



Welcome

to the Pharmaceutical Disposal Advisory Group Meeting, February 26th, 2010

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We will begin promptly at 9:00am.

Teleconference dial-in number: 1 866 456-0016

Room ID: \* 8 8 2 2 9 8 6 \*

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LiveMeeting Log-in:

https://www.livemeeting.com/cc/tceq_state_tx_us/join?id=PharmStudy2&role=attend&pw=PharmAttend1

Meeting Id : PharmStudy2
Attendee entry code: PharmAttend1



Facilitator/Chairman:



Elston Johnson

Manager, Public Drinking Water Section
Water Supply Division
Office of Water
TCEQ



Today's Agenda



- 9:00 - 9:10am: Welcome & re-cap (10 mins)
- 9:10 - 9:40am: Presentation: Tim Oden - USGS (30 mins)
- 9:40 - 10.20am: Presentation: Eric Beller & Jessica Huybregts
Regulations relating to Pharm Disposal
- 10:20 - 10:30am: Update on questionnaires (10 mins)
- **10:30 - 10:45am: Break (15 mins)**
- 10:45 - 11:30am: Break-out discussions in sub-groups (45 mins)
- 11:30 - 12:20am: Sub-groups report back key points to Group
(4 mins each)
- 12:20 - 12:30pm: Questions/discussion (10 mins)

Re-cap of Senate Bill 1757 Project



- TCEQ shall study and make recommendations regarding the methods to be used by **consumers**, health care **providers**, and **others** for disposing of unused pharmaceuticals so that they do not enter a wastewater system.
- Report due to legislature December 1, 2010



Re-cap of SB1757 Objectives

- (1) the methods currently used in Texas (by consumers, health care providers, and others);
- (2) alternative methods used, including methods used in other states; and
- (3) the effects on public health and the environment of the various methods used for that purpose.
- (4) The report must also provide an analysis of the feasibility of implementing the recommended disposal methods on a statewide basis.

Re-cap of Intent of Advisory Group



- To provide a forum for TCEQ to gather sufficient information to understand the:
 - **methods** currently used in Texas to dispose of unused pharmaceuticals;
 - **amount and type** of unused pharmaceuticals currently disposed of via various disposal methods;
 - **factors driving** disposal practices;
 - **regional differences** in disposal practices;
 - **desires** of consumers, the health-care industry and others for alternative disposal methods; and
 - **knowledge gaps**.



Regulations Related to Pharmaceuticals

- **Waste Regulations & Waste Classification**
 - Eric Beller, Waste Permits Division, TCEQ
 - <ebeller@tceq.state.tx.us>
- **Non-Waste Regulations (Health-care & Pharmacy)**
 - Jessica Huybregts, Water Supply Division, TCEQ
 - <jhuybreg@tceq.state.tx.us>





Waste Regulations & Waste Classification

- Waste classification based on generator status
 - Industrial – Manufacturing
 - Municipal – residential, commercial, health care services, recreational, municipalities, etc.

Industrial Generators



- Waste classification per Chapter 335 (Industrial Solid Waste & Municipal Hazardous Waste)
 - Hazardous Waste
 - Class 1 waste – based on constituent concentrations
 - Class 2 waste – below Class 1 concentrations
 - Class 3 waste – Inert material

Municipal Generators



- Waste classification per Chapter 335 and Chapter 330 (Municipal Solid Waste)
 - Hazardous waste
 - Conditionally exempt small quantity generator (CESQG) – less than 220 lbs/month
 - Non-hazardous municipal solid waste (MSW)
 - Household hazardous waste – not hazardous by exclusion in 40 CFR 261.4(b)(1)
 - Medical waste per 30 TAC 330.3(85)
 - Special waste per 30 TAC 330.3(148)(J)

Municipal Generators Disposal Requirements



- **Hazardous waste**
 - Small or Large quantity generators
 - > 220 lbs per month
 - Manage waste as hazardous
- **CESQG - < 220 lbs per month**
 - Disposal in an MSW landfill as a special waste per 30 TAC §330.171(c)(6)

Municipal Generators Disposal Requirements



- **Non-hazardous municipal waste**
 - Non-household or commercial
 - MSW landfill as special waste
 - MSW waste processing/treatment facility as or with medical waste
 - Discharge to a POTW or WWTP

Municipal Generators Disposal Requirements



- **Household waste**
 - MSW landfill with routine trash
 - Household hazardous waste (HHW) collection event conducted under 30 TAC §335.403
 - Discharge to POTW or WWTP

HHW collection event



- **Regulatory Conditions**

- Notification to TCEQ of collection event
- Waste must be managed as hazardous waste even if it is not hazardous
- No regulatory mechanism for collection events for non-hazardous household wastes



Non-Waste Regulations Related to Unused Pharmaceutical Handling and Disposal



- Federal Controlled Substances Act
- State:
 - Controlled Substances Act
 - Dangerous Drugs Act (~Prescription Drugs)
 - Other Prescription Drug Rules
 - Assisted Living Rules
 - Nursing Home Rules
 - Drug Donations
- Federal Disposal Guidelines

Controlled Substances



- **Federal Controlled Substances Act (CSA)**
 - Title 21 – United States Code (Food and Drugs), Chapter 13 - Drug Abuse Prevention and Control, Subchapter I - Control and Enforcement
- **State Controlled Substances Regulations – several references**
 - Title 6 Texas Health and Safety Code, Chapter 481 - Texas Controlled Substances Act
 - Title 37 Texas Administrative Code, Part 1 - Texas Department of Public Safety, Chapter 13 - Controlled Substances
 - Title 22 Texas Administrative Code Part 15 - Texas State Board of Pharmacy, Chapter 303 - Destruction of Dangerous Drugs and Controlled Substances

Federal Controlled Substance Act



- Controlled Substance Act does not address specific methods of disposal
- However, it is relevant because it defines who may **possess** controlled substances (which will impact how you can go about disposing of a controlled substance)
- Who must register?
 - Every person who **manufactures** or **distributes** any **controlled substance** or **List I chemical**, or who proposes to engage in this; and
 - Every person who **dispenses**, or who proposes to dispense, any **controlled substance**.
 - Does not apply to ultimate user.
 - The term "List I chemical" means a specified chemical used in manufacturing a controlled substance.

Federal Controlled Substance Act



- Transfer of controlled substances between registrants is allowable
 - Sec. 1307.11 Distribution by dispenser to another practitioner or reverse distributor
 - Sec. 1307.12 Distribution to supplier or manufacturer
- Transfer of controlled substances from a non-DEA registrant (e.g. “ultimate user”) is not allowable

Federal Controlled Substance Act



- **Except....under Sec. 1307.21**
 - (a) Any person in possession of any controlled substance and desiring/requiring disposal... **may request assistance** from Special Agent in Charge...for authority & instructions to dispose of such substance.
 - **What this means?** Residents (non-DEA registrants) may be able to transfer their controlled substances to law enforcement for destruction.
 - Regulations do not define how to dispose of the controlled substance once with law enforcement.

State Controlled Substance Act



- Title 6 TX HSC, Chapter 481 - TX Controlled Substances Act
- Sec. 481.115-118 (Possession of a Controlled Substance)
 - Except as authorized ...a person commits an offense if the **person knowingly or intentionally possesses a controlled substance...** unless the person obtained the substance under a valid prescription...
- Sec. 481.153 (Seized Controlled Substances)
 - (a)-(b) means that if controlled substance property is **seized it is forfeited to the state** & a court may order the **disposal of the property**, or the department or a peace officer may **destroy the property under the rules of the department.**
- Sec. 481.154 (Rules)
 - (b) The **rules for the destruction** of controlled substances must require [witnesses, inventory etc.].
 - No specific disposal methods defined

State Controlled Substances - DPS



- Title 37 TAC, Part 1-TX Dept of Public Safety, Chapt. 13
- Rule §13.21 defines **who must register with DPS**
 - (a) manufacture, distribute, prescribe, possess, analyze, dispense, or conduct research with a controlled substance
 - (e) Registrant may lawfully possess a controlled substance to the extent authorized by the registration.
- Must also be required to obtain Federal registration from DEA first.

State Controlled Substances - DPS



- Title 37 TAC, Part 1 – TX DPS, Chapt. 13
- RULE §13.152 Summary Forfeiture
 - (c) Controlled pharmaceuticals: not subject to summary forfeiture to the state, unless it [was voluntarily surrendered for destruction or was illegally sold/possessed]
- However, IF pharmaceuticals are forfeited a **laboratory or law enforcement agency must adopt a written SOP for destruction** of the item (§13.157).
- IF forfeited, §13.158 defines the manner of destruction:
 - (a) Destruction by anyone:by **burning in a suitable incinerator or by another method** as long as the destruction is safe & in compliance **all relevant federal, state, and local laws** (including TCEQ and EPA).
 - (b) Private contractor: ...rules apply
 - (c) Destruction by officer: ...possible but not recommended unless the officer has expertise in the safe and lawful disposal of controlled substances.

State Dangerous Drugs Act



- Title 6 TX HSC, Chapt. 483 - TX Dangerous Drugs Act
- "Dangerous drug" = a device or a drug that is unsafe for self-medication and requires a prescription, but is not a controlled substance
 - That is, any drug that requires a **prescription** but is not controlled substance.
- Disposal:
 - If a dangerous drug is **seized** ...the board may direct an employee of the board or an authorized peace officer to destroy the drug.[they] **shall destroy the drug in any manner designated as appropriate by the board**
 - **Specific disposal method not defined**

State Pharmacy Rules

- Controlled Substances and Dangerous Drugs



- Title 22 TAC Chapt. 303 (State Board of Pharmacy)
- §303.1 Destruction of Dispensed Drugs (Dangerous Drugs and Controlled Substances)
 - (a) Drugs dispensed to patients in health care facilities
 - (1) A consultant pharmacist... is authorized to destroy dangerous drugs and controlled substances dispensed to patients in health care facilities...
 - (D) The drugs must be destroyed (by the consultant pharmacist) in a manner to **render the drugs unfit for human consumption** and disposed of in compliance with all applicable state and federal requirements.
 - (2) The consultant pharmacist may also destroy the drugs (controlled substances and dangerous drugs) using a waste disposal service.
- 303.1(a) gives the health-care facilities disposal options.

State Pharmacy Rules

- Controlled Substances and Dangerous Drugs



- Title 22 TAC Chapt. 303 (State Board of Pharmacy)
- Under 303.1(b) **pharmacists may accept** and destroy dangerous drugs (**prescription drugs**), **BUT NOT** controlled substances, that have been **previously dispensed to a patient** and **returned to a pharmacy** by the patient.
 - These are prescription drugs from the patients of the pharmacy, **NOT patients in a health-care facility**.
 - 303.1 (b)(1) The dangerous drugs shall be destroyed ... to render the **drugs unfit for human consumption** and disposed of in compliance with all applicable state and federal requirements.

State Pharmacy Rules

- Controlled Substances and Dangerous Drugs



- Title 22 TAC, Chapt. 303 (State Board of Pharmacy)
- §303.2 (Stock Dangerous Drugs = packaged in the original manufacturer's container)
 - 303.2(b) A [licensed] pharmacist is authorized to destroy stock dangerous drugs **owned by a licensed pharmacy** if such dangerous drugs are destroyed in a manner to **render the drugs unfit for human consumption** and disposed of in compliance with all applicable state and federal requirements.
- §303.2 Stock Controlled Substances
 - 303.2(c) A [licensed] pharmacist, may dispose of stock controlled substances **owned by a licensed pharmacy** in accordance with procedures authorized by the Federal and Texas Controlled Substances Acts
 - (c)(2)(iii) The controlled substances shall be **destroyed beyond reclamation**
 - No specific disposal methods defined.

State Pharmacy Rules

- Prescription Drug Regulations



- Title 22 TAC Part 15 – State Board of Pharmacy, Chapt. 291
- §291.8 Return of Prescription Drugs (all pharmacies)
 - Relates to return of prescription drugs for re-sale (not for destruction)
 - Does not apply to controlled substances
 - Applies to nursing homes and penal institutions
- 291.8(a) General prohibition on return of prescription drugs:
 - A pharmacist may not accept an unused prescription or drug ...for the purpose of resale or re-dispensing to any person, after the prescription or drug has been originally dispensed, or sold except under (b).
- Under 291.8(b)(3), the dispensing pharmacy can accept unused prescription drugs from a licensed health care professional in a penal institution or they can accept them from a consultant pharmacist that serves as a consultant for a nursing home (as long as it hasn't been dispensed to a patient yet and meets all other criteria).

State Dangerous/Prescription Drug Regulations



- Title 6 TX HSC Chapter 431 (TX Food, Drug and Cosmetic Act)
- 431.021(ee): selling, distributing, or transferring a prescription drug to a person who is not authorized under state or federal law to receive the prescription drug in violation of Section 431.411(b) [which is about reverse distribution to the manufacturer];
- 483.041: POSSESSION OF DANGEROUS DRUG
 - (a) A person commits an offense if the person possesses a dangerous drug unless the person obtains the drug from a pharmacist.....
 - Except:
 - (c) Subsection (a) does not apply to the possession of a dangerous drug **in the usual course of business or practice or in the performance of
 - official duties** by specific people
 - Key term is “usual course of business”.
 - This is interpreted as **law enforcement or salvagers only** because handling drugs that have been dispensed is part of their normal job.
 - This may need to be addressed because it may have implications for household collection of pharmaceuticals.

Assisted Living Regulations



- Title 40 TAC, Part 1 (Dept of Aging & Disability Svcs), Chapt. 291
 - Rule §92.4: Standards for Type A, Type B, and Type E Assisted Living Facilities
 - (j) (6) Disposal:
 - (A) Medications **no longer being used by the resident** (because discontinued, expired or after patient dies) are to be kept separate from current medications and are to be **disposed of by a registered pharmacist licensed in the State of Texas.**

Nursing Home Regulations



- Title 40 TAC, Part 1), Chapt. 19 (Pharmacy Services within Nursing Facilities)
 - §19.1504 Drug Security
 - (a) The facility **must establish procedures** for storing and **disposing** of drugs and biologicals in accordance with **federal/state/local laws**.
 - (g) **Medications of deceased residents, expired medications, and discontinued medications** must be securely stored and reconciled... they **must be disposed of according to federal and state laws/rules on a quarterly basis** ... These meds cannot be given to a family member or representative.
 - §19.318 (s) Disposal facilities.... Space and **facilities** must be provided for the sanitary storage and **disposal of waste (not special waste)**, by **incineration, mechanical destruction, compaction, containerization, removal, or contract with outside resources**, or by a combination of **these techniques**.
 - Allows for many disposal options

Prescription Drug Donation Regulations



- Title 6 TX HSC, Chapter 431, Subchapter M (Drug Donation)
 - Applied to unused **prescription** drugs
 - **Cannot be** controlled substance
 - Must be approved drugs (FDA), that are **not expired** or and will be dispensed within appropriate shelf-life
 - Requires certification that the drugs have been properly sealed, stored (& other safeguards to ensure the drugs are not compromised)
 - Donation is by a charitable drug donor (eg. licensed nursing home, licensed hospice, hospital, physician, pharmacy etc.)
 - Donation can be accepted by a charitable medical clinic (eg. clinic or pharmacy). Both of these have specific definitions – see Sec. 431.321
 - Rule implies that it **does not allow** for donation of unused prescription medications **previously dispensed to patients.**

Other Regulations?



- Health Insurance Portability and Accountability Act of 1996 (HIPAA)
 - What does it mean for disposal of unused pharmaceuticals?
- Any other appropriate State regulations not listed here?
- Any rules for transfer of non-prescription pharmaceuticals?

Federal Disposal Regulations



- Do not exist
- Advice/guidelines are offered by:
 - Food and Drug Administration (FDA)
 - White House Office of National Drug Control Policy (ONDCP)
- This advice targets household drug disposal.
- Do not currently have consistent State guidelines – at this time we tend to direct people to the federal guidelines.



FDA Advice

Follow any specific disposal instructions on the drug label....
Do not flush prescription drugs down the toilet unless this information specifically instructs you to do so.

If no instructions are given, **throw the drugs in the household trash**....(with recommendations)

Take advantage of community drug take-back programs that allow the public to bring unused drugs to a central location for proper disposal.

FDA Consumer Health Information
www.fda.gov/consumer
www.fda.gov/consumer/updates/faq_disposal080909.html

How to Dispose of Unused Medicines

Is your medicine cabinet filled with expired drugs or medications you no longer use? How should you dispose of them?

Most drugs can be thrown in the household trash, but consumers should take certain precautions before tossing them out, according to the Food and Drug Administration (FDA). A few drugs should be flushed down the toilet. And a growing number of community-based "take-back" programs offer another safe disposal alternative.

Guidelines for Drug Disposal
FDA worked with the White House Office of National Drug Control Policy (ONDCP) to develop the first consumer guidance for proper disposal of prescription drugs. Issued by ONDCP in February 2007, the federal guidelines are summarized here:

- Follow any specific disposal instructions on the drug label or patient information that accompanies the medication. Do not flush prescription drugs down the toilet unless this information specifically instructs you to do so.
- If no instructions are given, throw the drugs in the household trash, but first:
 - Take them out of their original containers and mix them with an undesirable substance, such as used coffee grounds or kitty litter. The medication will be less appealing to children and pets, and unrecognizable to people who may intentionally go through your trash.
 - Put them in a sealable bag, empty can, or other container to prevent the medication from leaking or breaking out of a garbage bag.

Take drugs out of their original containers and mix them with an undesirable substance, such as used coffee grounds ...

FDA Consumer Health Information / U.S. Food and Drug Administration
1498 03 - 2008



FDA Advice – flushing limited to 26 meds for safety reasons

MEDICINES RECOMMENDED FOR DISPOSAL BY FLUSHING

This list from FDA tells you what unused or expired medicines you should flush down the sink or toilet to help prevent danger to people and pets in the home. Flushing these medicines will get rid of them right away and help keep your family and pets safe.

FDA continually evaluates medicines for safety risks and will update the list as needed.

<i>Medicine</i>	<i>Active Ingredient</i>
Actiq , oral transmucosal lozenge	Fentanyl Citrate
Avinza , capsules (extended release)	Morphine Sulfate
Daytrana , transdermal patch system	Methylphenidate
Demerol , tablets *	Meperidine Hydrochloride
Demerol , oral solution *	Meperidine Hydrochloride
Diastat/Diastat AcuDial , rectal gel	Diazepam
Dilaudid , tablets *	Hydromorphone Hydrochloride
Dilaudid , oral liquid *	Hydromorphone Hydrochloride
Dolophine Hydrochloride , tablets *	Methadone Hydrochloride
Duragesic , patch (extended release) *	Fentanyl
Embeda , capsules (extended release)	Morphine Sulfate; Naltrexone Hydrochloride
Fentora , tablets (buccal)	Fentanyl Citrate
Kadian , capsules (extended release)	Morphine Sulfate
Methadone Hydrochloride , oral solution *	Methadone Hydrochloride
Methadose , tablets *	Methadone Hydrochloride
Morphine Sulfate , tablets (immediate release) *	Morphine Sulfate
Morphine Sulfate , oral solution *	Morphine Sulfate
MS Contin , tablets (extended release) *	Morphine Sulfate
Onsolis , soluble film (buccal)	Fentanyl Citrate
Opana , tablets (immediate release)	Oxymorphone Hydrochloride
Opana ER , tablets (extended release)	Oxymorphone Hydrochloride
Oramorph SR , tablets (sustained release)	Morphine Sulfate
Oxycontin , tablets (extended release) *	Oxycodone Hydrochloride
Percocet , tablets *	Acetaminophen; Oxycodone Hydrochloride
Percodan , tablets *	Aspirin; Oxycodone Hydrochloride
Xyrem , oral solution	Sodium Oxybate

*These medicines have generic versions available or are only available in generic formulations.

List revised: August 2009

White House ONDCP Guidelines

- Do not flush (unless on FDA list of 26)
- Community take back programs
- Steps to dispose of in trash



Proper Disposal of Prescription Drugs

Office of National Drug Control Policy October 2009

Federal Guidelines:

- Do not flush prescription drugs down the toilet or drain unless the label or accompanying patient information specifically instructs you to do so. For information on drugs that should be flushed visit the [FDA's website](#).
- To dispose of prescription drugs not labeled to be flushed, you may be able to take advantage of community drug take-back programs or other programs, such as household hazardous waste collection events, that collect drugs at a central location for proper disposal. Call your city or county government's household trash and recycling service and ask if a drug take-back program is available in your community.
- If a drug take-back or collection program is not available:
 1. Take your prescription drugs out of their original containers.
 2. Mix drugs with an undesirable substance, such as cat litter or used coffee grounds.
 3. Put the mixture into a disposable container with a lid, such as an empty margarine tub, or into a sealable bag.
 4. Conceal or remove any personal information, including Rx number, on the empty containers by covering it with black permanent marker or duct tape, or by scratching it off.
 5. Place the sealed container with the mixture, and the empty drug containers, in the trash.



Update on Questionnaire



Purpose of Questionnaire



- To collect a baseline set of information documenting:
 - **how** health-care facilities/providers, consumers and others are currently disposing of unused pharmaceuticals in Texas;
 - **how much** of **what** is being disposed of via the various disposal practices;
 - **why** certain disposal practices are chosen; and
 - what are the **limitations** and **advantages** of the current methods of disposal.

Questionnaire Update



- 12 Questionnaires developed by TCEQ Study Team.
- Reviewed by ≥ 1 stakeholder in each group during Feb.
- TCEQ Study Team is currently consolidating comments.
- Once 1st draft comments are finalized, we'll send it for 2nd review.
- Team feels it's more important to formulate the right questions so we receive:
 - Good response rate; and
 - Most relevant information.



Questionnaire Update



- Once reviewers are happy with second draft, questionnaires will be loaded to Survey Monkey.
- Your TCEQ liaison will send you the link to the online questionnaire. Instructions will be provided.
- We'd then ask you to send the link to appropriate contacts/members (within Texas).
- If have time during group discussions, each group can talk about their questionnaires.

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(4 mins each)
- 12:20 - 12:30pm: Questions/discussion (10 mins)



Break-Out Discussions





Each Group Reports Back

- Each group provides 4-minute summary

Closing



- Thank you for your attendance and valuable discussions
- Next meetings: **March 24th**, **April 22nd**
- Topics for March meeting:
 - Complete discussions on **current** methods of disposal
 - Begin discussions of **alternative** disposal practices

Closing



- Agenda for March meeting & minutes for this meeting on website by **March 12th**.
- Provide comments on meeting location, format, discussion topics etc. to Jessica
 - **jhuybreg@tceq.state.tx.us**
- http://www.tceq.state.tx.us/permitting/water_supply/pdw/pdagroup