Considering the Optimal Management Options

Need to label items that need segregation in a manner that makes it easy for pharmacy and nursing personnel

Shelf stickers in pharmacy
Data Applied to Dispensing Software and/or
Message inserted into Pyxis, etc. and MAR (Medication Administration Record) and/or
Stickers Applied Manually

Think Green®
How Should RCRA Hazardous Waste be Handled?

Need a new waste stream in Pharmacy, Patient Care Areas, Oncology Clinics

RCRA Hazardous Waste: Toxic P, U, toxic Ds, (all Chemotherapy Residues, Chemo Spills)

RCRA Hazardous Waste: Ignitable (D001)

Hazardous waste vendor develops a waste profile that includes all possible waste codes
How Should RCRA Hazardous Waste Be Disposed?

Either contract with a hazardous waste broker or develop internal expertise for:

- Waste profiling
- Manifest preparation
- Land ban preparation

Contract with a federally permitted RCRA hazardous waste incineration facility (TSDF: Treatment, Storage & Disposal Facility)
Labeling the Pharmacy Shelves

Avery Standard Shipping labels
Label Alert: PYXIS

Medications dispensed by the PYXIS medication station
P, U, D, or HD a pop-up alert to properly dispose of the medication

*Pyxis alert:*

**THIS DRUG IS A FEDERAL HAZARDOUS WASTE TYPE**
(specifies P, U, D)

**DISPOSE >TRACE IN “BLACK” CONTAINER OR RETURN TO PHARMACY**

Courtesy Lahey Clinic Medical Center, Burlington, MA
IV / Medication Label Alert: P, U, D, HD

Courtesy Lahey Clinic Medical Center, Burlington, MA
Labeling & Containers

Items identified by PharmE Inventory Analysis
Marked with black labels
“Special Disposal Required”
Coded in Pyxis dispensing machine also

Black hazardous waste containers purchased from contracted vendor

SPECIAL DISPOSAL REQUIRED

Courtesy North Memorial Health Care
Federal Waste Generation Status

**Large Quantity Generator (LQG):** generates more than 1000 kg/month of hazardous waste or >1 kg/month “P” listed waste.

**Small Quantity Generator (SQG):** Generates <1000 kg/month but >100 kg/month of hazardous waste & < or = 1 kg/month “P” listed waste.

**Conditionally Exempt Small Quantity Generator (CESQG):** Generates < or = 100 kg haz waste/month, < or = 1kg P listed waste/month
Creating a Hazardous Waste Profile

Work with hazardous vendors to create a certified hazardous waste profile of all toxic & ignitable drug waste, including ignitable aerosols

Ship commingled as UN3248, Waste Medicine, Liquid, Flammable, Toxic, n.o.s., 3 (6.1), PG II

Ship any corrosive acids/bases or oxidizers separately
Percentage of Hazard Categories in 149 Hospitals (2008)

PharmE® Database
Summary of Actual Federally Hazardous Products

- Toxic, 58.1%, 66%
- Ignitable, 22.2%, 25%
- Ignitable Aerosol, 4.8%, 6%
- Corrosive Acid, 0.2%, 0%
- Oxidizer, 0.1%, 0%
- Corrosive Base, 0.1%, 0%
- Ignitable Oxidizer, 2.3%, 3%

97% Toxic or Ignitable
Hazardous Pharmaceutical Waste
Storage Accumulation
Examples of Non-Hazardous Pharmaceutical Waste Collection & Storage
Resources

NIOSH Hazardous Drug Alert
http://www.cdc.gov/niosh/docs/2004-165/#sum

ASHP Guidance on Handling Hazardous Drugs

OSHA Technical Manual
http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html

Practice GreenHealth (formerly Hospitals for a Healthy Environment)
http://www.practicegreenhealth.org/
Pharmaceutical waste webpage: http://www.h2e-online.org/hazmat/pharma.html

Healthcare Education Resource Center (HERC)
Blueprint on Pharmaceutical Waste Management (Revised)

WMHS PharmEcology Services
www.pharmecology.com
FAQs, state and federal waste regulations, PharmE® Waste Wizard identifies RCRA hazardous waste plus NIOSH hazardous drugs, among additional criteria
QUESTIONS?

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Alternative Methods for Managing Unused Pharmaceuticals – Consumers

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Alternative Options for Consumers

Common Goals:

To get unused drugs out of the house

Avoid accidental poisonings

Avoid unintended use

To provide alternative options to flushing

An education/awareness tool

Currently very difficult to know if it would impact environment at all.

Consumer behavior and desire
Success

Accessible
Cost effective
Simple to operate
Legal
Alternative Options for Consumers

1) One-time/Irregular Community Collection Events
2) Permanent Collection Facilities
   - Kiosk/drop box
   - Household Hazardous Waste (HHW) event
3) Mail-back Programs
4) Trash (municipal waste)
5) Other (need for regulatory direction/action)
Other – Regulatory Action and Direction Needed

Pharmacists – some taking back drugs
HHW program – dissolve in acid, controlled included
  – take back all drugs in 5-gal pail, landfill
Kiosks – outside
Irregular Community Collection Events

Drive-through or drive-up day time operation
To accept controls: requires law enforcement

- Immediate segregation into controlled/possibly controlled substances and other drugs.
- Law enforcement must secure controlled substances and witness/document disposal.

Various levels of sorting and inventorying collected items.
Irregular Community Collection Events

Regulatory Requirements:
Contact Waste Permits Division of TCEQ.
Requirements may differ depending on if event accepts HHW or only drugs.

Most examples of this event co-mingle all non-controlled pharmaceuticals.

Disposal choice:
- Permitted hazardous waste incineration if part of HHW event.
- Other options if an independent collection.
Irregular Community Collection Events

Pros:
- Alternative to flushing
- Reduced opportunity for poisoning or diversion (in some cases)
- Education and awareness
- Develop community partnerships (law enforcement, other)

Cons:
- No effect on excretion of meds (environmental impact questionable)
- Need law enforcement involvement for controlled substances
- Sorting may be necessary in most areas (controlled vs. non)
- Can be costly
- Need for transportation and disposal
Irregular Community Collection Events

Discussion point:

Can this work for Texas?
Permanent Collection Facilities - Drop Boxes/Kiosks

Examples of locations:
- Pharmacies
- Long-Term Care Facilities
- Police stations/sheriff’s offices

Most can’t accept controlled substances (except law enforcement office)

Co-mingling of hazardous and non-hazardous pharmaceuticals likely to occur.

Regulatory Requirements: Contact TCEQ Waste Permits Division for direction.
Permanent Collection Facilities - Drop Boxes/Kiosks

E.g. Retail Pharmacies, King County, WA:

Mechanism for refusing controlled substances

Consumers place drugs in tray
Pharmacy staff immediately inspect with customer present
Pharmacy staff refuse controlled substances (consumer keeps material not accepted)
Permanent Collection Facilities
- Drop Boxes/Kiosks

Pros:
- Alternative to flushing
- Reduced opportunity for poisoning or diversion (in some cases)
- Education and awareness
- Accessible
- Brings customers into store

Cons:
- Can’t accept controlled substances (law enforcement not onsite).
- Training staff to segregate accepted from not-accepted substances and available time.
- Cost of boxes and disposal services.
- May require TCEQ authorizations.
- Doesn’t address excretion component.
Permanent Collection Facilities
- Drop Boxes/Kiosks

Discussion point:

Can this work for Texas?
Permanent Collection Facilities
- via HHW event/station

Pros:
- Gets unused drugs out of house (may avoid potential for accidental poisoning and/or diversion).
- Can choose to accept or refuse certain drug/waste types if staff trained to identify those while customer waits.
- Provides alternative to flushing.
- Disposal facility and transport/disposal arrangements already established.

Cons:
- Can’t accept controlled substances (law enforcement not onsite).
- If co-mingle waste, must all be transported/disposed of as hazardous.
- Training staff to segregate accepted from not-accepted substances.
- Cost
- May require TCEQ authorizations.
- Doesn’t address excretion component.
Permanent Collection Facilities - via HHW event/station

Discussion point:

Can this work for Texas?
Mail-Back

For example, pre-paid mailing envelopes offered in pharmacies, clinics, nursing homes etc.

Consumers place unused drugs in envelope & post them back to pre-determined location.

Mail received at collection location & destroyed.

Example: Maine
  Goes through USPS – considered secure.
  US DoJ DEA approved to accept controlled substances.

Example: Illinois
  Goes to incinerator in Texas; no controlled substances allowed.
Mail-Back

Pros:
- Gets unused drugs out of house (may avoid potential for accidental poisoning and/or diversion).
- Provides alternative to flushing.
- May be good option for people with limited access (e.g. place envelopes in nursing homes, or with in-home care providers).

Cons:
- May not be able to accept controlled substances.
- Cost
- May require TCEQ authorizations.
- Doesn’t address excretion component.
Mail-Back

Discussion point:

Can this work for Texas?
Federal guidelines provide step-by-step instructions about how to dispose of unused drugs in household trash.

Examples are mostly consistent:

- White House Office of National Drug Control Policy
- Food & Drug Administration
- SMARxT Disposal partnership

http://www.smarxtdisposal.net/
Household/Municipal Trash

Should include significant education component

Examples:

Potential posters or brochures in pharmacies, clinics, nursing homes, police stations.

Labeling

Webpage & consistent messages across State/local agencies.

In home disposal kits.
Household Trash Combined with Education

Pros:
- Gets unused drugs out of house (may avoid potential for accidental poisoning and/or diversion).
- Provides alternative to flushing.
- Consistent with Federal disposal guidelines.
- No additional cost for consumer (except household waste collection/disposal fees)
- No authorizations or rule changes required.

Cons:
- Cost of advertising, webpage development, coordinating State staff member.
- Need support from all relevant state agencies, local government, law enforcement (all stakeholders).
- Recommendations based on current knowledge (will need to be flexible in future if knowledge base changes).
- Doesn’t address excretion component.
Household Trash Combined with Education

Discussion point:

Can this work for Texas?
Any other options for Consumers, Utilities, Government Bodies?

When assessing alternatives we should consider:

- What is the effect, if any, on public health?
- What is the effect, if any, on the environment?
- Feasibility and long-term sustainability
- What should be the measures of success?
Questions?

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