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Study of the Methods for Disposing of Unused Pharmaceuticals
Study of the Methods for Disposing of Unused Pharmaceuticals

Prepared by
Water Supply Division

SFR-098
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Executive Summary

In accordance with Senate Bill 1757, 81st regular session, the Texas Commission on Environmental Quality (TCEQ) conducted a study and made recommendations regarding methods for disposing of unused pharmaceuticals so that they do not enter a wastewater system as well as considered the feasibility of adopting those recommended methods on a statewide basis. As part of the study, the TCEQ was tasked to identify the current and alternative methods used by health-care providers, consumers and others in Texas for disposing of unused pharmaceuticals and determine the impact of those methods on both public health and the environment.

Pharmaceuticals in the Environment

Over the last decade, there has been discussion of the occurrence of pharmaceuticals in the environment. Researchers have determined that the majority of pharmaceuticals that are introduced to the environment are done so through aquatic systems, as raw or treated sewage or wastewater, with the terrestrial environment receiving a secondary input through land application of biosolids, wastewater, manure, and other agricultural practices.

Pharmaceuticals and their transformation compounds enter wastewater streams as a result of the use and excretion of pharmaceuticals and from the intentional disposal of pharmaceuticals. The intentional disposal of pharmaceuticals represents a real but less significant source of pharmaceuticals to the environment than excretion. Many wastewater treatment plants in Texas discharge to a body of surface water. Pharmaceuticals can ultimately be discharged to surface waters because conventional wastewater treatment technologies do not remove all pharmaceutical compounds completely and more effective advanced treatments are not commonly used.

Pharmaceuticals have been detected in surface waters, untreated drinking water sources, finished drinking water, groundwater, landfill leachate, biosolids and fish tissue. However, when these detections occurred they were oftentimes at the parts per billion (µg/L) or even parts per trillion (ng/L) level. Most of the studies regarding pharmaceutical occurrence in the environment have focused on detecting the presence or absence of pharmaceuticals in various media and not on the toxicological impact of the actual levels identified.

Current Methods of Pharmaceutical Disposal

There are a number of rules relating to the possession, generation, collection, transport and disposal of pharmaceuticals, activities which are regulated by a number of state and federal agencies. The TCEQ’s waste rules apply to all entities that are not households. This study identified several disposal practices currently in use in Texas. Health-care providers typically use a combination of methods for disposing of unused pharmaceuticals. Many times, solid dose pills that go unused and cannot be returned to a dispensing pharmacy will be placed in a biohazard box that is managed as medical waste, autoclaved and then sent
to a municipal solid waste landfill. In general, hospitals tend to dispose of unused open (unreturnable) liquids - usually the unused portions of fluids in IV bags and syringes - down the drain. Some hospitals separate out hazardous waste from non-hazardous waste and dispose of the wastes separately, while others dispose of all waste at a facility that is permitted to accept hazardous waste. Some hospitals manage all pharmaceutical waste (which contains about 5-10% hazardous waste in the hospital setting) as medical waste. In physicians’ offices and veterinary clinics, unused liquids are sometimes washed down the drain, but in many cases, unused pharmaceuticals are disposed of in biohazard boxes and managed as medical waste. Pharmaceutical manufacturers and reverse distributors generally dispose of returned, unsalable, unused and unwanted pharmaceuticals by means of incineration. Reverse distributors are entities that take unsalable, unused and unwanted pharmaceuticals from either a provider like a pharmacy or from a pharmaceutical manufacturer.

Nursing homes, assisted living facilities and some hospices generally manage all unused pharmaceuticals, including controlled substances, as medical waste. There is little to no segregation of waste at these facilities and many times no determination is made regarding whether the waste contains hazardous substances. In-home care providers usually do not dispose of pharmaceuticals for their clients but may advise patients to dispose of them in the drain so that they are irretrievable.

Ranchers and farmers generally do not have a significant amount of unused pharmaceuticals to dispose of because veterinarians or animal health specialist will take back the unused medications and will redistribute or dispose of the unused pharmaceuticals. When ranchers and farmers are left with unused pharmaceuticals, they manage them in a variety of ways including municipal trash disposal, drain disposal or continued storage.

Consumers tend to dispose of their unused pharmaceuticals directly in the municipal trash, which for the majority of the Texas population, is collected by a waste hauler and disposed of in a permitted municipal solid waste landfill. Very few Texans surveyed reportedly follow the Food and Drug Administration/White House Office of National Drug Control Policy guidance, which directs consumers to render the drugs undesirable before disposing of them in the municipal trash. Approximately 10% of consumers usually dispose of unused pharmaceuticals in the drain by means of a toilet or sink.

**Impact of Disposal Methods on the Environment**

The majority of the disposal methods adopted by health-care providers, consumers and others in Texas for disposing of unused pharmaceuticals tend to direct pharmaceuticals to the solid waste stream; most unused pharmaceuticals are either disposed of in a landfill, or sterilized or incinerated with the remaining products being disposed of in a landfill. This study identified that a low proportion of unused pharmaceuticals is disposed of directly into the wastewater.
Once the excretion of pharmaceuticals is excluded, the remaining pathways by which pharmaceutical compounds enter wastewater are direct drain disposal of unused pharmaceuticals and possibly the disposal of the wastewater associated with the treatment of pharmaceuticals as medical waste in an autoclave. Landfills, whether they are municipal solid waste landfills or hazardous waste landfills, and high temperature incinerators have been found to contribute a negligible amount of pharmaceuticals to the environment.

**Aquatic Life Impacts**

The majority of the published literature that was reviewed shows that little is known about the long-term effects of pharmaceuticals in waterways on aquatic organisms. However, there seems to be a sufficient body of evidence to suggest that trace environmental concentrations of some pharmaceuticals may have adverse effects on aquatic organisms in experimental situations. In an experimental lake area in Canada, fathead minnows were exposed to low concentrations (5–6 ng/L) of the synthetic estrogen (17α-ethinyl estradiol) that led to the feminization of male fish. In contrast, other research suggests that it is unlikely that 17α-ethinyl estradiol concentrations alone are causing these impacts. The impact of antidepressant exposure on larval fathead minnows has been shown in a controlled experimental setting to reduce predator avoidance behavior, which may ultimately impact survival and possibly reproductive fitness. However, it is unclear how this translates to the environmental setting, further research would be necessary to better understand the relative contribution of pharmaceutical compounds to observed impacts on aquatic species.

**Human Health Impacts**

While exposure to pharmaceuticals has been found to have some adverse effects on aquatic life in experimental settings, a similar link has yet to be established between ingestion of these compounds through drinking water and human health. The United States Environmental Protection Agency (EPA) continues to report, based on current knowledge, that the consumption of the low concentrations of pharmaceuticals found in drinking water does not represent a human health risk. Research suggests that for over 90% of the compounds that were studied, drinking two liters of water per day of water containing pharmaceuticals (at the concentrations found in drinking water) over a lifetime (70 years) would not cumulatively deliver the equivalent health impact of a single prescribed dose.

**Alternative Methods of Management and Disposal**

The TCEQ focused on three approaches to identify possible alternative methods for the management and disposal of unused pharmaceuticals: (1) identification of regulatory approaches adopted by other states; (2) identification of the methods used by health-care providers and others to manage, process and
dispose of unused pharmaceuticals; and (3) identification of alternative methods that could be adopted for collecting, managing, processing/disposing of consumers’ unused pharmaceuticals.

**Approaches Adopted by Other States**

Most of the alternative methods of pharmaceutical waste disposal that have been adopted by other states fall within four different categories. *First*, several states have amended their waste rules in order to create special requirements for pharmaceutical waste. These rule changes range from the creation of new hazardous waste categories to defining existing categories of waste, such as universal waste or medical waste, to include pharmaceuticals. States that have adopted one of these approaches include Arizona, California, Minnesota, and North Carolina. *Second*, several states have enacted or proposed legislation to establish community drug take-back events or mail-back programs. These states, which include Maine, Minnesota, Missouri, and Washington, have either funded these programs or amended their pharmacy rules to facilitate private programs. *Third*, some states or regions, for example Illinois and King County, Washington, have either banned disposal of pharmaceutical waste into wastewater systems or implemented special wastewater discharge provisions for pharmaceutical waste in particular. *Finally*, one state, New York, stepped up enforcement of waste rules and used resulting settlement agreements to reduce discharges of pharmaceutical wastes into waterways by requiring that sites cease discharges of pharmaceutical wastes into waterways or divert pharmaceutical waste to proper waste handling facilities for treatment and disposal.

**Alternative Methods of Management/Disposal for Health-Care Industry and Other Businesses**

Rules already exist to govern the disposal of unused pharmaceuticals by regulated entities. All facilities that engage in the collection, handling, transportation, processing and disposal of solid waste are regulated, except for households. Therefore hospitals, hospital pharmacies, nursing staff, physicians’ offices, nursing homes, assisted living facilities, hospices, veterinarians, law enforcement, retail pharmacies, clinics, dental offices, local government solid waste departments, and others are required to meet federal and state requirements for managing unused pharmaceuticals.

The EPA has developed guidelines for the health-care industry and other entities addressing alternative methods of disposal and management of unused pharmaceuticals. EPA guidance includes adopting best management practices to reduce or avoid the generation of unused pharmaceuticals, promoting the use of re-distribution options, and optimizing compliance with existing waste rules.
Alternative Methods of Management/Disposal for Consumers

The TCEQ identified current methods used by Texas households to manage or dispose of unused pharmaceuticals, including: (1) storage of unused pharmaceuticals in the household; (2) direct disposal in the drain by means of the toilet or sink; and (3) direct disposal in the municipal trash without having first rendered the pharmaceuticals undesirable. The TCEQ considered some alternative methods adopted in various areas of the United States for managing or disposing of unused pharmaceuticals by consumers that included: (1) disposal of unused pharmaceuticals at infrequent single-day collection events; continuous kiosk/drop box collection facilities; and household hazardous waste facilities with continuous collection; (2) use of mail-back programs; and (3) disposal of unused pharmaceuticals in municipal trash after they have been rendered undesirable.

Potential Impact of Alternative Methods of Management/Disposal

Currently there are no established chemical methodologies for determining what proportion of pharmaceuticals enter the wastewater system from excretion as opposed to intentional disposal. The available studies based on consumer pharmaceutical use data suggests that the majority of pharmaceuticals detected in wastewater come from excretion. Consequently, many of the alternative methods for managing and disposing of unused pharmaceuticals can only impact a small source of pharmaceuticals found in the environment; and thus, altering disposal habits will not greatly impact the amount of pharmaceuticals released into the wastewater system. However, minimizing the amount of pharmaceuticals that are intentionally disposed of into a wastewater system could reduce a known source of pharmaceuticals in the environment.

Recommended Approaches for Texas

Through coordination with the TCEQ’s Pharmaceutical Advisory Group, the TCEQ has identified a number of methods for managing and disposing of unused pharmaceuticals that could be feasibly implemented on a statewide basis in Texas. The TCEQ recommends these items because they are relatively effective and efficient methods of: (1) reducing the amount of pharmaceuticals that enter the wastewater system; and (2) raising awareness of the potential impacts of storing unused pharmaceuticals or disposing of them improperly. Additionally, the recommendations incorporate the concepts of accessibility, legality, and cost-effectiveness. Determining the feasibility of specific methods for health-care providers to dispose of unused pharmaceuticals is difficult because it varies greatly based on the facility type, size, and resource limitations, as well as the multiple regulatory provisions that apply to the handling and disposal of pharmaceuticals by health-care providers and health-care facilities. The effort for implementation of the recommendations can be scaled depending on the availability of financial resources.

The TCEQ recommends that a statewide education effort be considered in order to disseminate the most current information to health-care providers, consumers,
and others on the topic of unused pharmaceuticals and their proper disposal methods. Educational materials could be developed to provide a clear and consistent message for hospitals, physicians, home and community support services, pharmacies, law enforcement, veterinarians, local governments, and waste management/disposal companies. Extending outreach through a series of guidance documents, factsheets, posters, press releases and public service announcements on radio and television and other educational materials, may help facilitate better management and disposal of unused pharmaceuticals. An example is to encourage health-care facilities to review and consider implementing EPA’s *Best Management Practices for Unused Pharmaceuticals at Health Care Facilities* in order to reduce the amount of pharmaceuticals that go unused.

The TCEQ’s recommendations to consumers for managing unused pharmaceutical disposal in Texas households include: (1) encouraging and promoting the disposal of consumer’s unused pharmaceuticals into the municipal trash disposal after rendering the drugs undesirable; (2) supporting voluntary, infrequent single-day collection events; (3) promoting an educational program to provide information to the community about the proper disposal of drugs, the potential impact of pharmaceuticals released to the environment, and the potential impact of pharmaceuticals in water on human health and aquatic life; and (4) supporting the voluntary use of take-back programs.

**Conclusion**

Pharmaceuticals have been found at very low concentrations in a number of environmental media, most notably in surface waters, some of which are a source for public drinking water. Current research suggests that low concentrations of pharmaceuticals in drinking water present no appreciable risk to humans. Some experimental studies have shown that pharmaceuticals in water, even at parts per billion concentrations, may impact aquatic life. Real-world data are required to support those research efforts since current models suggest that concentrations of pharmaceuticals in real environmental settings in the United States are too low to result in the impacts seen in experimental settings.

The most current information suggests that compared to excretion, the intentional disposal of unused pharmaceuticals is a minor source of pharmaceuticals found in the environment. Accordingly, efforts to alter disposal habits will not completely prevent pharmaceuticals from being released into wastewater. Most current methods of disposal, such as the use of landfills or incineration, release only a negligible amount of pharmaceuticals into the environment. At present, given that there are no current means of reducing the excretion of pharmaceuticals, reducing the intentional disposal of pharmaceuticals into the wastewater system presents a practicable means of preventing at least a small percentage of pharmaceuticals from ending up in the environment. As pharmaceutical use continues to increase, reducing the generation of unused pharmaceuticals and determining how best to manage and dispose of them may become increasingly important.
The TCEQ recommends that a statewide education effort be initiated to begin providing the most current information to health-care providers, consumers and others on the topic of unused pharmaceuticals and their proper disposal. The education effort can vary in cost depending on available resources and the desired level of effort.
Introduction

Senate Bill (SB) 1757, passed by the 81st Texas Legislature, requires the Texas Commission on Environmental Quality (TCEQ) to study and make recommendations to the 82nd Legislature regarding the methods used by consumers, health-care providers, and others for disposing of unused pharmaceuticals so that they do not enter a wastewater system.

In conducting the study, the TCEQ considered:

- The current methods used for disposing of unused pharmaceuticals in Texas by consumers, health-care providers, and others;
- The alternative methods used for disposing of unused pharmaceuticals, including the methods used in other states; and
- The effects on public health and the environment of the various methods used for disposing of unused pharmaceuticals.

SB 1757 included a list of suggested stakeholders that the TCEQ could solicit input from to conduct the study. The suggested stakeholders included:

1) The Health and Human Services Commission;
2) The Department of Public Safety of the State of Texas;
3) Pharmaceutical manufacturers;
4) Pharmacies;
5) Health-care providers, including home health-care providers;
6) Hospitals;
7) Clinics;
8) Long-term care facilities;
9) Entities that engage in medical waste processing and handling;
10) Solid waste management service providers;
11) Local governments;
12) Ranchers and farmers;
13) End users of medication;
14) Water utilities and other water suppliers;
15) The United States Postal Service;
16) The United States Environmental Protection Agency; and
17) Any other entity the TCEQ considers necessary.

The TCEQ prepared this report based on information provided by the Pharmaceutical Disposal Advisory Group which included representatives from the public and private sectors, as well as state agencies. SB 1757 requires that the TCEQ submit a report of the results of the study to the legislature no later than December 1, 2010, and that the report also includes an analysis of the feasibility of implementing the recommended disposal methods on a statewide basis.
**TCEQ Study Approach**

The TCEQ developed an inter-disciplinary study team composed of ten TCEQ staff members from the areas of solid waste, water quality, water quality standards, public drinking water, environmental law, financial and strategic planning, toxicology, and pollution prevention.

The TCEQ employed a number of data collection methods throughout this study, including: review of current literature, communication with subject matter experts, coordination and communication with the TCEQ’s Pharmaceutical Disposal Advisory Group and online disposal surveys.

**Pharmaceutical Disposal Advisory Group**

The TCEQ determined that the interaction with state public health agencies as well as health-care providers and others who use or dispose of pharmaceuticals would be an integral part of this study. Additionally, pharmaceuticals in the environment and pharmaceutical disposal methods are issues being addressed within academic institutions, and are current topics of interest for local governments, drinking water and wastewater utilities and among the community.

The TCEQ voluntarily developed the Pharmaceutical Disposal Advisory Group (Advisory Group) to invite stakeholders to provide their expertise and voice their concerns in one central forum. The Advisory Group was developed as an information gathering tool to help the TCEQ understand crucial issues including:

- Who in Texas disposes of unused pharmaceuticals;
- How unused pharmaceuticals are disposed;
- What factors impact the decision to dispose of unused pharmaceuticals in a certain way;
- What challenges and constraints exist with the current methods of disposal;
- How disposal options and challenges vary across different regions of the state; and
- What disposal options are preferred by the different stakeholders and why.

Additionally, the Advisory Group provided an opportunity for stakeholders to share expertise and understand challenges. The Advisory Group was encouraged and designed for open participation to any interested person. The Advisory Group met monthly between January and June 2010. Ultimately, there were over 200 individuals involved in the Advisory Group. A web page was developed to post information about the Advisory Group, including: the purpose of the

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Advisory Group; a web link to SB 1757; information about upcoming meetings (location, agenda); a full list of stakeholders involved; and all information from past meetings (final agendas, meeting minutes, attendees and Microsoft PowerPoint presentations). Appendices A and B presents the full list of stakeholders who were involved in the Advisory Group meetings.

**Surveys**

In addition to establishing the Advisory Group, the TCEQ developed surveys for individual health-care providers, consumers and others to gain a comprehensive and more in-depth understanding of why pharmaceuticals go unused, how they are disposed and why, and any alternative options that may be available to each industry within Texas.

The Advisory Group suggested developing surveys for a number of different types of groups because they have distinct handling and disposal processes and requirements for unused pharmaceuticals. The Advisory Group suggested that surveys be developed for the following groups:

- **Group 1**: Health-Care Providers—Patient Floor (Hospitals, Clinics, Dentists)
- **Group 2**: Veterinary Providers
- **Group 3**: Pharmacies (including retail and clinical)
- **Group 4**: Waste Disposal/Management Service Providers
- **Group 5**: Pharmaceutical Manufacturers
- **Group 6**: Ranchers/Farmers
- **Group 7**: Consumers (all households in Texas)
- **Group 8**: Home Health and Hospice Providers (in-home and in-patient setting)
- **Group 9**: Drinking Water and Wastewater Utilities
- **Group 10**: Local Governments (solid waste departments, including household hazardous waste programs)
- **Group 11**: Law Enforcement
- **Group 12**: Research Institutions
- **Group 13**: Long-Term Care Facilities (nursing homes and assisted living facilities)

Comprehensive draft surveys were developed and sent to the Advisory Group, who volunteered to review the surveys and provide feedback. To facilitate a better rate of response, the Advisory Group suggested administering the surveys online. Thirteen surveys were posted on the Advisory Group’s webpage. The instructions and survey questions for each of the 13 surveys are included in Appendix C. The surveys were made available for a period of five weeks during
June and July 2010. The Advisory Group assisted with the distribution of the web links to their contacts across Texas.

The surveys were designed to be anonymous. A total of 1,581 surveys were received. Each of the 13 groups surveyed and the number of responses received in each group are identified in Table 1.

**Report Organization**

The “Introduction” section introduces the objectives of SB 1757; defines the stakeholder groups who were approached; identifies the approach the TCEQ took to complete the report; and includes the data gathering methods that were used. In addition, this section explains the sources of pharmaceuticals in the environment; provides an overview of technologies available for removing pharmaceuticals from water and wastewater; presents information on the occurrence of pharmaceuticals in various parts of the environment; and provides an explanation of the current and potential environmental standards related to pharmaceuticals.

The “Current Methods for Disposing of Unused Pharmaceuticals” section explains the current rules related to pharmaceutical management and disposal; defines how unused pharmaceuticals are currently disposed of in Texas by consumers, health-care providers and others; and discusses the effects of the current disposal methods on public health and the environment.

The “Alternative Methods for Disposing of Unused Pharmaceuticals” section identifies alternative regulatory approaches adopted in other states; explains some of the alternative methods to manage and dispose of unused pharmaceuticals by health-care providers and others; details examples of alternative approaches that have been used elsewhere for the collection and disposal of consumer’s unused pharmaceuticals; and addresses the potential impact of those alternatives on public health and the environment.

The “Analysis and Recommendations” section provides the TCEQ’s recommendations for managing and disposing of unused pharmaceuticals.
Table 1: Number of Pharmaceutical Disposal Surveys Completed

<table>
<thead>
<tr>
<th>Survey Group Number</th>
<th>Group Name</th>
<th>Surveys Completed</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Health-Care Providers—Patient Floor (Hospitals, Clinics, Dentists)</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Veterinary Providers</td>
<td>203</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Pharmacies</td>
<td>70</td>
<td>Four surveys represented a total of 344 retail pharmacies.</td>
</tr>
<tr>
<td>4</td>
<td>Waste Disposal/Management Service Providers</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Pharmaceutical Manufacturers</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Ranchers/Farmers</td>
<td>9</td>
<td>Nine surveys represented a total of 20 companies. One of those surveys represented approx. 200 cattle operations and another survey represented nineteen livestock members.</td>
</tr>
<tr>
<td>7</td>
<td>Consumers</td>
<td>860</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Home Health and Hospice Providers (In-home and In-patient setting)</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Drinking Water and Wastewater Utilities</td>
<td>85</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Local Governments (Solid Waste Department, including Household Hazardous Waste programs)</td>
<td>74</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Law Enforcement</td>
<td>81</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Research Institutions</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Long Term Care Facilities (Nursing Homes and Assisted Living Facilities)</td>
<td>149</td>
<td></td>
</tr>
</tbody>
</table>
Sources of Pharmaceuticals in the Environment

**Excretion**

Pharmaceuticals enter wastewater primarily as a consequence of their intended end-use. Once administered, a certain amount of a pharmaceutical is absorbed in the body; that amount absorbed is dependent on the characteristics of the individual taking the pharmaceutical (for example, gender, weight, age, genetics, metabolism), the timing of the dose and the pharmacokinetics of the individual drug. Residues of the parent pharmaceutical compound, and a complex array of active and inactive metabolites and other transformation products such as “degradates,”2 are then excreted by means of urine and feces, or are dislodged from the skin by sweating, bathing or swimming.3 Some drugs are excreted essentially unaltered in their free form (for example, antineoplastics, which combat the development of cancer), others are metabolized to various extents, while others are converted to even more soluble forms by the formation of conjugates.4 As a result of this, wastewater is likely to contain many more individual chemical compounds than just the original parent pharmaceutical administered.5 The suite of drugs that occur in waste streams from hospitals can differ in both classes and quantities from those emanating from private residences. Hospitals are major users of genotoxic drugs (chemotherapy agents), and it is likely that other pharmaceuticals such as x-ray contrast media would only be used in health care facilities and not households.

**Drain Disposal**

The secondary source of pharmaceuticals in the wastewater stream is through intentional disposal into the wastewater/drain. Historically, poison control centers and the health-care industry promoted the disposal of consumer’s unused and expired medications in the toilet or sink. That approach was encouraged because drain disposal was considered to be the quickest and the most unrecoverable method of removing medications from the household, in an effort to avoid potential poisonings and diversion for illicit uses.

Since distinguishing flushed pharmaceutical compounds from excreted pharmaceuticals compounds is currently not possible by chemical monitoring at this time, some have turned to more theoretical methods to determine the portion of pharmaceuticals in wastewater as a result of disposal versus intended

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2 “Degradates” are products from the environmental transformation of substances. For example, phototransformation or microbial processes may transform a pharmaceutical into different forms; those other forms would be considered degradates of the parent pharmaceutical.


4 See Daughton and Ternes, 1999.

5 Topical substances applied externally and washed off the body through bathing are more likely to contribute unaltered parent pharmaceuticals to the wastewater.
use. GlaxoSmithKline used information from consumer surveys found in the published literature (regarding what proportion of medicine goes unused as opposed to used and therefore excreted, as well as the proportion of the public that flush their unused medication as opposed to other disposal methods) to determine that greater than 90% of pharmaceuticals in wastewater is a result of excretion, or use, as opposed to intentional disposal in the drain. If more excessive estimates on the proportion of pharmaceuticals that go unused were included in that analysis, say if up to 40% of pharmaceuticals went unused, then the portion of pharmaceuticals in wastewater as a result of use and excretion would increase to about 80%. In the absence of any other information, one could use the 80-90% excretion and 10-20% disposal data as a guide, “excretion versus disposal” represents a major unanswered question on the topic of pharmaceuticals in the environment and in addressing the impact of unused pharmaceutical disposal methods.

**Wastewater and Biosolids**

The main source of human-use medicines in the environment is from discharge of treated wastewater effluents to the aquatic environment. This is because conventional wastewater treatment plants are not designed to remove synthetic compounds like pharmaceuticals and, while they remove some pharmaceuticals

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6 GlaxoSmithKline considered that about 10% of medication goes unused [(an average obtained from multiple peer-reviewed sources and scenarios, including 6.7% unused medication at long-term care facilities, based on financial data (Paone R.P., Vogenberg F.R., Caporello E., Rutkowski J., Parent R. and Fachetti F., 1996. Medication destruction and waste measurement and management in long-term care facilities. The Consultant Pharmacist, 1/1/1996, Vol. 11, 1), 13.1% unused medication at long-term care facilities, based on financial data (Bolvin M., 1997. The Cost of Medication Waste. Canada Pharm Journel, 5/1/1997, 1), 2.3% of the general public unused medication, based on financial data (Morgan T.M., 2001. The economic impact of Wasted Prescription Medication in an outpatient Population of Older Adults. The Journal of Family Practice, 9/1/2001, Vol. 50 No. 9, 1), general public 3% unused based on unit counts (Isacson, D. and Olofsson, C., 1999. Drugs up in smoke: a study of caseated drugs in Sweden. Pharm World Sci 1999; 21(2):96-99.)]. They assumed that if 10% is unused then 90% is used/taken and excreted. They also considered that 35% of the U.S. general public are flushing their unused medicine (Kuspis D.A. and Krenzelok E.P., 1996. What happens to expired medications? A survey of community medication disposal. Veterinary and human toxicology, 2/1/1996, 38(1), 1). Consequently, only 35% of that 10% (amounting to 3.5%) gets into the wastewater the remaining 6.5% does not get into the water and, therefore, of the 93.5% (90% plus 3.5%, from above) that gets into the water, 96% of it (90% of 93.5) comes from excretion after use and 3.7% (3.5% of 93.5) comes from flushing unused medicine. Additionally, they acknowledged that because the unused medicine is not metabolized it will contribute more, possibly around 4.5%, noting that metabolism is different for every compound. Taking that into account as much as possible without scientific data, they estimate that >90% of active parent pharmaceuticals in wastewater are from patient excretion and less than 10% is due to intentional disposal of unused medication. This represented the only known estimate of patient excretion versus disposal; no other empirical or theoretical data was available at the time of writing though they may become available in the future.

7 For example, Berckmans et al. (1997) cites work claiming that about 40% of drugs marketed in France annually remain unused [Berckmans, P., Dawans, V., Schmets, D., Vandenbergh, D. and Autier, P., 1997. Inappropriate Drug-Donation Practices in Bosnia and Herzegovina, 1992-1996. New England Journal of Medicine, Vol. 337 (25), p1842-1845]. Adopting the same analytical process as GlaxoSmithKline, if 40% are unused, then 60% are used and excreted and added to the wastewater. If 35% of the public flush their unused medications that equals 14% that gets into the wastewater system from flushing (35% flushed out of 40% unused). That totals 74% of pharmaceuticals in the wastewater (60% from use and 14% from flushing unused). Therefore 81% of the pharmaceuticals in wastewater would be a result of excretion/use (60% divided by the 74% in the wastewater), leaving 19% a result of intentional flushing (or 14%intentionally flushed divided by the total 74% in wastewater).

8 See Daughton and Ternes, 1999.
from the wastewater depending on the wastewater characteristics and the treatment technologies and operations employed at the plant, it is possible for some amount of pharmaceuticals to pass through the plant and remain in the treated wastewater discharge.

Many times, treated wastewater is either directly discharged to a surface water body or applied to land for irrigation purposes. Human-use pharmaceuticals may therefore impact soil primarily through the application of sewage sludge or “biosolids” as fertilizer to agricultural land, or irrigation of crops with treated wastewater.\(^9\)\(^{10}\) Approximately 60% of biosolids in the United States is directed to beneficial use (e.g. land application, advanced treatment such as composting).\(^11\) Additionally, pharmaceutical compounds deposited on the land may run off from soil into surface waters after rainfall events.\(^12\)\(^{13}\) Furthermore, it is possible for pharmaceuticals in biosolids and wastewater applied to land to be taken up by plants.\(^14\) Leakages and overflows from wastewater treatment plants and sewer drains may also occur, and as with soils, rainfall events may wash these compounds into nearby surface waters.\(^15\) There is also potential for pharmaceuticals and other compounds to leach into groundwater following the land application of wastewater and biosolids.

In some cases, untreated sewage finds its way into the environment. Approximately 25% of the nation’s population is not connected to a reticulated wastewater system, and instead they discharge their raw wastewater to septic tanks and leach fields. Septic overflows are possible, as well as leakage from aging storage units. As a result, septic systems and leach fields serve as potential sources of groundwater contamination. Daughton and Ternes (1999) quoted a media article noting that possibly more than a million homes in the United States do not have sewage systems but instead rely on direct discharge of raw sewage into streams by straight-piping\(^16\) or by outhouses not connected to leach fields. Illegal drug operations and laboratories may also discharge untreated wastewater to water bodies and therefore contribute illicit pharmaceuticals to


\(^14\) See Daughton and Ternes, 1999, and Daughton, 2007.


\(^16\) Straight-piping is the practice where untreated, raw sewage is illegally discharged without treatment directly to the environment immediately from the point of origin, often private residences. From Daughton and Ternes
the environment. Finally, the discharge of treated and untreated sewage from cruise ships probably presents another source of pharmaceuticals to the aquatic environment, though likely insignificant in terms of the overall environmental load.\(^\text{17}\)

**Agricultural Activities**

Pharmaceuticals are used in agricultural and aquaculture practices. Pharmaceuticals used by terrestrial animals (both domestic and farmed) leads to the direct deposition of residues on land by means of excrement. Cattle excretions, for example, have been shown to contain quantities of steroidal hormones.\(^\text{18}\) Therefore, the major transport routes for pharmaceuticals to enter the environment in animal husbandry operations may include runoff from impermeable surfaces and leaching through soil to groundwater.\(^\text{19}\)

**Manufacturing**

The manufacturing of pharmaceuticals can be divided into two main stages: the production of the active pharmaceutical ingredient (API) and the manufacture of the finished drug into a readily useable form (such as a tablet or syrup). In pharmaceutical manufacturing facilities, synthesis and purification of APIs are usually achieved with organic solvents that are often reused in the synthesis process and are then treated or disposed of by incineration.\(^\text{20}\) However, there may be the potential for some contribution to wastewater and the aquatic environment via the API development component. In pharmaceutical product manufacturing, most generated waste is solid, and this material is commonly incinerated (Williams 2005). Therefore, discharges of pharmaceuticals from the product finishing component into the aquatic environment are expected to be small. Releases from pharmaceutical manufacturing are generally well regulated in the United States. The United States Geological Survey (USGS) led a recent study on the contribution that pharmaceutical formulation facilities may have on the concentrations of pharmaceuticals in the wastewater, as identified in wastewater treatment plant effluents in New York. The study demonstrated that while a broader range of pharmaceuticals are commonly found in wastewater treatment plant effluents and streams below treated wastewater discharges (generally at <1 \(\mu\)g/L), specific sources such as pharmaceutical formulation facilities can lead to circumstances where pharmaceutical concentrations are 10-1000 fold higher than generally measured in wastewater treatment plant effluent.

\(^{17}\) See Daughton, 2007.


samples without such input. Consequently, while pharmaceutical manufacturing and formulation facilities in the United States are well regulated and most likely incinerate the bulk of unused product, there is still the potential for them to act as a source of pharmaceuticals in the environment via the wastewater.

Landfills

Pharmaceuticals can be introduced to landfills directly by domestic (household trash) and industrial waste disposal. An additional indirect route exists because approximately 17% of biosolids from wastewater treatment plants in the United States are landfilled, and those biosolids may contain some measurable amounts of pharmaceuticals.

Unregulated, unlined landfills, or poorly constructed or maintained landfills could potentially contribute pharmaceuticals to groundwater. Landfill leachate may also collect pharmaceuticals or their transformation products. Most Type I landfills in Texas send leachate to a privately or publicly owned wastewater treatment plant. A Type I landfill is a facility that can accept solid waste resulting from or incidental to municipal, community, commercial, institutional, and recreational activities, including garbage, rubbish, ashes, street cleanings, dead animals, abandoned automobiles, and all other solid waste other than industrial solid waste. Other options for the management of landfill leachate noted in TCEQ’s permits include re-circulation of the leachate back into the landfill, solidification and evaporation in a lined surface impoundment. Out of 36 Type I landfill permits reviewed, all were authorized to discharge leachate to a wastewater treatment plant, 22 were authorized to recirculate leachate, two landfills had leachate evaporation surface impoundments, and one was authorized to solidify the leachate in a lined liquid waste solidification unit. No Type I landfills in Texas treat leachate to the point that it may be discharged to surface water.

Consequently, the generation of landfill leachate may potentially contribute some pharmaceuticals to the environment through the contribution to wastewater treatment plants and if the landfills themselves are poorly designed or maintained.

Technologies for Removing Pharmaceuticals from Wastewater and Drinking Water

Treatment technologies are currently available for use at both wastewater treatment plants and drinking water treatment plants that are capable of reducing the concentrations of most known pharmaceuticals (those that have

23 It should be noted that there are no landfills in Texas that are still operating unlined pre-subtitle D cells.
been sampled/analyzed for, to date). The majority of pharmaceuticals removed under primary and secondary treatment processes at conventional wastewater treatment plants will be removed via biological treatment processes, as opposed to chemical or mechanical processes. However, some pharmaceuticals in wastewater cannot be removed by biological treatment. As a result, it is possible for wastewater treatment plants in Texas that are limited to conventional treatment processes to contribute some pharmaceuticals to their discharging water bodies or land application areas. In drinking water treatment, chlorination, ozonation, activated carbon, and high energy UV can remove some pharmaceuticals from raw water, however, they do not remove all pharmaceuticals to below detection.

Removal of many of the remaining pharmaceuticals present following conventional wastewater and drinking water treatment processes is possible through advanced technologies such as reverse osmosis and nanofiltration. It is possible for a few pharmaceuticals to remain in the water (at current detection limits) following treatment by reverse osmosis and nanofiltration but those instances and compounds are very limited. The implementation of these advanced technologies, although effective for removing pharmaceuticals, will result in additional capital, operation and maintenance costs for treatment. These costs will vary depending on the size, configuration and purpose of each facility and may be substantial. For example, estimated initial capital plus 10 years of operating costs for granulated activated carbon (GAC) adsorption facilities were quoted at approximately $131,000 for a 1 million gallons per day (MGD) drinking water treatment plant and approximately $2.5 million for a 76 MGD water plant. While noting that the costs are not directly comparable to Texas, the additional capital cost for reverse osmosis and advanced oxidation process (AOP) systems at a proposed 32 MGD wastewater treatment plant in Arizona is estimated to be $200 million to $250 million; the additional operation and maintenance costs are estimated to be $15 to $20 million per year. Since pharmaceuticals in wastewater and drinking water are not currently regulated in Texas or nationally by the EPA, there is limited incentive to adopt these potentially costly additional treatment processes at this time.

Some innovative wastewater and drinking water utilities, as well as utility associations, research groups and federal agencies have made a concerted effort over the last 10 years to understand the issue of pharmaceuticals from the water and wastewater perspective. A significant amount of work has been performed to date on assessing the effectiveness of conventional and advanced treatment technologies for removing pharmaceuticals during wastewater and drinking water treatment and some generalizations and conclusions about removal efficiencies have been made. Since the characteristics of raw wastewater and drinking water sources vary across the United States, the specific removal efficiencies found in the research conducted to date will not reflect the

effectiveness of every wastewater or drinking water treatment plant in Texas. At this time, there are few laboratories in the state capable of conducting analyses for pharmaceuticals (and those that exist are expensive), nor are there guidelines for what pharmaceuticals would be the most pertinent to test for. These factors, combined with the lack of regulations regarding pharmaceuticals in wastewater and drinking water as noted above, may result in little impetus for the average utility in Texas to test for pharmaceuticals in wastewater and drinking water at this time.

Occurrence and Regulation of Pharmaceuticals in the Environment

Over the last ten years a wealth of information has emerged on the occurrence of pharmaceuticals in ambient surface waters, wastewater, sewage sludge, raw water supply sources, finished drinking water, groundwater, landfill leachate, aquatic life and sediment. While some use the term “emerging contaminants” when referring to pharmaceuticals in the environment, in most cases, the chemicals have been used and would have likely existed in the environment for a long time. Only due to improved analytical instrumentation and more sensitive analytical methods, are we now able to detect these substances in environmental samples at very low concentrations, and as such, are “emerging” as a potential issue. Additionally, some substances included in “emerging contaminant” occurrence studies, are naturally produced by the body and excreted, such as the hormone estradiol, as opposed to those that are man-made, such as the synthetic hormone 17α-ethynyl estradiol.

Most of the studies on pharmaceuticals in the environment have focused on detections; that is, whether or not pharmaceuticals could be detected in the media, as opposed to focusing on the toxicological impact of the actual levels identified. Before delving into the occurrence studies, it must be recognized that the findings may not be representative of all streams, groundwater, drinking water sources, leachate, fish or other components of the environment across the United States, throughout the year. Most occurrence studies are highly targeted in that the selection of surface water sample locations is usually directed to areas susceptible to contamination, such as locations downstream of intense urbanization or livestock or known to be wastewater effluent-dominated. Additionally, the studies are only based on discrete samples (sometimes not even representing an average concentration from multiple samples) that often do not take into account low or high flow periods. The temporal fluctuations are especially important when addressing pharmaceutical occurrence in wastewater effluent. Nevertheless, identifying the occurrence of pharmaceuticals in various parts of the natural or man-made environment is the fundamental initial step in understanding the sources and fate of pharmaceuticals in the environment and whether or not the concentrations found in the environment should be considered an ecological or human health risk.

This section introduces the more significant studies performed to date on pharmaceuticals in: ambient surface water (streams), groundwater, raw drinking water sources, pre- and post- wastewater and drinking water treatment, landfill
leachate, fish and soils. In most cases national studies are cited, but other important regional and Texas-based studies are noted where data were available.

**Surface Water**

In 1999 and 2000, the United States Geological Survey (USGS) conducted the “National Stream Reconnaissance Study” to identify the occurrence of organic wastewater contaminants (OWCs) in 139 streams across 30 states that were thought to be susceptible to contamination from agriculture or urban activities. Of the 95 contaminants analyzed for in this study, a significant number were prescription and over-the-counter (OTC) pharmaceuticals and were chosen because they were expected to enter the environment through human, industrial or agricultural wastewater pathways, are used in significant quantities, may have human or environmental health implications, and could be accurately measured using available technologies. These included many human and veterinary antibiotics and their metabolites, prescription analgesics, cardiac stimulants, anti-hypertensives, antidepressants, anti-diabetics, anticoagulants, steroids and hormones (both natural and synthetic) among others, and common OTC pharmaceuticals such as caffeine, nicotine, acetaminophen and the anti-inflammatory ibuprofen. Of the 139 streams sampled in this study, one was located in the Trinity River downstream of Dallas in North Texas.

The results of the National Stream Reconnaissance Study showed that one or more of the emerging contaminants (including the non-pharmaceuticals tested) were found in 80% of the streams sampled. Eighty-six percent (82 of 95) of the contaminants targeted this study were detected in at least one sample; only eight antibiotics and five prescription pharmaceuticals were not detected in any of the samples analyzed. More frequently detected pharmaceuticals included caffeine (stimulant), cotinine (nicotine metabolite), acetaminophen (antipyretic), dehydronifedipine (antianginal), diltiazem (an antihypertensive), and codeine (analgesic) in 71%, 38%, 24%, 14%, 13% and 11% of samples, respectively. Steroids and hormones were also commonly found in surface waters, with the birth control hormone active ingredients 17α-ethynyl estradiol and mestranol found in 16% and 10% of samples, respectively. Some antibiotics were also found in the surface water samples, including the antibiotics trimethoprim and sulfamethoxazole, both used in humans for urinary tract infections, which were detected in 27% and 19% of samples analyzed, respectively. In general, non-prescription drugs (OTCs) were found in greater frequency than antibiotics, reproductive hormones and prescription drugs. Of the many pharmaceuticals analyzed in the sample collected from the Trinity River downstream of Dallas, only 6 substances were detected above their analytical reporting levels; those were caffeine, cotinine, dehydronifedipine, tylosin (veterinary antibiotic), cholesterol (plant/animal steroid) and coprostanol (fecal steroid). All of those detected substances in the Trinity River sample were detected at concentrations

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less than 0.6 micrograms per liter (µg/L). The National Stream Reconnaissance Study concluded for the first time that pharmaceuticals can be detected at low concentrations in streams in the United States. Additionally, the study confirmed that organic wastewater contaminants tend to occur in mixtures, with 75 percent of the streams sampled in this study having more than one OWC identified. Contaminants in this national study were analyzed at the parts per billion (ppb), or micrograms per liter (µg/L), level, and many of the median concentrations for each chemical were found to be less than 1 ppb.

**Groundwater**

Following the first National Stream Reconnaissance Study, the USGS conducted another study to collect baseline information on the environmental occurrence of emerging contaminants in groundwater in the United States. In the National Groundwater Reconnaissance Study, water samples were collected from a network of 47 groundwater sites across 18 states in 2000 and analyzed for 65 different emerging contaminants, some of which were pharmaceuticals. Site selection focused on a variety of geohydrologic areas suspected to be susceptible to contamination from either animal or human wastewaters and were in aquifers not necessarily used as a source of drinking water. One groundwater site included in the study was located in central Texas.

The organic wastewater contaminants studied were detected in 81% of the groundwater sites sampled, with 54% of the contaminants being found at least once. The most frequently detected pharmaceutical in the groundwater samples was sulfamethoxazole (a veterinary and human antibiotic), found in 23% of samples. The concentrations of chemicals detected in groundwater were very low; most were less than 1 microgram per liter (µg/L). Mixtures of chemicals were common. Although similar chemicals were detected in the previous National Stream Reconnaissance Study, the chemicals were detected less frequently in the ground-water sites (35 percent of the sites) than they were in the stream reconnaissance (86 percent of the sites). The study noted that, although sampling procedures were intended to ensure that all groundwater samples analyzed were indicative of aquifer conditions, it is possible that detections of some OWCs could have resulted from leaching of well-construction materials or other site-specific conditions related to well construction and materials.

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30 See Barnes, et al., 2008,
Several studies have focused on the occurrence of pharmaceuticals in groundwater known to be impacted by human activities, including a study on groundwater impacted by domestic septic systems in Cape Cod, Massachusetts, and shallow groundwater impacted by leachate from unlined municipal landfills in Elkhart, Indiana, and Norman, Oklahoma. Although some pharmaceuticals in these targeted studies were not detected at the sub-µg/L detection limits, where detections occurred, pharmaceuticals were generally shown to occur in µg/L or sub-µg/L concentrations. In the Indiana study, for example, ibuprofen was detected in one out of the three observation wells downgradient of the unlined landfill at 3.1 µg/L; in the same study acetaminophen, 1, 7-dimethylxanthine and cotinine were each detected once at 0.022, 0.057 and 0.10 µg/L, respectively. At the Norman unlined landfill site in Oklahoma, of the 21 antibiotics (including antibiotic metabolites) tested in four groundwater wells located within the leachate plume only one was detected above reporting limits (lincomycin, detected at 0.10 µg/L in one well downgradient of the landfill). Additionally, only one of the 15 prescription and OTC pharmaceuticals tested was detected in the leachate-impacted groundwater, and the highest concentration detected in the groundwater was 0.13 µg/L.

**Raw Drinking Water Sources**

The occurrence of prescription and OTC pharmaceuticals, and their metabolites, has been studied in untreated ground waters and surface waters that may become future sources of drinking water. These are referred to as “raw” drinking water sources and would usually involve treatment before being consumed.

Another of the targeted national-scale studies conducted by the USGS to collect baseline information on the environmental occurrence of pharmaceuticals and other emerging contaminants was the “National Source (Untreated Drinking) Water Reconnaissance Study”. Water samples were collected from untreated sources of drinking water at 25 groundwater and 49 surface water sites in 25 states and Puerto Rico in 2001 and analyzed for 100 analytes with sub-µg/L detection capabilities. Samples were collected prior to any water treatment. The study found that 63% of the targeted chemicals were detected in at least one water sample, however 60% of the 36 pharmaceuticals (including prescription drugs and antibiotics) analyzed were not detected in any water sample. The most

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32 Landfill leachate is the substance derived from the interaction of infiltrating water with fluids, solids and gases within the landfill waste. Definition from Buszka et al. 2009.


34 Various research conducted on the Norman, OK, landfill site can be found at <ok.water.usgs.gov/projects/norlan>.

frequently detected pharmaceuticals in surface water were cotinine and 1,7-dimethylxanthine (nicotine and caffeine metabolites, respectively); and in groundwater were carbamazepine (anti-epileptic) and 1,7-dimethylxanthine. Overall, detections were more common in water collected from surface water sites than from groundwater sites, and the maximum concentrations of the measured chemicals were only slightly above detection levels.\textsuperscript{36} 

As part of a larger study on the occurrence of pharmaceuticals and endocrine disrupting compounds in public drinking water systems in the United States, at least one raw water sample was collected from the source water for 19 drinking water treatment plants.\textsuperscript{37} Those raw samples, 18 of which were from surface water sources and only one was from a raw groundwater source, would later be treated and provided to customers as drinking water. Prior to treatment, samples were analyzed for 20 pharmaceuticals, 4 naturally-synthesized steroid hormones and a synthetic steroid hormone, in addition to other potentially endocrine-disrupting compounds. In the raw/untreated source water samples, five pharmaceuticals were not detected, even with the very low, sub-ng/L, detection limits. The three pharmaceuticals detected at the highest concentrations in the raw water samples were sulfamethoxazole, meprobamate and carbamazepine, found at 110, 73 and 51 ng/L, respectively (found in discrete samples; the median concentrations of those pharmaceuticals from all raw water samples were approximately 10\% of those maximum levels). As may be expected, the drinking water treatment plants utilizing water from reservoirs with no direct input of wastewater and where no recreational use is permitted had the lowest number of compounds detected in source waters (note, that comparison is based on all compounds analyzed, not solely pharmaceuticals). Interestingly, the four drinking water treatment plants that utilized water from reservoirs with no direct wastewater input, but where recreational use is allowed, had similar numbers of individual compounds detected in their source waters as compared to those plants withdrawing water from wastewater impacted source water.

In conjunction with the USGS, the San Antonio Water System (SAWS) arranged for two Edwards Aquifer wells within the City of San Antonio to be sampled and analyzed for a range of pharmaceuticals, including 19 steroids and hormones and 14 other pharmaceutical compounds, in February 2009.\textsuperscript{38} Groundwater from the Edwards Aquifer is the primary source of drinking water for the City of San Antonio. The group of hormones was analyzed with detection limits at the parts per trillion [nanograms per liter (ng/L)] level, and the rest of the pharmaceutical compounds were analyzed with detection limits at the parts per billion [micrograms per liter (\(\mu\)g/L)] level. The results indicated that there were no detected concentrations of the 33 compounds found in the SAWS's water supply wells.

\textsuperscript{36} <toxics.usgs.gov/highlights/gwsw_ec.html>  
\textsuperscript{38} Diehl, K., 2010a. Information and data regarding the SAWS study on Edwards Aquifer water supply wells was provided by Mr. Ken Diehl, San Antonio Water System, via electronic correspondence on 17 December 2009.
Pre- and Post- Treatment Occurrence Studies – Wastewater and Drinking Water

A number of studies have attempted to understand the occurrence of pharmaceuticals in water samples pre- and post- wastewater treatment, and pre- and post- drinking water treatment.

One significant piece of work by the American Water Works Association Research Foundation (AWWARF) was a study initiated to determine the removal of endocrine disrupting compounds during a variety of conventional and advanced drinking water treatment processes using bench-, pilot- and full-scale evaluations.39 The study report provides a comprehensive literature review of other drinking water treatment removal studies. Additionally, in August 2010, the EPA released report EPA-820-R-10-002, Treating Contaminants of Emerging Concern, A Literature Review Database.40 The report contains the results of an extensive review of the recent literature on wastewater treatment technologies and their ability to remove a number of chemical contaminants of emerging concern (CECs).

In the study of pharmaceuticals and endocrine disrupting compounds in public drinking water systems in the United States, referenced in the raw drinking water conducted by USGS,41 samples were also collected of the finished drinking water immediately after treatment and in distribution (where the water is served to customers). Compounds were less frequently detected in finished water as compared to source water. The pharmaceuticals carbamazapine, gemfibrozil and sulfamethoxazole were detected in finished water. However, the median concentration of compounds detected in finished water were less than 10 ng/L (except for a few personal care products, like the active ingredient in insect repellent and fragrances, a herbicide and a food preservative). In water samples collected in the water distribution system (“tap water”), even fewer compounds were detected than in the finished water immediately after treatment. Meprobamate and phenytoin (anti-convulsant) were detected in greater than half of the distribution samples but, again, at low concentrations.

The following two studies focus on research undertaken within Texas to identify the occurrence of pharmaceuticals pre- and post- drinking water or wastewater treatment.

In 2006, in an effort to establish baseline data for its water supply, the City of Arlington, Texas, arranged for water samples to be collected in its raw water supply and treated (finished) water at two drinking water treatment plants and analyzed for a number of pharmaceuticals.42 Pharmaceuticals included in this study were sulfamethoxazole (antibiotic used to treat urinary tract infections), meprobamate (an anti-anxiety/sedative product), dilantin (an antiepileptic drug), carbamazepine (an anticonvulsant/antiepileptic) and naproxen (an anti-

41 See Benotti et al. 2009.
42 Hunt, J., 2010. Information and data regarding the City of Arlington Drinking Water Treatment Plant study was provided by Ms. Julie Hunt, Director of Water Utilities, City of Arlington, via electronic correspondence on 17 December 2009.
inflammatory drug). The samples were analyzed at the parts per trillion [nanograms per liter (ng/L)] level. Results indicated that each of the pharmaceuticals were detected in the raw water entering both drinking water treatment plants, except for naproxen which was only detected above the analytical detection limits in raw water for one of the two drinking water treatment plants. However, only one of the pharmaceuticals (meprobamate) was detected in the finished treated drinking water that would be distributed to customers; the other pharmaceuticals tested were not present above detection limits in finished water generated from either of the two plants. Concentrations detected were low in this study, the highest concentration of a pharmaceutical in the raw water was 3.5 ng/L (meprobamate), and the highest concentration of the only detected compound found in the finished drinking water was 1.4 ng/L. If the detection limits of these chemical analyses were higher (that is, less sensitive, for example at the part per billion or µg/L level) then it is highly unlikely that any of the pharmaceuticals analyzed would have been detected in either the raw or treated drinking water samples.

Texas State University in San Marcos, in conjunction with the City of San Marcos, Texas, conducted a study on endocrine disruptors in 2006 and 2007.43 Water samples were collected from: the San Marcos River, influent and effluent of the San Marcos Wastewater Treatment Plant, a hospital’s wastewater discharge and the raw and treated/finished water entering and leaving the San Marcos Drinking Water Treatment Plant. Those samples were analyzed for 24 compounds, including 13 pharmaceuticals. The detection limits for those samples were at the parts per trillion (ng/L) level. Data show that the San Marcos Wastewater Treatment Plant was effective in removing many of the compounds in the study; although several pharmaceuticals including carbamazepine, diltiazem, sulfamethoxazole, the naturally-produced hormone estradiol and the fecal steroid coprostanol were detected in water samples collected from the wastewater effluent. However, none of the compounds were found at detectable levels in the finished drinking water following final treatment at the San Marcos Drinking Water Treatment Plant.

Landfill Leachate

Most landfill studies related to pharmaceuticals have focused on the occurrence of pharmaceuticals in landfill-leachate impacted groundwater below unlined (usually closed) landfills. However, limited information exists on the occurrence of pharmaceuticals in leachate at landfills that are still accepting municipal waste. One study on the occurrence of pharmaceuticals in landfill leachate is that performed by the Maine Department of Environmental Protection (DEP) in October 2009.44 The following information has been taken directly from the Maine DEP’s preliminary report. The Maine DEP collected and analyzed leachate samples from three municipal solid waste landfills (August, Bath and

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43 Sprencel, E., 2009. Final unpublished report on the San Marcos Organic Wastewater Contaminant study was provided by Mr. Ed Sprencel, City of San Marcos, Texas, via electronic correspondence on 16 December 2009.  
Brunswick) to assess the types and concentrations of pharmaceuticals that may be present. The landfills were selected because they have engineered liner systems that serve to contain and collect leachate, have received significant quantities of household waste, and have received little or no sludge from municipal wastewater treatment plants. By selecting landfills that do not receive appreciable amounts of wastewater treatment plant sludge, the Maine DEP proposed that one may conclude that any pharmaceuticals detected in the leachate result from their direct disposal via household waste rather than their indirect disposal via excretion and assimilation into wastewater treatment plant sludge. Samples were analyzed for 135 individual pharmaceutical and personal care products and detection limits were at the ng/L level. Results showed that the leachate samples contained a large number of pharmaceuticals and personal care products (PPCPs); 47 out of the 135 target analytes (or 34%) were detected in at least one of three samples. Twenty compounds were found in all three leachate samples. Some of the pharmaceuticals detected in all three landfills include: albuterol (asthma relief), atenolol (high blood pressure medication), carbamazepine, cimetidine (ulcer and acid reflux medication) cotinine, gemfibrozil (lipid regulator) and ibuprofen, among several others. The highest concentration of a pharmaceutical detected in any of the landfill leachate samples was 117,000 ng/L (0.117 µg/L) of acetaminophen, though the compound was not detected at quantifiable levels in one of the three landfills.

**Biosolids and Soil**

Limited studies have been performed on the occurrence of pharmaceuticals in the biosolids\(^4\) that are generated from wastewater treatment and are commonly applied to land for soil amendment purposes. Additionally, few studies have been undertaken on the occurrence of pharmaceuticals in soil irrigated with treated wastewater effluent. The studies below present the most significant and well known studies that focus on these two aspects of understanding the occurrence of pharmaceuticals in various components of the environment.

To identify the presence of pharmaceuticals and other household chemicals in biosolids generated from wastewater treatment, USGS researchers obtained nine different commercially or publicly available biosolids and analyzed them for 87 organic chemicals found in cleaners, personal care products, pharmaceuticals, and other products.\(^{46}\) Fifty-five of the 87 organic chemicals measured were detected in at least one of the nine biosolids collected, with as many as 45 chemicals found in a single sample. Twenty-five of the chemicals were present in every biosolid sample. Three of those were pharmaceuticals; the median concentrations of the antiepileptic drug carbamazepine, the antihistamine diphenhydramine, and the antidepressant fluoxetine found in the biosolids were

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\(^4\) Biosolids are the treated sludge generated by the treatment of sewage at wastewater treatment plants.

68, 340 and 370 \( \mu g/kg \),\(^{47}\) respectively. The results of this study indicated that biosolids have high concentrations of emerging contaminants compared to treated liquid wastewater effluent.

The USGS also monitored three sites in Colorado from May through September 2003 to assess the presence and distribution of pharmaceuticals in soil irrigated with reclaimed water from an urban wastewater treatment plant.\(^{48}\) Soil cores were collected before, during, and after the irrigation season on a monthly basis and tested for the presence of 19 pharmaceuticals. In addition, samples of reclaimed wastewater used for irrigation were analyzed three times during the study to assess the input of pharmaceuticals from the wastewater. The study found that soil samples collected before the irrigation season in 2003 contained pharmaceuticals, including erythromycin (an antibiotic), carbamazepine, fluoxetine (an antidepressant), and diphenhydramine (a common non-prescription antihistamine), which were most likely left over from the previous year’s irrigation. Several of the pharmaceuticals detected in the soil cores increased in concentration during the study, which suggests that the soil retained or absorbed the pharmaceuticals. Several other pharmaceuticals appeared to be transported through the soil zone to greater depths. Throughout the study, measured concentrations of pharmaceuticals were low (0.02 to 15 milligrams/kilogram dry soil). The results of this study demonstrate that use of reclaimed water can result in the presence and accumulation of pharmaceuticals in soil.

**Aquatic Life**

A national pilot study was initiated in the United States to assess the accumulation of PPCPs in fish sampled from five effluent-dominated rivers that receive direct discharge from wastewater treatment facilities in the USA.\(^{49}\) The sites were selected primarily because they were effluent dominated river segments near wastewater treatment plant (WWTP) discharges, subject to different levels of treatment, and therefore detections of PPCPs, was expected to occur. The Trinity River, in Dallas, Texas, was one of the five sites selected in this study. The WWTP that discharges to the Trinity River uses advanced treatment ("wastewater discharged after receiving biological treatment, physical or chemical treatment, or both") with nutrient (nitrogen or phosphorous) removal. In October 2006, 18 adult smallmouth buffalo fish were collected from the Trinity River downstream of the WWTP discharge. The fillets of the 18 fish

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\(^{47}\) Median concentrations were normalized to organic carbon and given in micrograms per kilogram of organic carbon.


were composited and screened for 36 target chemicals: 24 pharmaceuticals and 12 PCPs, while the fish liver specimens were screened for pharmaceuticals only.

The results from the five-river study showed that the total number of compounds detected, the concentration of compounds detected, and the frequency of detection were higher in liver tissue than fillets.

Antidepressants (norfluoxetine, sertraline), an antihistamine compound (diphenhydramine), an antihypertension compound (diltiazem), an antiseizure compound (carbamazepine), and an antimicrobial compound (triclosan) were not detected at the method detection limits in any of the six fish fillet composite samples collected from the Trinity River. 50

Among fish liver composites, the antidepressant norfluoxetine was most frequently detected, identified in samples from all five rivers, and in four of the six fish liver composite samples collected from the Trinity River. Also detected in fish liver samples from the Trinity River were the antidepressant sertraline and the antihistamine diphenhydramine.

An important point to note is that 17 pharmaceuticals and eight personal care products were not detected (at the ng/L method detection limit) in any of the fish fillet or liver samples in this study. Additionally, in this study, fish tissue analyses from the two sampling sites receiving more advanced treatment (Dallas, Texas - feeding the Trinity River, and Orlando, Florida) showed lower overall concentrations of PPCPs, fewer compounds detected, and lower frequency of detection compared to the other three sampling sites which employed less advanced treatment, according to National Pollutant Discharge Elimination System data.

Drinking Water Standards

Under the Safe Drinking Water Act (SDWA), EPA sets legal limits, known as Maximum Contaminant Levels (MCLs), on the levels of certain contaminants (physical, chemical, biological, or radiological substances) in drinking water that is supplied by regulated public drinking water systems to consumers. Those MCLs reflect both the level that protects human health and the level that water systems can achieve using the best available technology. The SDWA rules also define water testing schedules and methods and list acceptable techniques for treating contaminated water.

Currently, there are over 80 contaminants included in the National Primary Drinking Water Regulations51, which are enforceable drinking water standards related to acute or chronic human health effects. 52 Those are in addition to a

50 However, galaxolide and tonalide, both fragrances (not pharmaceuticals), were detected in all 6 fish fillet composite samples in the Trinity River, with maximum concentrations of 1800 nanograms per liter (ng/g) and 150 ng/g, respectively.
51 See <www.epa.gov/safewater/contaminants/index.html>.
52 Acute effects occur within hours or days of the time that a person consumes a contaminant and typically don't have permanent effects, while chronic effects occur after people consume a contaminant at levels over EPA's safety standards for many years. For further information see <www.epa.gov/ogwdw000/dwh/health.html>.
number of National Secondary Drinking Water Regulations which are non-enforceable guidelines for contaminants that may cause cosmetic effects or aesthetic effects as a result of their consumption in drinking water.

No pharmaceuticals are currently included in the National Primary or Secondary Drinking Water Regulations. This means that public water systems, which provide drinking water to over 95 percent of the nation’s population, are not required to sample their finished (treated) water for the presence of pharmaceuticals and are not required to meet any legal limits if they do voluntarily test their water because the legal limits for pharmaceuticals in drinking water are not established. The fact that legal limits have not been established for pharmaceuticals in drinking water may be due to a number of reasons; analytical methods have not been sensitive enough to detect pharmaceuticals in water samples until recently, EPA approved analytical methods have not yet been developed for a wide range of pharmaceutical compounds, occurrence data for pharmaceuticals in the environment and in drinking water is not widespread across the country and human health risk assessments have not been conducted on many pharmaceutical compounds.

While pharmaceuticals are not currently within the EPA’s or TCEQ’s regulatory authority for drinking water, the EPA does develop a Contaminant Candidate List (CCL) which identifies substances that are not currently subject to the National Primary Drinking Water Regulations.

In October 2009, a select group of pharmaceuticals were included on the CCL3. Eleven active pharmaceutical ingredients and another two substances used in the development of pharmaceuticals are included in the CCL3. Pharmaceuticals in the CCL3 are mainly hormones and substances that are used in antibiotics and anti-malarial pharmaceuticals.

In Texas, surface water and groundwater are not routinely tested for pharmaceuticals. At the present time, no water quality criteria for specific pharmaceuticals have been established by the EPA or the State of Texas with respect to aquatic life protection. Pharmaceuticals are usually not referenced in the TPDES permitting process or the TCEQ’s Rivers, Lakes and Estuaries programs (for example, the Clean Rivers Program, Total Maximum Daily Load Program, or the Non-Point Source Pollution Program). The numerical criteria for toxic materials found in 30 TAC § 307.6 do not specifically include active pharmaceutical ingredients as contaminants of concern.

53 Lindane is included in the National Primary Drinking Water Regulations, and although it is not specifically a pharmaceutical it is an ingredient in shampoo for lice control.


pharmaceutical ingredients. The most likely way that pharmaceuticals would fall within the coverage of current water quality rules is if a major discharger created a toxic condition with its effluent because of a pharmaceutical waste, and either a WET limit or Chemical Specific Limit were sufficient to identify it or control it.

**Environmental Monitoring Associated with Permitted Municipal Solid Waste Landfills**

A Subtitle D permitted Municipal Solid Waste (MSW) landfill is required to be lined, have a leachate collection system capable of maintaining less than one foot of leachate on the landfill liner, have a methane monitoring system, and have a groundwater monitoring system capable of determining water quality and detecting a release from the waste management unit for the active life and 30 year post-closure period of the landfill. A standard groundwater monitoring system consists of a sufficient number of groundwater monitoring wells spaced no greater than 600 feet apart and within 500 feet of the down gradient edge of the waste management unit. Landfill permittees are required to establish background groundwater quality, sample and analyze groundwater from each well every six months for the hazardous constituents identified in Appendix I of Title 40 of the Code of Federal Regulations (C.F.R.) Part 258, and conduct a statistical evaluation of the groundwater sampling data with the established background groundwater quality as required by 30 TAC § 330.407. The Appendix I list of constituents does not include specific pharmaceutical compounds and is mainly a list of chlorinated solvents. If a hazardous compound is determined to be statistically greater than background groundwater quality, then the facility is considered to have contaminated groundwater and must conduct assessment monitoring to determine the health risk of contamination. Currently, no sediment quality sampling is required for pharmaceuticals or any other compound at or surrounding MSW landfills.

**Environmental Monitoring Associated with Permitted Industrial and Hazardous Waste Disposal Units**

A Subtitle C industrial and hazardous waste disposal unit, which include landfills and surface impoundments, are required to be lined and have a groundwater monitoring system capable of detecting a release of hazardous constituents at the point of compliance which is the down gradient edge of the unit. A standard groundwater monitoring system consists of a sufficient number of groundwater monitoring wells spaced between 150-200 feet apart by agency practice. The unit operator is required to sample for the hazardous constituents

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56 However, hexachlorocyclohexane (lindane) is listed and is used in the manufacture of shampoo used as a second-line therapy for control of lice.
57 30 TAC § 330.331.
58 30 TAC § 330.333.
59 30 TAC § 330.371.
60 30 TAC § 330.403.
61 30 TAC § 335.157(a).
listed in Appendix VIII of Title 40 C.F.R. Part 261, in accordance with 30 TAC § 335.159(a), as part of a detection monitoring program. Most constituents listed in Appendix VIII are chlorinated solvents and heavy metals, although a few active pharmaceuticals ingredients are included because they are listed as Resource Conservation and Recovery Act (RCRA) hazardous substances, such as warfarin, arsenic trioxide, nicotine and chlorambucil, among others. If hazardous constituents are detected in the groundwater monitoring network, the operator is required to submit a compliance plan that details continued monitoring and assessment of constituent concentrations and remedial actions if hazardous constituents are detected above the groundwater protection standards. No sediment quality sampling is required for pharmaceuticals or any other compound at or surrounding industrial and hazardous waste disposal units.

**Air Quality Standards**

The air quality standards detailed in this section relate to incineration as a form of processing pharmaceutical waste. Incineration is the thermal destruction of waste. During incineration, the organic components of pharmaceutical waste are oxidized to carbon dioxide, water vapor, oxygen, nitrogen, and acid gases. However, the inorganic components of the waste and byproducts of incineration can be released to the atmosphere through the incinerator exhaust, discharged to wastewater by means of wet air pollution control technologies (e.g., scrubbers

62), or disposed to landfill with the incinerator ash.63 However, active pharmaceutical ingredient (APIs) is usually destroyed in a properly functioning incinerator.

Hazardous waste incinerators and medical waste incinerators mainly differ in their permitting requirements, operating temperatures, emissions control, with hazardous waste incinerators being subject to more stringent permitting and emissions control requirements and higher operating temperatures than medical waste incinerators. The ash recovered from hazardous waste incinerators must be sent to a lined hazardous waste landfill. Ash recovered from medical waste incinerators may be disposed of in a municipal landfill. Incinerators must comply with the Clean Air Act (1970) and hazardous waste incinerators must also comply with the Resource Conservation and Recovery Act (1976) and Hazardous and Solid Wastes Amendments (1984). Additionally, municipal solid waste may be incinerated in a municipal waste combustor.

Air emissions from permitted hazardous waste incinerators are highly regulated. Title 40 C.F.R. 60 defines the Standards of Performance for New Stationary Sources (NSPS). These standards generally include limitations for particulates, opacity, heavy metals (lead and cadmium), mercury, dioxins and furans, carbon monoxide, nitrogen oxide, and acid gases (sulfur dioxide and hydrochloric acid) however, they do not include pharmaceutical compounds. Hazardous waste incinerators have additional emissions limitations including hydrocarbons, chlorine, additional heavy metals, but again no pharmaceutical compounds because they are expected to be destroyed or oxidized into other compounds as

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62 Scrubbers are designed to remove particulate, heavy metals, hydrocarbons, dioxins and furans, and acid gases produced from waste containing chlorine, sulfur, phosphorus, and nitrogen.

63 See ERG, 2009a.
part of the incineration process. TCEQ’s air emission monitoring/permitting requirements for incinerators in Texas would reflect those required in the applicable NSPS.

Neither the TCEQ nor the EPA\textsuperscript{64} is aware of any testing of APIs in incinerator scrubber wastewater. Additionally, there are no requirements in the EPA’s NPDES or TCEQ’s TPDES permitting requirements or rules to test for APIs in scrubber wastewater.

\textsuperscript{64} Id.
Current Methods for Disposing of Unused Pharmaceuticals

This section addresses how unused pharmaceuticals are currently disposed of in Texas by consumers, health-care providers and others and considers the effects of the current disposal methods on public health and the environment. In addition, this section discusses the current federal and state regulations related to the generation, handling and disposal of pharmaceuticals. This section also addresses how pharmaceuticals are managed and disposed of on a day-to-day basis by the health-care industry, consumers and others, based on knowledge gained through the literature search by the TCEQ, input from the Advisory Group and from the disposal surveys.

Current Rules Related to the Disposal of Unused Pharmaceuticals

Federal Guidance for Consumers

There are no specific requirements for consumers to dispose of their unused pharmaceuticals in a certain way in the United States. In the absence of regulation, two federal agencies [the Food and Drug Administration (FDA) and the White House Office of National Drug Control Policy (ONDCP)] have developed guidance documents or factsheets to provide options for consumers when disposing of their unused prescription and OTC medication.

The FDA consumer disposal guidance recommends consumers: 65

- 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 the information specifically instructs the consumer 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 cat litter. The medication will be less appealing to children and pets, and unrecognizable to people who may intentionally go through the 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 advantage of community drug take-back programs that allow the public to bring unused drugs to a central location for proper disposal. The consumer

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can call the city or county government’s household trash and recycling service to see if a take-back program is available in their community.

At the end of the FDA’s disposal factsheet is an internet link to the list of substances that the FDA recommends flushing down the drain when the drug is no longer needed. Currently, there are 27 pharmaceuticals on the FDA’s recommended “flush list”.66 As with the original disposal factsheet, the “flush list” is a recommendation to consumers, not a requirement for consumers.

The ONDCP’s factsheet provides the following guidance to consumers for disposing of their unused prescription drugs:67

- Do not flush prescription drugs down the toilet or drain unless the label or accompanying patient information specifically instructs the consumer to do so. For information on drugs that should be flushed the consumer can visit the FDA’s website.

- To dispose of prescription drugs not labeled to be flushed, the consumer 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. The consumer can call your city or county government’s household trash and recycling service and ask if a drug take-back program is available in their community.

- If a drug take-back or collection program is not available:
  - Take prescription drugs out of their original containers.
  - Mix drugs with an undesirable substance, such as cat litter or used coffee grounds.
  - Put the mixture into a disposable container with a lid, such as an empty margarine tub, or into a sealable bag.
  - 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.
  - Place the sealed container with the mixture, and the empty drug containers, in the trash.

Essentially, both the FDA and ONDCP suggest that consumers dispose of most unused medications in the household trash after mixing them with some unpalatable substance and sealing them in a container, and to consider taking advantage of community take-back programs if available, unless they are one of the medications that are recommended to be flushed for safety reasons.

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At this time, the EPA has not established any additional medication disposal guidance for consumers. Under the EPA’s Pharmaceuticals and Personal Care Products (PPCP) webpage, under “Additional Resources” the EPA refers the public to the ONDCP “Proper Disposal of Prescription Drugs” factsheet.\textsuperscript{68}

From the information received from the consumer disposal surveys, the federal medication disposal guidance documents may not be well known among the Texas community.

\textbf{State Guidance for Consumers}

At this time, there is a limited presence of information related to the disposal of unused pharmaceuticals at the state level. During the 81st Legislative Session, House Bill 19 was proposed and became effective requiring changes to the prescription drug labeling requirements for pharmacies in Texas and was added to the Occupations Code, Section 562.0062, to require pharmacists, when dispensing certain drugs, to include on the dispensing container label or in the information required by Section 562.0061 the statement "Do not flush unused medications or pour down a sink or drain." To implement this, the Texas State Board of Pharmacy has also updated the Texas Administrative Code (TAC). Effective January 2011, consumer guidance will exist on prescription labels or on the accompanying drug information when pharmaceuticals are dispensed to consumers in Texas. Under Title 22 TAC § 291.33(c)(7)(A)(xvi) the patient medication package shall bear either on the prescription label or the written information accompanying the prescription, the statement “Do not flush unused medications or pour down a sink or drain.” However, the “do not flush” label is not required on OTC pharmaceuticals sold in Texas and it does not apply to the 27 pharmaceuticals on the FDA’s “flush list”.

\textbf{Solid Waste Regulations}

The TCEQ has broad authority over the handling, processing, collection, transportation, storage, and disposal of solid waste. Unused pharmaceuticals fall within the definition of solid waste once the pharmaceuticals are discarded by the user. Pharmaceutical waste was never contemplated as a wholly unique waste stream, its regulation arises from its place within the broader context of waste regulations.

The proper disposal of pharmaceutical waste, under current regulations, depends on multiple factors. For example, a particular pill, depending on its characteristics, could be hazardous waste or regular municipal solid waste ("MSW" or what most people think of as household garbage). Within the world of MSW, that pill could be a “special waste” or even “medical waste.” Likewise, within the world of hazardous waste, that pill could be regular hazardous waste, universal waste, or completely exempt as a household hazardous waste. That pill could be subject to different regulations depending on who possesses it and what

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they are doing with it. For example, different regulations may apply to the
generator of the pill as a waste, the person who stores it on its way to its ultimate
disposal, and the owner of the incinerator or landfill where it finds its
permanent demise. The pill’s fate may depend on whether it is in a segregated
and distinct waste stream, or whether it is mixed with other wastes.

Solid waste does not need to be solid. In fact, the definition of solid waste
includes “solid, liquid, semisolid, or contained gaseous material,” and
would therefore include all pharmaceutical waste, regardless of its physical state. MSW,
hazardous waste, universal waste, industrial waste and all other categories of
waste are all subsets of solid waste. In other words, before a waste can be
“municipal” or “hazardous,” it must first be a “solid waste” generated by the act
of discarding.

Municipal Solid Waste

Municipal Solid Waste (MSW) is what most people think of when they picture
household garbage. The term “municipal solid waste” is defined as “solid waste
resulting from or incidental to municipal, community, commercial, institutional,
or recreational activities, and includes garbage, rubbish, ashes, street cleanings,
dead animals, abandoned automobiles, and other solid waste other than
industrial solid waste.” The definition encompasses almost all waste that is not
hazardous and that is not industrial. MSW includes regular garbage from
households, stores, schools, hospitals, and any other non-industrial generator. If
a particular pharmaceutical waste is not hazardous and does not result from an
industrial process, then it falls under the broad umbrella of MSW.

The authority of the TCEQ to develop and implement rules related to MSW
management derives from the Texas Health and Safety Code and the federal
Solid Waste Disposal Act (as amended by the RCRA). The TCEQ promulgated
MSW rules to implement these statutes and are found in 30 TAC Chapter 330.
The MSW rules apply to any person involved in any aspect of the management
and control of MSW and MSW facilities, including, but not limited to storage,
collection, handling, transportation, processing and disposal of MSW.

In order to conduct waste management activities, a person must first obtain
authorization from the TCEQ’s MSW Permits Section, unless the activity is
specifically exempted from regulation under 30 TAC § 330.13. Authorizations

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69 See 30 TAC §§ 330.3(145) and 335.1(138).
70 TEX. HEALTH & SAFETY CODE § 361.005(2); see also 30 TAC § 330.3(88).
71 Industrial solid waste is defined as “Solid waste resulting from or incidental to any process of industry or
manufacturing, or mining or agricultural operation, which may include hazardous waste as defined in this section.”
See 30 TAC § 330.3(79).
72 TEX. HEALTH & SAFETY CODE § 361.011.
73 See 42 U.S.C. §§ 6941 through 6949 (also known as Subtitle D of RCRA).
74 TCEQ’s industrial and non-household hazardous waste rules are codified in 30 TAC Chapter 335.
75 TCEQ’s rules define “person” as “[a]n individual, corporation, organization, government or governmental
subdivision or agency, business trust, partnership, association, or any other legal entity.” 30 TAC § 3.2(25).
76 30 TAC § 330.1(a).
77 Pharmaceutical waste management is not specifically exemption by 30 TAC § 330.13.
may be in the form of a permit, registration, or a notification. The authorizations addressed in the current Chapter 330 rules relate to stationary facilities, certain waste transporters, and mobile waste processing units. In general, the Chapter 330 rules have a number of requirements that are specifically aimed at landfills and waste processing facilities. The concept of a processing facility broadly encompasses transfer stations or facilities that bale, shred, grind, incinerate, salvage, separate, dewater or reclaim solid waste.78

When pharmaceutical waste is regulated by the TCEQ, it is either because the waste falls within the greater context of MSW (i.e., individuals legally place their personal pharmaceutical waste in their household waste, which is then treated like regular trash through traditional waste management practices), or because a specific waste management activity involving pharmaceutical waste as a segregated waste stream “fits” within a traditional, regulated, waste management activity.

If the pharmaceutical waste falls within the greater context of MSW, the waste would follow the regulated processes for the regular garbage in which it is contained. If the waste passes through a transfer station (or other processing facility),79 the handling of the waste would be subject to Subchapter E, Operational Standards for MSW Storage and Processing Units. These requirements apply to both the permitted and registered facilities authorized by the MSW Permits Section of the TCEQ. If the waste ends up in a landfill, then the landfill would be subject not only to Subchapter D, Operational Standards for MSW Landfill Facilities, but also for requirements for landfill liner design, leachate collection and treatment, landfill gas management, groundwater monitoring, facility closure and closure costs, financial assurance, and other requirements.

When an entity segregates pharmaceutical waste into a distinct waste stream, the TCEQ’s MSW rules relating to municipal solid waste identify a distinction between the generation and the processing of waste. Under current TCEQ rules, an individual, hospital, pharmacy, veterinarian, or any other non-industrial facility could dispose of their own non-hazardous pharmaceutical waste as MSW. Unlike the hazardous waste rules described below, and with the limited exception of special waste rules, the TCEQ’s MSW regulations have very few requirements for individuals who generate municipal solid waste. However, when an individual or organization collects waste from others, they potentially engage in the “storage, collection, handling, transportation, processing, and disposal” of MSW.80 The clearest, current example of this distinction is the concept of a transfer station. Another example is a citizen’s collection station, which is a simple facility, usually rural, involving a storage bin or trailer and established for the convenience and exclusive use of local residents.81 In both cases, the mere act of collecting the waste becomes a regulated activity, even though the operator has not necessarily changed the physical state of the waste.

78 See 30 TAC § 330.5(a)(3).
79 A transfer station is a processing facility where waste from small, local collection trucks is collected, compacted, and transferred to a larger vehicle for long-distance hauling to a landfill. See 30 TAC § 330.3(157).
80 See 30 TAC § 330.1(a).
81 See 30 TAC § 330.3(20).
Special Waste

One subset of MSW is “special waste,” which is any solid waste that “because of its quantity, concentration, physical or chemical characteristics, or biological properties requires special handling and disposal to protect the human health or the environment.”\(^{82}\) The definition of special waste provides a list of wastes that fall within this definition, which includes “drugs” (other than those found in normal household waste).\(^{83}\)

As indicated by the definition of special waste, it does not apply to drugs within ordinary household waste. Therefore, as is often the case with waste disposal, drugs contained in an individual resident’s household garbage are not regulated as special waste. However, hospitals, clinics, long-term care facilities, pharmacies, veterinarians or other commercial operations that generate pharmaceutical waste could choose to manage the waste as special waste and send the waste directly to a MSW landfill.

Entities that elect to manage their waste as special waste must submit a Request for Authorization for Disposal of a Special Waste prior to actual disposal in order to dispose of the waste in an MSW landfill.\(^{84}\) A generator may receive an authorization for disposal of a “one time shipment” of special waste or for a “one year period” for special waste that is routinely generated. The Special Waste Authorization must accompany the special waste to the landfill. Additionally, generators of special waste are also not required to obtain a Special Waste Authorization if they send special waste for processing, such as to an autoclave commingled in medical waste.

Based on 2009 data, there are approximately 109 Type I MSW landfills and approximately 43 Type I arid exempt (AE) landfills in Texas. In accordance with the MSW rules, these are the only landfills that may accept special waste such as waste pharmaceuticals.\(^{85}\) There are no landfills in Texas that are still operating unlined pre-subtitle D\(^{86}\) cells.

Medical Waste

Regulated “medical waste” in Texas includes such items as animal waste, bulk blood, bulk human blood, bulk human body fluids, microbiological waste, pathological waste, and sharps, generated at health-care related facilities (not households).\(^{87}\)

Currently, the regulation of medical waste does not include pharmaceutical waste. Entities may commingle pharmaceutical waste (special waste) with

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\(^{82}\) 30 TAC § 330.3(148).

\(^{83}\) 30 TAC § 330.3(148)(J). Although the term “drug” is not defined more precisely, it is considered to be synonymous with the term “pharmaceutical.”

\(^{84}\) Id.

\(^{85}\) Information obtained from the TCEQ Waste Permits Division, Municipal Solid Waste Section, July 19, 2010.

\(^{86}\) “Sub-title D” refers to Subtitle D of RCRA.

\(^{87}\) 30 TAC § 330.3(85).
medical waste for convenience; commingled waste is subject to medical waste requirements.  

Generators of medical waste must segregate the medical waste from ordinary rubbish at the source of generation. Storage of medical waste must be done in a manner that protects the waste from theft, vandalism, inadvertent human or animal exposure, wind, rain, water, and rodents. The generator must contain the medical waste in packaging that is approved for transport by the U.S. Department of Transportation, which is generally a plastic bag held within a rigid, leak-resistant plastic container that is impervious to moisture. The containers must be appropriately labeled with specific descriptions and warnings regarding the contents. Finally, the generator must retain signed shipping receipts from a TCEQ registered medical waste transporter for a period of three years and make the receipts available for inspection.

Treated medical waste may be disposed of in a permitted MSW landfill. To operate a medical waste treatment facility in Texas, an operator needs to obtain a registration for a Type V MSW processing facility. A Type V MSW facility is a processing plant that transfers, incinerates, shreds, grinds, bales, salvages, separates, dewater, reclams, or provides other storage or processing of solid waste. Untreated medical waste is a special waste under the MSW rules, and must be treated prior to disposal in an MSW landfill unless authorized by the Executive Director, but disposal without treatment is typically only authorized during natural disaster events where treatment prior to disposal is not feasible.

An example of an approved method for treatment of medical waste is thermal inactivation, such as processing in an autoclave (i.e. an industrial size pressure cooker), followed by disposal in an MSW landfill. Medical waste may also be directed to a medical waste incinerator which is another approved method of treatment. There are currently only two permitted medical waste incinerators in Texas.

If the generator of the unused pharmaceuticals discards the waste pharmaceuticals into a biohazard bag, essentially commingling the waste with medical waste, then the entire content of the biohazard bag is considered to be medical waste. This commingling activity forces the generator to manage and process all the commingled waste as regulated medical waste, even if the

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88 The definition of “medical waste” is found at 30 TAC § 330.3(85) and does not specifically include pharmaceuticals or drugs. The Texas medical waste definitions adopt by reference the definitions of the Department of State Health Services (DSHS) found at 25 TAC §§ 1.132 and 1.134, and the MSW general definitions found at 30 TAC § 330.3 and 30 TAC § 330.1205. This includes the DSHS definition of “special waste from a health care related facility.”

89 30 TAC § 330.1207(a).

90 30 TAC § 330.1209(a).

91 30 TAC §§ 330.1207(c)(1) and (2).

92 30 TAC §§ 330.1207(c)(4) - (7).

93 30 TAC §§ 330.1207(b)(1) - (4).

94 30 TAC § 330.1219(e). Medical waste is “treated” if it meets the treatment requirements of 30 TAC § 330.1219(a).

95 30 TAC § 330.9(n).

96 30 TAC § 330.171(c)(1).

97 30 TAC § 330.1207(a).
pharmaceuticals would not have been considered medical waste if they were kept separate.

**Incineration**

Incineration as a disposal method for pharmaceutical waste garners substantial attention because of its utility in the destruction of controlled substances. Law enforcement departments often use incinerators in the destruction of controlled substances that are collected as evidence. The Drug Enforcement Agency (DEA) and local law enforcement have taken the position that only incineration is acceptable for disposal of controlled substances and no other form of destruction is acceptable. Texas has a very limited number of incinerators permitted to receive controlled substances. While Texas has numerous incinerators for waste disposal purposes, such as animal crematories, and incinerators for medical, industrial, and hazardous wastes, most of these facilities are not authorized to receive MSW or pharmaceuticals.

Law enforcement departments may dispose of controlled substances in their possession in a dual-chamber incinerator, which only requires a permit-by-rule (PBR). The MSW regulations allow a PBR for animal crematories, dual chamber incinerators, and air curtain incinerators, provided that the owner operates the facility within applicable air regulations. Each of these PBRs has a corresponding PBR under the air regulations found in Chapter 106 of the Texas Administrative Code (TAC). However, while a dual chamber incinerator that is in compliance with 30 TAC § 106.491 and 30 TAC § 330.7(f), may accept illegal drugs confiscated by federal, state, or local law enforcement agencies, an animal crematory and a pathological waste incinerator do not have this specific allowance and therefore, may not be utilized for destruction of pharmaceuticals.

Entities not mentioned above could dispose of pharmaceutical waste by sending the waste to an incinerator provided the incinerator has the appropriate air, water and waste authorizations.

Currently, there are several facilities in Texas that are permitted to incinerate MSW, but only one facility is currently active and receiving MSW for incineration.

**Industrial Solid Waste**

While the TCEQ regulates industrial solid waste, the impact of industrial solid waste regulations on pharmaceutical waste is likely to be quite minimal. Industrial solid waste is merely “solid waste resulting from or incidental to any process of industry or manufacturing, or mining or agricultural operation.” In other words, industrial solid waste is defined by its origin, and not necessarily by its characteristics. However, industrial solid waste is divided into three

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98 See 30 TAC §§ 330.7(e)-(g).
99 See 30 TAC § 106.491(a).
100 30 TAC § 335.1(79). See also 30 TAC § 330.3(66).
classes, with Class 3 waste including inert, insoluble material (e.g., rock, glass, bricks, and dirt), Class 1 including potentially toxic or dangerous waste, and Class 2 including everything else.\textsuperscript{101}

There are very few \textit{permitted} landfills dedicated exclusively to industrial solid waste in Texas. This occurs for several reasons. First, because a lot of industrial solid waste is little more than inert material, MSW landfills are allowed to accept this waste.\textsuperscript{102} Depending on the individual permit, an MSW landfill may accept all Class 3 waste, most Class 2 wastes, and even Class 1 waste in certain, limited circumstances.\textsuperscript{103} Next, an industrial waste generator is allowed to dispose of its non-hazardous, industrial waste on its own property without obtaining a permit (only a notification is required).\textsuperscript{104}

Consequently, the only generators of pharmaceutical waste that could potentially be affected by industrial solid waste rules are pharmaceutical manufacturers.

\textbf{Hazardous Waste}

Hazardous waste is solid waste that is dangerous or potentially harmful to human health or the environment. Hazardous wastes can be liquids, solids, gases, or sludges. The generation, transport, treatment, storage and disposal of hazardous waste is regulated under the Federal Resource Conservation and Recovery Act (RCRA), which is implemented by the TCEQ in Texas. Hazardous waste could be considered to have the most stringent management requirements set in rule, followed by medical waste and then followed by MSW. That hierarchy is a result of the potential impact on the environment should the waste be uncontained or mismanaged.

State and federal rules for hazardous waste may impact efforts to divert pharmaceutical wastes from the wastewater stream; however, the degree of impact currently depends on the generator of the waste.\textsuperscript{105} Hazardous waste rules have different applications depending on the source of the waste. In particular, the application of the rules depends upon whether or not the waste is generated by a household or by a manufacturer. As an example, current hazardous waste rules would have different impacts on a hospital that generates hazardous pharmaceutical waste, on a hypothetical community collection event where pharmaceutical waste is collected from residents, and on a hypothetical consumer pharmaceutical disposal kiosk at a pharmacy.

There are few pharmaceuticals that are designated RCRA “hazardous” waste and pose a danger to those that may come in contact with the substance if not prescribed for them. In a survey of 149 hospitals in 2008, PharmEcology found

\begin{footnote}
\footnotetext{101} 30 TAC §§ 330.3(21)-(23). \textit{See also} 30 TAC §§ 335.1(19)-(21).
\footnotetext{102} 30 TAC § 330.173.
\footnotetext{103} \textit{Id}.
\footnotetext{104} \textit{See} 30 TAC § 335.2(d).
\footnotetext{105} Texas has a federally-authorized RCRA hazardous waste program. \textit{See} 40 C.F.R. § 272.2201. Consequently, most Texas Hazardous Waste rules either parallel federal rules or incorporate them by reference. This section will describe the regulations currently employed by the state of Texas.
\end{footnote}
that about 4% of pharmaceuticals in the marketplace are RCRA hazardous substances, though the proportion of pharmaceuticals that would be designated as RCRA hazardous waste is less well understood. The EPA’s Health-Care Industry study noted that approximately 5% of waste in health-care settings is RCRA hazardous.

General Disposal Requirements for Hazardous Waste. Hazardous waste generated by a small quantity generator (SQG) and a large quantity generator (LQG), universal waste, and aggregated household hazardous waste (HHW) must be disposed of at a facility that can accept hazardous waste. MSW landfills can, under limited circumstances, accept hazardous waste from municipal generators as allowed by the MSW rules which states “municipal hazardous waste from a conditionally exempt small quantity generator (CESQG) may be accepted at a Type I or Type IAE (MSW) landfill provided the amount of waste does not exceed 220 pounds (100 kilograms) per month, per generator and provided the MSW landfill owner or operator authorizes acceptance of the waste.” In this situation, the CEQSG generator is required to submit a Notification for Hazardous or Industrial Waste Management. Additionally, hazardous waste generated by a CESQG may be disposed of in a facility that can accept hazardous waste. Facilities permitted to accept hazardous waste include hazardous waste landfills and hazardous waste incinerators. Note that hazardous waste incinerators are different from, and have more stringent requirements than, medical waste or MSW incinerators. There are currently three permitted hazardous waste incinerators in Texas that are authorized to accept commercial waste.

Household Hazardous Waste

Pharmaceutical waste that is generated by a household is not regulated “hazardous waste,” even if the substance would ordinarily fall under the hazardous waste definition if it were generated in a business such as a hospital. Federal rules specifically exclude household waste from the definition of hazardous waste, which includes garbage and trash from residences, hotels, motels, bunkhouses, ranger stations, crew quarters, campgrounds, picnic grounds, and day-use areas. A resident may legally dispose of any pharmaceuticals in their household trash.

However, some municipalities and other solid waste operators have special HHW programs in place that collect segregated waste that would otherwise fall under the definition of hazardous waste (if they were not generated in a household) with the goal of diverting some of this potentially dangerous waste from a MSW landfill to an appropriate hazardous waste disposal facility. The TCEQ HHW regulations take effect when individuals or entities collect “household hazardous waste” (or more accurately, household waste that would otherwise be considered “hazardous waste” if it were generated at a location

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106 Ms. Charlotte Smith, PharmEcology Services, information provided by email communication 29 October 2009.
107 30 TAC § 330.171(c)(6)
108 See 40 C.F.R. § 261.4(b)(1).
other than a household) at a collection event, permanent collection site, or through curbside collection programs. The rules establish requirements for persons who are involved in any combination of collecting, aggregating, offering for reuse, recycling, transporting, or disposing of household hazardous wastes and other types of household waste materials that may, due to their quantity and characteristics, pose a potential endangerment to human health or the environment if improperly handled.

An individual seeking to operate a HHW collection event, permanent collection center, or curbside collection program that may collect waste that would otherwise be considered hazardous if it were not generated in a household must submit a notification to the TCEQ at least 45 days prior to conducting collection activities. In addition to the notification, operators must develop and follow an operational plan and arrange for proper processing or disposal of waste collected at a hazardous waste facility. This includes using a licensed hazardous waste transporter to transport the HHW to the final disposal facility. They may also be required to submit a financial assurance mechanism for site closure. The HHW notification process is simple relative to other hazardous waste and municipal solid waste authorizations. Fulfilling the TCEQ's requirements in no way exempts a HHW collection event from complying with the rules related to controlled substances, which need to be addressed in the operational plan, if a HHW event accepted unused pharmaceuticals from consumers/households. The DEA and the Department of Public Safety have the right to inspect any HHW event that accepts unused pharmaceuticals to insure that no controlled substances are accepted without law enforcement presence. Finally, while HHW is not technically regulated hazardous waste, collected HHW must be disposed of at a facility authorized to accept hazardous waste (a hazardous waste landfill or hazardous waste incinerator); that is, as if it were hazardous waste.

Sometimes HHW events collect items that would not be considered hazardous even if they were generated by a business; that is, the event receives routine MSW. The rules require that the operator of a HHW collection event must develop and follow an operational plan. The operational plan must identify the nature, type and quantity of “household hazardous waste and other materials proposed for collection and reuse, recycling, processing or disposal.” The plan must also indicate how the operator intends to screen against unwanted wastes, and Class 1 waste (which are prohibited). If collected wastes are separated into

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109 For purposes of this section, “household hazardous waste” is defined as “[a]ny solid waste generated in a household by a consumer which, except for the exclusion provided in 40 Code of Federal Regulations (CFR) §261.4(b)(1), would be classified as a hazardous waste under 40 CFR Part 261.” 30 TAC § 335.401(6).
110 See 30 TAC § 335.401(b).
111 30 TAC § 335.401(a).
112 30 TAC § 335.403(b).
113 See generally 30 TAC § 335.403.
114 30 TAC § 335.403(c).
115 30 TAC § 335.403(d)(1).
116 30 TAC §§ 335.405(a)(1) (emphasis added).
117 30 TAC §§ 335.405(a)(5)-(6).
hazardous and non-hazardous, then the non-hazardous waste may be managed as MSW. However, if the other materials (MSW) are commingled with HHW (i.e. those substances that would be considered hazardous waste outside of the household setting), then all of the waste must be disposed of at a facility authorized to accept hazardous waste.

A HHW event operator also maintains the ability to reject items that they do not desire to collect. To do this, the HHW operator would note on the 45-day notification form which items will be accepted at the HHW event. In effect, a HHW event operator could reject non-hazardous pharmaceuticals (those that would be considered non-hazardous even outside of the household setting) by excluding it from the list of acceptable items if they did not want to dispose of non-HHW waste (or MSW). However, that would require the skills to distinguish hazardous from non-hazardous pharmaceuticals.

Regulated Hazardous Waste

The TCEQ’s hazardous waste rules have different requirements for different facilities depending upon whether they generate, store, treat, or dispose of the hazardous waste. Different requirements also apply depending on how much hazardous waste a facility produces in a given time period.

Generator Requirements

Several regulations apply to “generators” of hazardous waste, regardless of whether the generator only intends to store the waste onsite for as much time as it takes to send it off site for proper disposal. All generators of hazardous waste must identify whether the waste is hazardous and submit a notification to the TCEQ. All waste must be classified at the point of generation. Additional regulations for generators depend on the amount of regulated hazardous waste accumulated per month. The rules make a distinction between Large Quantity Generators (LQG), Small Quantity Generators (SQG), and Conditionally Exempt Small Quantity Generators (CESQG). A LQG produces 1,000 kilograms or more of hazardous waste per month, a SQG produces between 100 and 1,000 kilograms a month, and a CESQG generates 100 kilograms per month or less.

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117 “Generator” is defined as the following:
Any person, by site, who produces municipal hazardous waste or industrial solid waste; any person who possesses municipal hazardous waste or industrial solid waste to be shipped to any other person; or any person whose act first causes the solid waste to become subject to regulation under this chapter. For the purposes of this regulation, a person who generates or possesses Class 3 wastes only shall not be considered a generator. (30 TAC § 335.1(65).
Cf. 40 C.F.R. § 260.10.

118 30 TAC § 335.62.
119 30 TAC § 335.6.
120 30 TAC § 335.503(a)(1).
121 30 TAC §§ 335.74 and 335.1(137).
122 Id.
For LQGs and SQGs (but not for CESQGs), the generator must obtain an EPA identification (ID) number. Generators must also prepare waste for transport through methods of packaging, labeling, marking, and placarding that are approved by the Texas Department of Transportation regulations. These types of generators must keep records of hazardous waste determinations and submit annual and biennial reports to the TCEQ. Finally, these types of generators must fill out and submit the standard RCRA manifest whenever hazardous waste is transported off site. A CESQG is exempt from these generator requirements. It should be noted that a generator that qualifies as a CESQG one month may lose its CESQG status in the next month if they exceed 100 kilograms of hazardous waste generated. Therefore, in the second month the generator might need to meet the requirements of a LQG or SQG.

Under these rules, health-care facilities and other entities not considered a “household” must characterize their waste and identify which wastes are hazardous and the quantity of hazardous wastes that they generate, notify the TCEQ and, if applicable (not applicable if a CESQG), prepare the wastes for transport off site, maintain records and submit waste generation reports to the TCEQ periodically.

Controlled Substances

A controlled substance is a drug or chemical whose manufacture, possession, and use are strictly regulated by government under the federal and state Controlled Substance Acts. Controlled substances are listed substances that have some potential for abuse or addiction. Controlled substances are those listed Schedule I, II, III, IV, or V of Part B of Title 21 United States Code Section 802. Schedule I substances are illicit drugs that have a high potential for abuse and no accepted medicinal use in the United States, and therefore are illegal to obtain even with a prescription. Drugs in Schedules II through V can be dispensed with a prescription.

Federal Controlled Substances Act

The Controlled Substances Act mainly concerns possession and distribution of controlled substances; it does not provide for disposal methods in its language. Under federal law, the Drug Enforcement Agency (DEA) enforces the Controlled Substances Act (CSA) which, in combination with the rules promulgate pursuant to it (21 C.F.R. Parts 1300 to 1399), creates a “closed system” of...
distribution. Under the system, controlled substances may be transferred only between DEA registrants or to persons who are exempt from the Act, i.e., ultimate users. However, while an ultimate user is exempt under the CSA, the ultimate user is only allowed to possess a controlled substance to the extent that the controlled substance was lawfully obtained, and is not allowed to distribute the controlled substance to any other person (even a DEA registrant). Otherwise, under the CSA, it is illegal “knowingly or intentionally” to possess a controlled substance.

The CSA provides options for how to transfer a controlled substance but does not provide clear ruling or guidance on allowable ultimate disposal methods. Hospitals, pharmacies, and other entities that regularly have a DEA registrant on staff may dispose of pharmaceutical waste in one of three ways under DEA guidance. First, these entities may transfer the controlled substances to another pharmacy, supplier, manufacturer or reverse distributor (if they are also DEA registrants). This option tends to occur when a pharmacy goes out of business. This situation could also occur with overstocked/ordered items. Next, the DEA can grant either a once-a-year authorization for destruction or blanket authorization for destruction. For a once-a-year authorization, DEA requires the entity to submit DEA Form-41 (Registrants Inventory of Drugs Surrendered), as well as a letter to the DEA Diversion Field Office describing the date of the destruction and the method proposed. The DEA Diversion Field Office must receive these documents at least two weeks before the date of destruction. For a blanket authorization, the DEA assesses requests on a case-by-case basis, and generally limits the authorization to hospitals and other registered entities that produce syringes, and other injectable objects that may have become contaminated. For both once-a-year and blanket authorizations, the DEA recommends contacting the local environmental agency to ensure compliance with environmental regulations. Finally, pharmacies, hospitals and other entities with DEA registrants on staff may turn over their controlled substances to DEA registered reverse-distributors that have authorization to destroy and dispose of controlled substances.

Some issues identified by the Advisory Group concern DEA’s destruction methods and the availability of reverse-distributors. Neither the CSA nor the DEA rules indicate what methods of destruction are acceptable. DEA guidance states that controlled substances should be “destroyed in such a manner that

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131 Id.
132 Id.
135 Id. at 12.
136 Id. at 14-15.
137 Id. at 16.
138 Id. at 15.
they are beyond reclamation.” The structure of DEA’s requirements for destruction (i.e., requiring prior notification to regional DEA offices) is such that the agency seems to approve disposal methods on a case-by-case basis. Some stakeholders have commented that they have had a difficult time locating reverse distributors.

A Long Term Care Facility (LTCF) is defined by federal regulations as a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients. Because LTCFs are seldom registered with the DEA, the facilities consult their local DEA Diversion Field Office or local state agencies with authority over controlled substances. The Federal Register notice concerning DEA’s proposed rules for Disposal of Controlled Substances by Persons Not Registered with the Drug Enforcement Administration and DEA’s Pharmacist’s Manual both contain some discussion of disposal of controlled substances by LTCFs. The guidance is not clear on what requirements apply to disposal of controlled substances by these facilities, but they do indicate that DEA is aware of issues facing LTCFs with regard to the dispensing and handling of controlled substances. The Pharmacy Manual recommends that, "LTCFs should contact the local DEA Diversion Field Office ... for drug disposal instructions." The Federal Register notice states that "LTCFs that are not DEA registrants may not transfer the controlled substances to either the pharmacy that supplied them or to a reverse distributor for disposal."

The collection of consumer’s unused controlled substances raises difficult issues under the federal CSA because, under the CSA, it is an illegal distribution for an ultimate user to dispose of a controlled substance by giving it to another person (such as a DEA registered pharmacist or reverse distributor) even if that person is a DEA registrant. For example, while a DEA-registered reverse distributor may collect controlled substances for the purpose of disposal from a DEA registered pharmacy, they would not be able to collect controlled substances from a community drug collection event because they can only accept controlled substances from other DEA registrants. A reverse distributer is the only type of DEA registrant that may receive controlled substances for the sole purpose of disposal. However, a registered reverse distributor may only accept controlled substances from other DEA registrants and not from ultimate users (because they are outside of the “closed system” and not DEA registrants). In addition, while a reverse distributor may collect controlled substances from a DEA-registered pharmacy, it could only collect the pharmacy’s waste because a pharmacy cannot receive authorization to accept controlled substances from ultimate users for the purpose of disposal.

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139 Id. at 16.
140 Id. at 52.
141 Id.
142 74 FR 3480-01, 2009 WL 122690 (F.R.)
143 See DEA, 2004.
144 See supra note 79 at 3481.
145 Id.
The CSA provides the procedure for disposing of controlled substances by persons who are not registrants (ultimate-users or LTCFs). This procedure involves the nonregistrant submitting a letter to the local DEA Special Agent in Charge. Essentially, the only legal disposal methods for ultimate users of controlled substances involve either contacting the local DEA Special Agent in Charge for express permission and disposal instructions, which is labor-intensive, or to transfer the controlled substances to a law enforcement officer, which according to the CSA is only allowed by a special, temporary authorization by the DEA.

In light of the difficulty of consumers and LTCFs disposing of controlled substances and the recent increase in requests for community programs to collect unused drugs, the DEA initiated a rulemaking in 2009 to address the problem. DEA requested public comment on the advanced notice of proposed rulemaking between January 21 and March 23, 2009. Ultimately, if the rulemaking proceeds it may take many years to be promulgated. This report bases its recommendations on the current version of the CSA, whereby consumers may not return controlled substances to any other person unless allowed under 21 C.F.R. 1307.21(b).

In part due to questions regarding the authority of the DEA to adopt those new regulations, in 2010 Congress passed Public Law 268-273, the Secure and Responsible Drug Disposal Act of 2010. The purpose of the act is to facilitate the collection and destruction of controlled substances medications in state and local drug take-back programs. The bill authorizes the Attorney General to adopt new rules that will allow patients to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion.

Texas Controlled Substances Act

The State of Texas regulates the distribution of controlled substances through the Texas Controlled Substances Act (a statute that roughly parallels the federal CSA). The Texas Controlled Substances Act (Texas CSA) creates an intricate schedule of offenses for the knowing or intentional possession of controlled substances. The authority to establish rules under the Act, to issue registrations, and to enforce the terms of the Act is vested in the director of the Department of Public Safety (DPS). Similar to the federal CSA, the Texas CSA divides controlled substances into “schedules” and “penalty groups.” A person may only possess a controlled substance if they have a valid prescription.
they are a practitioner acting in the course of professional practice, or if they are registered by the Department of Public Safety. Practitioners licensed in Texas are required to store controlled substances in secure, locked cabinets.

As with the federal CSA, the Texas CSA gives individuals a limited right to possess controlled substances (i.e., with a prescription), but limits all distribution of controlled substances to DPS registrants. For example, an individual may not possess a controlled substances listed in Penalty Group 1 without a valid prescription. An individual may not distribute, prescribe or dispense a controlled substance unless they are registered with the DPS.

One apparent difference between the state and federal rules regarding controlled substances is the additional detail of destruction methods and procedures promulgated by the Texas rules. The Texas Department of Public Safety established rules for the forfeiture and destruction of controlled substances and dangerous drugs in 37 TAC, Chapter 13. Under the Forfeiture and Destruction rules, a crime laboratory or law enforcement administration may destroy controlled drugs either under court order or without a court order when the confiscated drugs have no evidentiary value (summary forfeiture and destruction). The latter occurs either when a legitimate possessor of the drugs voluntarily surrenders the drugs to law enforcement, or when law enforcement cannot reasonably establish the lawful possessor.

The DPS rules for forfeiture and destruction go even further in describing the methods and procedures that are necessary for the proper destruction of controlled substances and dangerous drugs. A crime laboratory or a law enforcement agency must establish Standard Operating Procedures for the destruction of drugs. Under the rules, two witnesses must document and observe the destruction as well as report any suspicious activity, such as broken seals or non-matching inventories. As for the precise method of destruction, DPS rules state that law enforcement may destroy an item by burning it in a suitable incinerator. However, law enforcement may use “another method” as long as the item is destroyed in a safe and responsible manner that complies with all relevant federal, state, and local law, including “compliance with all requirements of the TCEQ and the EPA.”

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156 Id.
157 Id. at § 481.061.
158 For example, in veterinarian offices, controlled substances “must be stored in a securely locked, substantially constructed cabinet or security cabinet. 22 TAC § 273.61.
159 Id. at § 481.115(a).
160 TEX. HEALTH & SAFETY CODE ANN. at § 481.061(a).
161 37 TAC §§ 13.151 through 13.165.
162 37 TAC § 13.155(a).
163 37 TAC § 13.152(b).
165 See 37 TAC § 13.161.
166 37 TAC § 13.158(a).
167 37 TAC § 13.158(a).
Dangerous Drugs and the Regulation of Pharmacies and Pharmacists

A “dangerous drug” is a drug or device that is unsafe for self-medication, but that is not listed in Schedules I through V or Penalty Groups 1 through 4 of the Texas CSA.\textsuperscript{168} The definition is sufficiently broad to encompass drugs that are in a solid, liquid, topical, or aerosol form. The term includes any drugs or devices that bear or are required to bear the legend:

- “Caution: Federal law prohibits dispensing without prescription”;
- “Rx only”; or
- “Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.”\textsuperscript{169}

In other words, dangerous drugs make up the remaining world of prescription drugs that are not controlled substances. Dangerous drugs do not include OTC drugs. The Act offers a limited list of persons who may possess dangerous drugs in their “usual course of business”. The list of exempted individuals and entities specifically includes the following persons, as well as their agents and employees:

- Pharmacies;
- Medical practitioners;\textsuperscript{170}
- Persons who obtain a dangerous drug for lawful research, teaching, or testing, but not for resale;
- Hospitals that obtain a dangerous drug for lawful administration by a practitioner;
- Officers or employees of the federal, state, or local government;
- Licensed manufacturers and wholesalers;
- Carriers and warehousemen;
- Licensed home and community support services agencies;
- Midwives;

\textsuperscript{168} \textit{Id.} at § 483.001(2).
\textsuperscript{169} \textit{Id.} at § 483.001(2)(A)-(B).
\textsuperscript{170} A “practitioner” is a person licensed by the Texas State Board of Medical Examiners, State Board of Dental Examiners, Texas State Board of Podiatric Medical Examiners, Texas Optometry Board, or State Board of Veterinary Medical Examiners to prescribe and administer dangerous drugs; by another state in a health field in which, under the laws of this state, a licensee may legally prescribe dangerous drugs; in Canada or Mexico in a health field in which, under the laws of this state, a licensee may legally prescribe dangerous drugs; or an advanced practice nurse or physician assistant to whom a physician has delegated the authority to carry out or sign prescription drug orders. \textit{See} \textsc{Tex. Health & Safety Code} § 483.001(12).
• Licensed salvage brokers and operators (persons who engage in the business of selling, distributing, or otherwise trafficking in distressed or salvaged merchandise\(^{171}\) and persons who operate a salvage establishment\(^{172}\); and

• Laser hair removal professionals.\(^{173}\)

**Texas State Board of Pharmacy Regulations**

The Texas Dangerous Drug Act gives the Texas State Board of Pharmacy (TSBP) authority to establish and enforce rules relating to the use and possession of dangerous drugs.\(^{174}\) The TSBP also adopted rules pursuant to the Texas Pharmacy Act §§ 551.002 and 554.051, which the TSBP interprets as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy and to adopt rules for the proper administration and enforcement of the Act. The TSBP promulgated rules are codified in Title 22 of the Texas Administrative Code (TAC), Chapters 281 through 311. TSBP’s rules contain provisions addressing the destruction of dispensed drugs, the disposal of stock prescription drugs and for the handling of drugs within a number of separate pharmacy operations. The storage and management of pharmaceuticals in a hospital falls under the pharmacy rules in Title 22 TAC Chapter 291, Subchapter A (All Classes of Pharmacies) and Subchapter D (Institutional Pharmacies – Class C Pharmacies). Those Institutional Pharmacy rules relate to general hospitals and special hospitals [defined in Title 4, Texas Health and Safety Code (THSC), § 241.003 (5) and (15)], mental health hospitals (those licensed under Title 7 THSC Chapter 577), licensed hospice patient facilities (under Title 2 HSC Chapter 142), ambulatory surgical centers (Title 4 THSC Chapter 243), and all state maintained or operated hospitals. Retail pharmacies are regulated under the pharmacy rules in Title 22 TAC Chapter 291, Subchapter A (All Classes of Pharmacies) and Subchapter B (Community Pharmacies – Class A Pharmacies).

One important element to be aware of is the point at which drugs become “dispensed” to patients, since a number of rules related to drug disposal hinge on that point of transfer. In a retail or “community” pharmacy, “dispensing” is not when the patient physically uses the product (that would be the point at

\(^{171}\) “Salvaged merchandise” means distressed merchandise that has been reconditioned. **Tex. Health & Safety Code** § 432.003(18). “Distressed merchandise” means any food, drug, device, or cosmetic that is adulterated or misbranded for purposes of Sections 431.081 (Adulterated Food), 431.082 (Misbranded Food), 431.111 (Adulterated Drug or Device), 431.112 (Misbranded Drug or Device), 431.141 (Adulterated Cosmetic), or 431.142 (Misbranded Cosmetic), as interpreted by board rule and judicial decision. The term includes a food, drug, device, or cosmetic that: (A) has lost its label or is otherwise unidentified; (B) has been subjected to prolonged or improper storage; (C) has been subjected for any reason to abnormal environmental conditions, including temperature extremes, humidity, smoke, water, fumes, pressure, or radiation; (D) has been subjected to conditions that result in either its strength, purity, or quality falling below that which it purports or is represented to possess; or (E) may have been rendered unsafe or unsuitable for human consumption or use for any reason other than those specified by this subdivision. **Tex. Health & Safety Code** § 432.003(6). “Reconditioning” means any appropriate process or procedure by which distressed merchandise can be brought into compliance with departmental standards for the consumption or use of that merchandise by the public. **Tex. Health & Safety Code** § 432.003(12).


\(^{173}\) Id. at § 483.041(c).

which the drug is administered). In a retail pharmacy, drugs are dispensed at the point when the finished drug is prepared, labeled and sold to the customer/patient. When patients residing at a nursing home require prescription pharmaceuticals their practitioner issues a prescription which is usually dispensed for the full amount by a registered pharmacy. The nursing home, under direction of the consultant pharmacist, holds the prescribed drugs in a custodial manner for the patient and administers the medications according to the schedule that the practitioner orders. As a result, pharmaceuticals contained within the drug storage area of a nursing home have already been dispensed to the patient, and they are the patient’s property.

Hospitals (and clinics) will usually have an onsite or “in-house” pharmacies. Unlike retail/community pharmacies, an institutional pharmacy does not have “customers.” Drugs are the property of the hospital, not the hospital patient, until the drugs are administered. Many times, drugs on the patient floor are kept in their original packaging under the custody of nursing staff before they are administered to patients. Since most of the time drugs have not been “dispensed” to patients when in the custody of a nurse or medical practitioner, hospitals could return unused/unopened pharmaceuticals that have not yet expired to their in-house pharmacy for redistribution. If the pharmacy is on site, both controlled and non-controlled pharmaceuticals can be returned. Hospitals can return non-controlled substances to off-site pharmacies and can also return controlled substances if both facilities are controlled substance registrants with the DEA. Expired medications may also be returned to the pharmacy. The institutional pharmacy can then either send to the reverse distributor for credit or dispose of the medications.

Hospital pharmacies operate under self-imposed, written policies and procedures as required by TSBP rules. These procedures must cover a broad array of pharmaceutical practices, ranging from the dispensing of drugs to the disposal of unusable drugs and supplies.

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175 Administer means “the direct application of a prescription drug by injection, inhalation, ingestion, or any other means to the body of a patient by: (A) a practitioner, an authorized agent under his supervision, or other person authorized by law; or (B) the patient at the direction of a practitioner.” 22 TAC § 291.72(3).

176 Dispense technically means “preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.” 22 TAC § 291.72(14).

177 A clinic is “a facility/location other than a physician's office, where limited types of dangerous drugs or devices restricted to those listed in and approved for the clinic's formulary are stored, administered, provided, or dispensed to outpatients.” 22 TAC § 291.91(4). A common example of a clinic pharmacy would be a Planned Parenthood pharmacy, not a primary care physician’s office.

178 An institutional pharmacy is an “area or areas in a facility where drugs are stored, bulk compounded, delivered, compounded, dispensed, and distributed to other areas or departments of the facility, or dispensed to an ultimate user or his or her agent.” 22 TAC § 291.72 (27). A facility is (A) a hospital or other patient facility that is licensed under Chapter 241 or 577, Health and Safety Code; (B) a hospice patient facility that is licensed under Chapter 142, Health and Safety Code; (C) an ambulatory surgical center licensed under Chapter 243, Health and Safety Code; or (D) a hospital maintained or operated by the state.” 22 TAC § 291.72 (21).

179 See 22 TAC § 291.74(f)(5)(B).

Disposal of Stock Prescription Drugs

The TSBP authorizes pharmacists to destroy their stock pharmaceutical waste, if necessary. Under TSBP rules, “stock” means dangerous drugs or controlled substances which are packaged in the original manufacturer's container.\(^{181}\) A pharmacist, licensed by the TSBP, is authorized to destroy stock dangerous drugs owned by a licensed pharmacy if the dangerous drugs are destroyed in a manner that renders them unfit for human consumption and are disposed of in compliance with all applicable state and federal requirements.\(^{182}\) While no specific disposal requirements are defined, as implied by the reference to state requirements, all pharmacies, as non-household entities, would be required to abide by the TCEQ’s waste rules for the disposal of unused pharmaceuticals generated by their operations.

Under certain circumstances, a pharmacist is also authorized to destroy stock controlled substances under TSBP rules.\(^{183}\) TSBP rules track the language of DEA rules and guidance, so pharmacists essentially must destroy controlled substances pursuant to the methods described above in the section entitled “Federal Controlled Substances Act.” TSBP rules direct pharmacists to comply with DEA regulations, which limit disposal methods to transfers or DEA-approved periodic destruction under DEA Form-41.\(^{184}\) The only additional requirement imposed by TSBP over DEA regulations is that community pharmacies may only destroy stock controlled substances once a year, while institutional pharmacies (i.e., pharmacies in hospitals) may do so as needed.\(^{185}\)

Drugs Returned to a Pharmacy – Destruction and Resale

The TSBP allows pharmacies to take back drugs both for disposal purposes and for redistribution/re-sale; however these mechanisms are allowable under completely different scenarios.

Destruction of Drugs Returned by Consumers

A pharmacist in a pharmacy may accept and destroy dangerous drugs that have been previously dispensed to a patient and returned to a pharmacy by the patient or the patient’s agent.\(^{186}\) This is only allowable for consumers; an institution or consultant pharmacist cannot return drugs to the dispensing pharmacy for the purpose of disposal once the drugs have been opened or dispensed. If the pharmacy accepts the dangerous drugs from the consumer, they must be destroyed by the pharmacy in a manner that will render the drugs unfit for human consumption and disposed of in compliance with all applicable state and federal requirements.\(^{187}\) Records regarding the drugs that were destroyed

\(^{181}\) 22 TAC § 303.2(a).
\(^{182}\) 22 TAC § 303.2(b). Note that for nalbuphine (e.g., Nubain), and carisoprodol (e.g., Soma) the following procedures must also be performed: (1) the dangerous drugs must be inventoried before disposal; and (2) the destruction must be witnessed by another licensed pharmacist or a commissioned peace officer.
\(^{183}\) See 22 TAC § 303.2(c).
\(^{184}\) Id.
\(^{185}\) Id.
\(^{186}\) 22 TAC § 303.1(b)(1).
\(^{187}\) 22 TAC § 303.1(b)(1).
must be maintained. Finally, pharmacists may not accept controlled substances that have been previously dispensed to a patient unless allowed by federal laws of the DEA. In summary, under the current rules, it is legal for consumers to return their prescription drugs, but not controlled substances, to a pharmacy for disposal, in which case the pharmacy should dispose of the drugs in accordance with TCEQ's waste rules.

Under limited circumstances, a pharmacist may redistribute/re-sell certain prescriptions. Generally, a pharmacist may not accept an unused prescription for the purpose of resale or re-dispensing to any person, after the prescription or drug has been originally dispensed. However, health care facilities (consultant pharmacists for nursing homes) and penal institutions may return unused drugs to a dispensing facility for resale, if certain conditions are met. A licensed health care professional in a penal institution or a consultant pharmacist may return to a pharmacy certain unused drugs, other than a controlled substance, purchased from the pharmacy. These unused drugs must be FDA approved and be sealed in unopened, tamper-evident packaging. The unopened, sealed packages can be unit-doses, oral or parental medication in single-dose containers, unit-of-use topical inhalant containers, or parental medications in multiple-dose containers. The drug cannot have been in the physical possession of the person for whom it was prescribed or subject to a mandatory recall. Finally, a drug may not be returned if it has been compounded, appears to be adulterated, requires refrigeration, or has less than 120 days until the expiration date or end of the shelf life. The consultant pharmacist or the licensed health care professional in a penal institution is responsible for ensuring that an inventory of the drugs is completed and sent to the pharmacy as well as to the Health and Human Services Commission. If the pharmacy accepts the return of unused drugs, a pharmacist employed by the pharmacy shall examine the drugs to ensure the integrity of the drug product. The pharmacy must then reimburse or credit the entity that paid for the drug.

188 22 TAC § 303.1(b)(2).
189 22 TAC § 303.1(b).
190 Tex. Health & Safety Code § 431.021(w); 22 TAC § 291.8(a).
191 Health care facility--A facility regulated under Chapter 242, Health and Safety Code. See 22 TAC § 291.8(b)(2)(B). This is a nursing home.
192 Penal institution--A place designated by law for confinement of persons arrested for, charged with, or convicted of an offense. A penal institution includes a city, county or state jail or prison. See 22 TAC § 291.8(b)(2)(D).
193 22 TAC § 291.8(a). The regulations do not require that consultant pharmacists, health care facilities, penal institutions, or pharmacies participate in the return of unused drugs. Id.
194 Licensed health care professional--A person licensed by the Texas Medical Board, Texas Board of Nurse Examiners, or the Texas State Board of Pharmacy. See 22 TAC 291.8(b)(2)(C).
195 Consultant pharmacist--A pharmacist who practices in or serves as a consultant for a health care facility in this state. 22 TAC § 291.8(b)(2)(A).
196 Texas Occupations Code §562.1085; 22 TAC § 291.8(b)(3).
197 22 TAC § 291.8(b)(3)(A).
198 Id.
199 22 TAC § 291.8(b)(3)(A).
200 22 TAC § 291.8(b)(3)(B).
201 22 TAC § 291.8(b)(3)(C)-(3)(D).
202 22 TAC § 291.8(b)(4)(A).
including the state Medicaid program. If all of these requirements have been met, the pharmacy may restock and redispense the unused dangerous drugs, bearing in mind that this does not apply to controlled substances.

**Destruction of Drugs Dispensed to Patients in Health Care Facilities or Institutions (Nursing Homes)**

Dangerous drugs and controlled substances dispensed to patients in health care facilities or institutions may be destroyed by a consultant pharmacist. For the purposes of the TSBP rules, a “health care facility” is defined as a facility regulated under Chapter 242 of the Texas Health and Safety Code, or rather nursing homes. Consultant pharmacists that are in good standing with the TSBP, are authorized to destroy dangerous drugs and controlled substances dispensed to patients in health care facilities or institutions, provided that a written agreement exists between the facility and the consultant pharmacist and certain other conditions are met.

Under TSBP rules, the drugs must be inventoried and the inventory must be verified by the consultant pharmacist. The drugs must be destroyed in a manner that will render them unfit for human consumption and disposed of in compliance with all applicable state and federal requirements. The actual destruction of the drugs must be witnessed by: a commissioned peace officer, a TSBP agent, an agent of the Texas Health and Human Services Commission authorized by the TSBP to destroy drugs, an agent of the Texas Department of State Health Services authorized by the TSBP to destroy drugs; or any two individuals working as a facility administrator, director of nursing, acting director of nursing, or licensed nurse at the facility. If the actual destruction of the drugs is conducted at a location other than the facility or institution, the consultant pharmacist and witness(es) must retrieve the drugs from the facility or institution, transport, and destroy the drugs at the other location. All records must be maintained by the consultant pharmacist at the health care facility or institution for two years after the date of destruction.

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203 22 TAC § 291.8(b)(4)(B).
204 22 TAC § 291.8(b)(4)(C).
205 22 TAC § 303.1(a).
206 See 22 TAC § 291.8(b)(2)(B). See generally TEX. HEALTH & SAFETY CODE § 242 (relating to convalescent and nursing homes).
207 An “institution” in Chapter 242 of the Texas Health and Safety Code (THSC) means: “an establishment that:(A) furnishes, in one or more facilities, food and shelter to four or more persons who are unrelated to the proprietor of the establishment; and (B) provides minor treatment under the direction and supervision of a physician licensed by the Texas State Board of Medical Examiners, or other services that meet some need beyond the basic provision of food, shelter, and laundry” [Title 4 THSC 242.002(10)] however it is not a hotel, hospital, massage therapy clinic, church, spa, chiropractic office, intermediate care facility for the mentally retarded or foster care facility (Title 4 THSC § 242.003).
208 22 TAC § 303.1(a)(1).
210 22 TAC § 303.1(a)(1)(D).
211 22 TAC § 303.1(a)(1)(E).
212 22 TAC § 303.1(a)(1)(F).
213 22 TAC § 303.1(a)(3).
According to the TSBP rules, a consultant pharmacist at a nursing home may alternatively use a waste disposal service to destroy both dangerous drugs and controlled substances dispensed to patients, provided certain conditions are met.\(^{214}\) The TSBP rules state that the waste disposal service must be in compliance with applicable TCEQ and EPA rules relating to waste disposal.\(^{215}\) The drugs must be inventoried and the inventory must be verified by the pharmacist before the drugs are placed in an appropriate container, which must then be sealed by the pharmacist in the presence of the facility administrator and the director of nursing or acting director of nursing.\(^{216}\) The sealed container must then be maintained in a secure area at the facility or institution until it is transferred to the waste disposal service by the consultant pharmacist, facility administrator, director of nursing, or acting director of nursing.\(^{217}\) Records of the transfer must be maintained and attached to the inventory of drugs.\(^{218}\) The rules state that the waste disposal service is required to provide the facility with proof of destruction of the sealed container\(^{219}\) and all records must be maintained by the consultant pharmacist at the health care facility or institution for two years after the date of destruction.\(^{220}\)

While the TSBP rules allow for both controlled substances and dangerous drugs to be transferred to a waste disposal service for ultimate disposal, the DEA rules do not provide for this method of disposal. At the time of this writing, the TSBP was working with DEA and the National Association of Boards of Pharmacy to address these disposal issues.

**Texas Food, Drug and Cosmetic Act**

In Texas, the FDA and the Department of State Health Services (DSHS) has jurisdiction over the Texas Food, Drug, and Cosmetic Act as set forth in the Health and Safety Code, Chapter 431. The Food, Drug, and Cosmetic Act is further mandated in the Texas Administrative Code, Titles 22 and 25, and set forth Examining Boards to implement state law such as the State Board of Dental Examiners (Part 5), the Texas Medical Board (Part 9), the Texas State Board of Pharmacy (Part 15), and the Texas Board of Veterinary Medical Examiners (Part 24), among others.

**Regulation of Drug Disposal by Physicians, Dentists and Veterinarians**

As mentioned above, for hospitals or clinics with in-house pharmacies, either contracted or on staff, the licensed pharmacist and the operation of the pharmacy is under the jurisdiction of the Texas State Board of Pharmacy rules. However, physician, dental and veterinarian offices do not usually have their own in-house licensed pharmacies; instead they usually obtain drugs from a

\(^{214}\) 22 TAC § 303.1(a)(2).
\(^{215}\) 22 TAC § 303.1(a)(2)(A).
\(^{216}\) 22 TAC § 303.1(a)(2)(B)-(2)(C).
\(^{217}\) 22 TAC § 303.1(a)(2)(D).
\(^{218}\) 22 TAC § 303.1(a)(2)(E).
\(^{219}\) 22 TAC § 303.1(a)(2)(F).
\(^{220}\) 22 TAC § 303.1(a)(3).
licensed drug wholesaler. Jurisdiction over storage, handling, transfer and disposal of pharmaceuticals would fall to the corresponding Examiners Board and licensed health-care provider. Typically, physician offices differ from veterinarian offices in terms of the quantity of drugs kept onsite. A physician usually only stores drugs onsite that may be administered to the patient at the physician’s office, or they may provide the patient with a limited supply when they depart the physician’s office but only in quantities as are necessary to meet the patient’s immediate needs. In a small animal veterinarian office, more pharmaceuticals would likely be maintained onsite because a veterinarian usually supplies a pet owner with a full regimen of medication to treat the animal when away from the veterinarian’s office (as opposed to writing a prescription for the owner to obtain that medication from a separate pharmacy, though that may occur in animal husbandry operations which may require significant quantities of drugs to treat a large number of animals).

Ultimately, all licensees must comply with the federal and state Food, Drug, and Cosmetic Act and associated Texas Administrative Codes. Under the Texas Health and Safety Code (THSC), Section 431.111, a drug is considered adulterated if stored improperly. Under the THSC, Chapter 431, there are no additional requirements beyond ensuring a drug in commerce does not become adulterated or misbranded and would include adequate storage under adequate conditions. So, while the closed system of distribution ends with the final sale of drugs to the physician, dentist, veterinarian or anyone else authorized by law to possess dangerous drugs or controlled drugs, they must store and handle drugs in a manner that prevents adulteration.

In summary, it is the licensed professional that has the final responsibility for the proper storage and proper disposal of pharmaceuticals in a physician, dental or veterinarian office. There does not appear to be any formal regulations in the Medical, Dental or Veterinarian Examining Board rules regarding disposal of pharmaceuticals stored under the control of a licensed health care professional (except in the very uncommon scenario if they have an in-house pharmacy, which would therefore fall under the TSBP rules). Physician, dental and veterinarian offices must comply with the TCEQ waste rules when disposing of unused drugs generated in their practice, in addition to the CSA rules that may also apply if controlled substances must be disposed of.

Charitable Drug Donation

The Texas Food, Drug and Cosmetic Act does allow for the donation of unopened dangerous drugs from one entity to another under limited

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221 22 TAC § 169.4., except in rural areas where, under 22 TAC § 169.5, a licensed physician who practices medicine in a rural area may maintain a supply of dangerous drugs in his or her office to be dispensed in treating his or her patients and may be reimbursed for the cost of supplying those drugs.

222 “In commerce” includes the administration of medication to the final recipient.

223 If the drug is classified as a “Dangerous Drug”, additional record keeping requirements for acquisition or disposal are set forth in the Texas Health and Safety Code, Section 483.024. If the drug is classified as a “Controlled Substance”, additional requirements relating to security, recordkeeping, and inventory control are set forth in 37 TAC Chapter 13.

224 See 25 TAC Chapter 229.
circumstances from certain individuals to specified facilities.\(^{225}\) According to the rules, a “charitable drug donor” can only be a licensed convalescent or nursing home or related institution, licensed hospice, hospital, physician, pharmacy, or a pharmaceutical seller or manufacturer.\(^{226}\) The charitable drug donor can only provide dangerous drugs to a charitable medical clinic, which is defined as a clinic, including a licensed pharmacy that is a community pharmaceutical access program provider,\(^{227}\) that provides medical care or drugs without charge or for a substantially reduced charge, complies with the insurance requirements of Chapter 84, Civil Practice and Remedies Code, and is exempt from federal income tax under Section 501(a) of the Internal Revenue Code of 1986 by being listed as an exempt organization in THSC Section 501(c)(3) or 501(c)(4) and is operated exclusively for the promotion of social welfare by being primarily engaged in promoting the common good and general welfare of the people in a community.\(^{228}\)

Additionally, several restrictions apply to a drug donation program regulated under the Texas Food, Drug and Cosmetic Act. The donated drugs must be drugs that require a prescription, but may not be a controlled substance under the Texas Controlled Substances Act. To be able to be accepted and dispensed the donated drugs must also: be approved by the FDA; be sealed in the manufacturer's unopened original tamper-evident packaging and either individually packaged or packaged in unit-dose packaging; be oral or parenteral medication in sealed single-dose containers approved by the FDA; be topical or inhalant drugs in sealed units-of-use containers approved by the FDA; or be parenteral medication in sealed multiple-dose containers approved by the FDA from which no doses have been withdrawn; and must not be the subject of a mandatory recall by a state or federal agency or a voluntary recall by a drug seller or manufacturer. Finally, the charitable medical clinic may dispense or administer the donated drugs only before the expiration date or within the recommended shelf life of the donated drugs, as applicable; and after a licensed pharmacist has determined that the drugs are of an acceptable integrity.

Under these rules, a charitable medical clinic cannot accept unused pharmaceuticals from consumers. Drugs in the possession of consumers are outside the secure chain with no way to ensure that the drugs are unadulterated.

\(^{225}\) All rules related to drug donation programs are found in 6 THSC § 431.321.
\(^{226}\) 6 THSC § 431.321(d). Also, a seller or manufacturer of a drug may not donate drugs to a charitable medical clinic except pursuant to a qualified patient assistance program. A seller or manufacturer of a drug that donates drugs through a qualified patient assistance program shall be considered a charitable drug donor. 6 THSC § 431.322(b). A patient assistance program means “a qualified program offered by a pharmaceutical manufacturer under which the manufacturer provides drugs to financially disadvantaged persons at no charge or at a substantially reduced cost. The term does not include the provision of a drug as part of a clinical trial.” Title 6 THSC § 431.321(e).
\(^{227}\) A "community pharmaceutical access program" means a program offered by a licensed pharmacy under which the pharmacy assists financially disadvantaged persons to access prescription drugs at no charge or at a substantially reduced charge.
\(^{228}\) Title 6 THSC § 431.321(a).
Long Term Care Facilities

The Texas Human Resources Code defines long-term care (LTC) services as, “the provision of personal care and assistance related to health and social services given episodically or over a sustained period to assist individuals of all ages and their families to achieve the highest level of functioning possible, regardless of the setting in which the assistance is given.” Long-term care facilities must be licensed and maintain compliance with licensing rules in order to operate in Texas. Long-term care providers in Texas include: nursing facilities/homes, intermediate care facilities for the mentally disadvantaged/related conditions, assisted living facilities, adult day care facilities, and home and community support services agencies, including home health, hospice and personal attendant services. These types of facilities/services are subject to many regulations, including regulations related to the management and disposal of medications at the facilities.

Nursing Homes

Nursing homes are defined as institutions that provide organized and structured nursing care and service and are licensed under the Texas Health and Safety Code. An “institution” is defined as an establishment that: furnishes, in one or more facilities, food and shelter to four or more persons who are unrelated to the proprietor of the establishment; and provides minor treatment under the direction and supervision of a physician licensed by the Texas Medical Board, or other services that meet some need beyond the basic provision of food, shelter, and laundry.

Nursing homes are required to employ a licensed pharmacist responsible for operating the institution’s pharmacy; or contract with a licensed pharmacist to advise the institution on ordering, storage, administration, and disposal of medications and biologicals and related recordkeeping. The regulations provide that nursing homes must store medications under appropriate conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security. Nursing homes must also “properly” dispose of medications that have discontinued or are outdated and any medication in a container with a worn or illegible label or that is missing a label. Medications of deceased residents, medications that have passed the expiration date, and medications that have been discontinued must be securely stored and reconciled. These

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229 Texas Human Resources Code § 22.0011.
231 40 TAC § 19.101(87), defining “nursing facility/home” as “[a]n institution that provides organized and structured nursing care and service, and is subject to licensure under Health and Safety Code, Chapter 242. The nursing facility may also be certified to participate in the Medicaid Title XIX program. Depending on context, these terms are used to represent the management, administrator, or other persons or groups involved in the provision of care to the residents; or to represent the physical building, which may consist of one or more floors or one or more units, or which may be a distinct part of a licensed hospital.”
233 TEX. HEALTH & SAFETY CODE § 242.602(a).
234 TEX. HEALTH & SAFETY CODE § 242.603(a).
235 TEX. HEALTH & SAFETY CODE § 242.603(b).
236 40 TAC §19.1504(g).
medications must be disposed of according to federal and state laws or rules on a quarterly basis.\textsuperscript{237} These medications cannot be given to a family member or representative.\textsuperscript{238}

As mentioned earlier, the TSBP rules allow a nursing home’s consultant pharmacist to destroy both controlled and non-controlled unused prescription drugs, if certain inventorying and witness conditions are met.\textsuperscript{239} Alternatively, the TSBP rules allow consultant pharmacist to utilize a waste disposal service to destroy controlled and non-controlled prescription drugs dispensed to patients in a nursing home, provided conditions are met.\textsuperscript{240} In both cases, the TSBP rules require that the drugs be disposed of in a manner to “render them unfit for human consumption and in compliance with all applicable state and federal requirements.”\textsuperscript{241} No specific disposal methods that would make drugs unfit for human consumption are offered in the TSBP or the nursing home rules in the THSC. Also, the nursing home rules relate to “medications”, which under the definition includes both OTC and prescription drugs. The nursing home rules require that the consultant pharmacist is required to provide advice on the disposal of “medications”, therefore also including OTC and prescription pharmaceuticals. However, the TSBP rules related to disposal by a consultant pharmacist only reference disposal of controlled substances and dangerous drugs (prescription drugs); there are no requirements included for the disposal of OTC non-prescription drugs.

**Assisted Living**

Assisted living facilities provide individualized health and personal care assistance in a homelike setting, which can range from large apartment-like settings to private residences. “Assisted living facility” is defined in the THSC as a facility that: furnishes, in one or more facilities, food and shelter to four or more persons who are unrelated to the proprietor of the establishment; provides personal care services or administration of medication by a person licensed or otherwise authorized in this state to administer the medication; and may provide assistance with or supervision of the administration of medication.\textsuperscript{242} As with nursing homes, pharmaceuticals in an assisted living facility are the property of

\textsuperscript{237} Id.
\textsuperscript{238} Id.
\textsuperscript{239} 22 TAC § 303.1(a)(1).
\textsuperscript{240} 22 TAC § 303.1(a)(2). If the consultant pharmacist employs a waste disposal service, the waste disposal service must be in compliance with applicable rules of the TCEQ and EPA relating to waste disposal. The drugs must also be inventoried and such inventory verified by the consultant pharmacist prior to placing the drugs in an appropriate container, and sealing the container. The consultant pharmacist must seal the container of drugs in the presence of the facility administrator and the director of nursing or one of the other witnesses listed in paragraph (1)(D) of this subsection (tamper resistant tape must be placed on the container in such a manner that any attempt to reopen the container will result in the breaking of the tape; and the signature of the consultant pharmacist must be placed over this tape seal. The sealed container must be maintained in a secure area at the nursing home until transferred to the waste disposal service by the consultant pharmacist, facility administrator, director of nursing, or acting director of nursing. A record of the transfer to the waste disposal service must be maintained and attached to the inventory of drugs. The waste disposal service must also provide the facility with proof of destruction of the sealed container. All records required must be maintained by the consultant pharmacist at the nursing home for two years from the date of destruction.
\textsuperscript{241} 22 TAC § 303.1(a)(1)(D).
\textsuperscript{242} TEX. HEALTH AND SAFETY CODE § 247.002(1).
the patient/resident. Unlike nursing homes, assisted living facilities are not required to employ or contract a consultant pharmacist. Assisted living facilities are required to provide for proper storage of medication.243 Residents who are able to administer their own medication may do so,244 however, assisted living facilities may provide supervisory assistance to residents who are unable to self-administer their medication.245 Medications that are no longer being used by the resident are to be kept separate from current medications and are to be disposed of by a registered pharmacist licensed in the State of Texas.246 Unused medications subject to this requirement include: medications discontinued by order of the physician; medications that remain after a resident is deceased; or medications that have passed the expiration date.247 Those situations would likely cover the majority of unused medications generated in an assisted living environment. The only other scenario where pharmaceuticals may go unused and require disposal would be if medications are dropped, spilled or potentially adulterated after they had been dispensed from the pharmacy to the patient.

Some pharmaceuticals that go unused and require disposal at assisted living facilities will probably be either characteristic- or listed-RCRA hazardous waste. As with nursing homes (and all other health-care institutions and long-term care facilities), an assisted living facility must be able to identify what hazardous wastes they may generate.

In contrast to nursing homes, patients who self-administer medications and secure them in their own room are responsible for their disposal. Patients with medications in their room at an assisted living facility are responsible for those medications and may employ their own disposal methods.

Home and Community Support Services (Home Health and Hospice)

Home and community support services can include hospice services and independent living environments. “Home and community support services agency” is defined in the TAC as “a person who provides home health, hospice, or personal assistance services for pay or other consideration in a client's residence, an independent living environment, or another appropriate location.”248 Home health services include the provision of one or more of the following health services required by an individual in a residence or independent living environment: nursing, including blood pressure monitoring and diabetes treatment; physical, occupational, speech, or respiratory therapy; medical social service; intravenous therapy; dialysis; or service provided by unlicensed personnel under the delegation or supervision of a licensed health professional.249 “Hospice” is defined as “[a] person licensed...to provide hospice

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243 40 TAC § 92.41(j)(5).
244 40 TAC § 92.41(j)(3).
245 40 TAC § 92.41(j)(2). Supervision includes and is limited to: reminders to take their medications at the prescribed time; opening containers or packages and replacing lids; pouring prescribed dosage according to medication profile record; returning medications to the proper locked areas; obtaining medications from a pharmacy; and; listing on an individual resident's medication profile record the medication. Id.
246 40 TAC § 92.41(j)(6).
247 40 TAC § 92.41(j)(6).
248 40 TAC § 97.2(42).
249 40 TAC § 97.2(45).
services, including a person who owns or operates a residential unit or an inpatient unit.\textsuperscript{250} Hospice services include palliative care for terminally ill clients and support services for clients and their families that: are available 24 hours a day, seven days a week, during the last stages of illness, during death, and during bereavement; are provided by a medically directed interdisciplinary team; and may be provided in a home, nursing facility, residential unit, or inpatient unit according to need.\textsuperscript{251}

Hospices are also required to employ a licensed pharmacist or have a formal agreement with a licensed pharmacist to advise the hospice on the ordering, storing, administration, disposal and recordkeeping of medication.\textsuperscript{252} The hospice service must have procedures for control and accountability of all medications throughout the facility.\textsuperscript{253} In accordance with state laws, all medications must be stored in locked compartments, for which only authorized personnel have keys.\textsuperscript{254} Controlled medications that are not longer needed by the client/patient must be disposed of in compliance with state requirements; the pharmacist and registered nurse must dispose of medications and prepare a record of the disposal.\textsuperscript{255}

When hospice services are provided within a nursing facility, the registered pharmacist and a nurse are required to dispose of controlled medications that are no longer needed in compliance with state requirements. Since it is the facility and an agent of the facility (nurse and contracted pharmacist) who collect and dispose of unused pharmaceuticals, the facility is responsible for disposal.

When hospice services are performed at a patient’s residence, group home, independent living community or other residential unit (“in-home hospice services”), hospices are required to have and enforce a policy for the disposal of controlled medications maintained in a client’s residence for when the medications are no longer needed by the client.\textsuperscript{256} For in-home hospice services, staff may provide recommendations and physical assistance in the destruction of unused pharmaceuticals, however, the unused pharmaceuticals are the patient’s/resident’s responsibility.

When hospice services are performed in an in-patient setting (that is, in a hospice section of a hospital), the hospital, or rather the hospital’s in-house pharmacy, provides pharmaceuticals to the hospice section and, as such, management and disposal of unused pharmaceuticals in the hospice section would follow the same requirements as the hospital.\textsuperscript{257}

\textsuperscript{250} 40 TAC § 97.2(36).
\textsuperscript{251} 40 TAC § 97.2(37).
\textsuperscript{252} 40 TAC § 97.403(w)(12)(A).
\textsuperscript{253} 40 TAC § 97.403(w)(12)(F).
\textsuperscript{254} 40 TAC § 97.403(w)(12)(H).
\textsuperscript{255} 40 TAC § 97.403(w)(12)(I).
\textsuperscript{256} 40 TAC § 97.403(u).
\textsuperscript{257} Dunaway, R., 2010. Information provided by Ms. Rose Dunaway, Community Care and Hospice Specialist, Texas Association for Home Care & Hospice, email correspondence 2 September 2010.
**HIPAA and the Protection of Personal Information**

The Health Insurance Portability and Accountability Act (HIPAA) potentially impacts pharmaceutical waste disposal because of its restrictions upon the dissemination of protected health information (PHI). Generally speaking, HIPAA has twofold protection based upon civil rights and privacy. The civil rights element of the Act protects against discrimination of customers by health care providers and social service programs while the privacy element of the Act protects against the dissemination of PHI by “covered entities.” The United States Department of Health and Human Services (HHS) maintains an Office for Civil Rights (OCR) that enforces the provisions of HIPAA.

As an example, a pharmacy could potentially violate the terms of HIPAA if it collects used pharmaceuticals (potentially with patient information on the bottle) and then releases those bottles to a disposal company.

**United States Postal Service Regulations Regarding Mailing of Pharmaceuticals**

*Mail-back Programs.* The United States Postal Service (USPS) has regulations limiting the types of drugs that may be sent through the US mail service. USPS Publication 52, Hazardous, Restricted, and Perishable Mail, provides information concerning what may be mailed and how certain items must be packaged. USPS also publishes the standards for hazardous, restricted, and perishable mail in Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM®) Section 601, “Mailability.” For drugs that are legal to mail, the postal service standards limit who may send and receive these drugs and also requires that certain packaging requirements are met. Mailers are responsible for ensuring compliance with Postal Service standards, as well as any other applicable federal laws and regulations. Mailers are also responsible for being familiar with the characteristics of any drug(s) they are mailing, such as flammability, toxicity or corrosivity and may affect mailability.

*Mailing Controlled Substances*

The USPS standards provide that controlled substances and drugs containing controlled substances may only be mailed through domestic mail provided that the following conditions are met:

1. Both the mailer and the addressee must meet one of the following two conditions:
   - Be registered with the DEA; or
   - Be exempted from DEA registration requirements.

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258 Available online at: <pe.usps.com/text/pub52/welcome.htm>.
259 Available online at: <pe.usps.com/text/dmm300/601.htm>.
260 If distribution of a controlled substance is unlawful under 21 U.S.C. § 801 or any of the rules in 21 C.F.R. § 1300, then mailing of the substance is also unlawful. 18 U.S.C. § 1716.
For prescription medicines containing narcotic drugs, only a pharmacist, medical practitioner, etc., who dispenses the medication may mail these substances to patients that are under their care.\textsuperscript{261}

There are also specific packaging requirements that apply to the mailing of controlled substances. The inner packaging must be marked and sealed in accordance with the applicable provisions and regulations of the CSA (21 U.S.C. § 801, et seq., and any implementing regulation in 21 C.F.R. § 1300, et seq.) and must also be securely contained within a plain outer wrapper or packaging.\textsuperscript{262} The outside of the mail piece may not have markings of any kind indicating the nature of its contents.\textsuperscript{263} General packing requirements also apply.\textsuperscript{264}

**Mailing Prescription, Over-the-Counter, and Patent Medicines and Related Items (Excluding Controlled Substances)**

The USPS allows mailing of all prescription, nonprescription, and patent medicines and related items, including solicited and unsolicited samples of such items that are not controlled substances, under the following conditions:

1. Prescription medications containing non-narcotic drug(s) may be mailed only by a pharmacist, medical practitioner, etc., who dispenses the medication at issue to a patient under their care.

2. OTC medications may be mailed provided that they meet all federal, state or local law that may be applicable, such as the Poison Prevention Packaging Act of 1970 (15 U.S.C. § 1471(2) and the Consumer Product Safety Commission requirements (16 C.F.R. § 1700).\textsuperscript{265}

Mail pieces containing these prescription, nonprescription, and patent medicines and related items must be held in a plain outer wrapper or packaging without any markings on the outside that indicate the nature of the contents.\textsuperscript{266} General packaging requirements also apply.\textsuperscript{267}

**Returning Prescription Drugs**

The USPS allows the consumer to return prescription drugs through the mail, but only for very limited purposes. Mailers are allowed to use merchandise return service to mail prescription drugs if there has been: (1) a drug recall; (2) a

\textsuperscript{261} United States Postal Service (USPS), 2008a. Publication 52, Hazardous, Restricted, and Perishable Mail, Section 473.1 Controlled Substances (January 2008); DMM § 601, Subpart 12.12.3 Controlled Substances.

\textsuperscript{262} United States Postal Service (USPS), 2008b. Publication 52, Hazardous, Restricted, and Perishable Mail, Section 474(a) (January 2008); DMM § 601, Subpart 12.12.6 Mailing Standards.

\textsuperscript{263} Id.

\textsuperscript{264} Id.

\textsuperscript{265} United States Postal Service (USPS), 2008c. Publication 52, Hazardous, Restricted, and Perishable Mail, 473.2 Drugs (Other Than Controlled Substances) (January 2008); DMM § 601, Subparts 12.12.1 Over-the-Counter Drugs and 12.12.2 Prescription Drugs.

\textsuperscript{266} United States Postal Service (USPS), 2008d. Publication 52, Hazardous, Restricted, and Perishable Mail, 474(b) (January 2008); DMM § 601, Subpart 12.12.4 Packaging and Markings.

\textsuperscript{267} Id.
voluntary manufacturer withdrawal; (3) or if a dispensing error occurred such as incorrect drug, dosage or strength.  

Manufacturers or their registered agents must provide mailing containers to their customers for purpose of mailing back the drug at issue. The mail piece must be addressed to the manufacturer or its registered agent. Manufacturers and their registered agents are required to use merchandise return service with First-Class or Priority Mail for these returns. Manufacturers or their registered agency are also responsible for maintaining any records required by DEA regulations or the FDA.

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268 United States Postal Service (USPS), 2008e. Publication 52, Hazardous, Restricted, and Perishable Mail, 473.6 Return of Prescription Drugs (January 2008); DMM § 601, Subpart 12.12.5 Return of Prescription Drugs; see also 21 CFR 1307.12.

269 Id.

270 Id.

271 Id.

272 Id.
Current Unused Pharmaceutical Disposal Practices

This section presents how unused pharmaceuticals are currently disposed of in Texas. Each type of stakeholder group that manages or disposes of pharmaceuticals is discussed separately; health-care providers are discussed first, followed by other business entities that manage or dispose of unused pharmaceuticals, followed by consumers. The information regarding current disposal methods was obtained through: discussions with the Advisory Group; the disposal surveys; the EPA’s Health Care Industry (HCI) study; and consultation with health-care experts in Texas throughout this study.

Health-Care Providers

Physician’s offices

Physicians’ offices tend not to store large amounts of pharmaceuticals at their offices. The types of pharmaceuticals administered to patients within a physician’s office are commonly liquids, such as vaccines, which may be contained within pre-filled syringes, or may be drawn up into a syringe by facility staff. Other pharmaceuticals that are housed in a physician’s office are samples obtained from pharmaceutical manufacturers which are provided at no cost to patients.

Unused pharmaceuticals in physicians’ offices that require disposal will generally be the leftover liquid pharmaceuticals contained within syringes and leftover/expired solid dose pharmaceutical samples. Additionally, in some cases, as a result of poor stock use, ordering or rotation practices, some unopened pharmaceuticals may expire while housed in the physician’s office drug storage area.

In terms of transferring the unused pharmaceuticals to another entity, physician’s offices will not send unused pharmaceuticals back to a reverse distributor since they have already been issued from a pharmacy or wholesaler. According to the Texas Health and Safety Code, physician’s offices could take advantage of the state’s drug donation program if the unused drugs met all criteria; however, based on feedback from the Advisory Group, and from verbal communication with physicians who own private practices, it is unlikely that they would have significant amounts of unopened unused pharmaceuticals to provide to a donation program.

Health-care providers on the Advisory Group noted that expired professional samples in a physician’s office can be, and usually are, taken back by the vendor when they next visit. The Advisory Group also noted that unused pharmaceuticals in the solid form (leftover or expired solid doses, and those expired samples not returned to the vendor) and some liquids leftover in syringes will be disposed of in a biohazard box/red-bag which will be periodically taken away for disposal by a waste management service. It is unlikely that physicians’ offices in Texas have their own autoclave to treat the waste contained in the biohazard container, so the treatment and ultimate
disposal of most pharmaceutical waste generated by the physician’s office is undertaken by the waste disposal company.

There seems to be a number of reasons why physician’s offices dispose of most unused pharmaceuticals in the biohazard box, as regulated medical waste. Primarily, disposing of all substances in one manner is convenient, time-efficient, requires very little staff training and likely less expensive than spending time segregating out hazardous substances and special waste unused drugs which may then require, at the minimum, obtaining an authorization from the TCEQ, and possibly disposing of hazardous waste at a permitted hazardous waste disposal facility which may be more expensive than treating medical waste and disposing of it in a landfill. Additionally physicians consider the biohazard box/red-bag an irretrievable method of disposal since it is unlikely that someone will seek to obtain pharmaceuticals, even controlled substances, from a biohazard box which also contains sharps.

Dental Offices

The following information regarding unused pharmaceuticals and their disposal in dental offices was provided by the Texas Dental Association.273

While it is common for dentists to prescribe pharmaceuticals to their patients, dentists in Texas do not act as pharmacists. Instead, they provide their patients with a written prescription which the patient then fills at his or her local pharmacy. Texas law prohibits dentists from selling prescription products from their dental offices or anywhere else unless the dentist holds a license to practice pharmacy; however, a dentist may provide samples of prescription products at no charge.

Due to the prohibition against selling prescription products, Texas dentists do not purchase pharmaceuticals in significant quantities. The American Dental Association (ADA) survey of dental practices for 2006 (“The Survey of Dental Practice 2006”) reported that drugs accounted for only 0.4% of a solo practitioner's expenses.

The most commonly used pharmaceutical in dental offices are injectable local anesthetics. (These are not included in the data from the 2006 survey reported above.) In most cases local anesthetics will be the only pharmaceuticals that dental offices store onsite. Regardless of the specific drug administered, local anesthetics for dental use are supplied in single-use glass cartridges containing approximately 2 milliliters (ml) of solution. Disposable syringes are available, but the vast majority of cartridges are used with stainless steel dental syringes. A disposable dental needle is then attached to the syringe for delivery of the drug.

Before and during the injection, aspiration is used to confirm that local anesthetic is not introduced into a blood vessel and, as a result of this process, after injection the spent cartridge may contain blood. If it contains blood, the spent cartridge is disposed of in the medical waste sharps container, along with

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the disposable dental needle. As with physician’s offices, a medical waste disposal service periodically collects the biohazard boxes, treats the waste then disposes of it in a permitted MSW landfill. Once the anesthetic is administered, if the cartridge seems free from blood and if all anesthetic is expelled the empty cartridge is simply disposed of in the municipal trash.

**Hospitals**

In general, pharmaceutical waste is generated at hospitals before, during and after patient treatment, as well as during stocking activities. Pharmaceutical waste can be generated in the hospital pharmacy, patient care units, emergency rooms, intensive care units, oncology/hematology, radiology, ambulances, outpatient clinics, and hospital drug storage areas. In the hospital pharmacy, waste can be generated as a result of stocking activities to ensure sufficient materials are available for regular care (i.e. expired pharmaceuticals) and as a result of the discontinuation of products. Pharmaceutical waste can also be generated before treatment during drug preparation such as during compounding and when preparing IVs and filling syringes, which might occur in the pharmacy or at another satellite part of the hospital. Pharmaceutical waste can be generated on the patient floor during treatment if excess medication is prepared (e.g. excess fluids are drawn up into syringes or IV bags) and also after patient treatment (for example, unused unit doses).

Since pharmaceuticals are still under the control of health-care professionals within a hospital until the pharmaceutical is administered to the patient, many unused pharmaceuticals can be, and are, returned to the hospital pharmacy. Nursing staff and physician’s can return unused and unopened (still contained within protective packaging) substances brought to the patient floor back to the hospital’s pharmacy for redistribution to another patient or another part of the hospital. Even unopened expired drugs in a hospital can be returned to the pharmacy which the pharmacy can arrange to be returned to the wholesaler/manufacturer (through a reverse distributor) for a small credit. The hospital pharmacy may also house unused pharmaceuticals that cannot be sent away with a reverse distributor or transferred to another location, therefore the disposal of the pharmaceuticals become the responsibility of the hospital pharmacy.

While unused pharmaceuticals on the hospital patient floor can be returned to the hospital’s in-house pharmacy in some cases, there are still a number of

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275 Id.

276 Compounding means to mix drugs to fit the patient’s need. This is usually done by a pharmacist but sometimes a physician for a number of reasons such as to avoid a nonessential ingredient that causes a patient allergies, to obtain the exact dose needed and not more than in required and to change a solid dose pill into a liquid form (ERG, 2009b).

277 See ERG, 2009b.

278 The patient floor is patients are located during treatment. Whether it is a clinic or hospital or other facility, once the nurse/physician has obtained pharmaceuticals from the in-house pharmacy or drug storage area and intends to administer them to patients in their care, the pharmaceuticals are considered on the patient floor.
scenarios when unused pharmaceuticals within a hospital cannot be returned to
the in-house pharmacy and therefore require disposal: when the patient only
requires the portion of a solid dose pill; when only a portion of a pre-filled
syringe or intravenous (IV) fluid bag was required by the patient; when the
pharmaceutical was dropped or spilled after being obtained from the pharmacy;
and after the pharmaceutical packaging had been opened but ultimately not
administered to the patient. Essentially, unused pharmaceuticals in hospitals
could not be returned to their dispensing pharmacy in cases where the secure
containment of the pharmaceutical is compromised and has potentially been
exposed to impurities.

Additionally, there may be a few circumstances where the hospital does not
have its own pharmacy onsite, in which case it is more likely that some unused
pharmaceuticals may be stored and disposed of onsite at the hospital, because of
convenience reasons (storing unused drugs onsite before coordinating returns to
the offsite pharmacy may be cumbersome and limited by the facilities of the
hospital, i.e. space). However, as long as the off-site pharmacy the hospital uses
is a DEA registrant, both controlled and non-controlled unused and unopened
pharmaceuticals could be returned to the off-site pharmacy for restocking or
transfer to the manufacturer or distributor. If the offsite pharmacy was not a DEA
registrant, it could still accept non-controlled substances back from the hospital
that were unused, unopened and not compromised in any way, but the hospital
would then be responsible for disposal of unused controlled pharmaceuticals.

Unused pharmaceuticals that cannot be returned to the hospital pharmacy can
either be (1) disposed of by staff on the patient floor, that is, as the drugs become
unused, or (2) disposed of after staff return them to a hospital’s drug
sorting/storage area, if one exists (separate to a hospital pharmacy). Therefore,
along with the in-house pharmacy itself, there are three areas in a hospital
whereby unused drugs may be disposed of. Overall, if a hospital cannot
redistribute, send to a reverse distributor or donate pharmaceuticals (according
to the requirements of the state’s Drug Donation Program), then unused
pharmaceuticals must be disposed of.

The disposal surveys revealed the three most common reasons why
pharmaceuticals go unused on the patient floor in Texas which are: (1) patients
only require a portion of a solid dose drug, and the excess portion was
unwanted/unneeded and could not be re-used on another patient (34.6% of
respondents); (2) excess liquid pharmaceuticals were leftover in pre-
manufactured/pre-filled syringes or IV bags (30.8% of respondents); and (3)
excess samples were provided by pharmaceutical manufacturers to physicians
and those expired before being offered to patients (23.1% of respondents).

The disposal survey confirmed that a low proportion of pharmaceuticals that
reach the patient floor go unused, compared with what is used, consistent with

279 Interestingly, some health-care providers involved in the Advisory Group noted that expired professional samples
can be taken back by some vendors when they next visit; however, as identified in the disposal surveys, this was
either not known or not arranged by the health-care providers surveyed, or perhaps not a policy of every vendor.
suggestions made during the Advisory Group meetings.\textsuperscript{280} The disposal survey indicated that most (56\%) health-care industry respondents reported that only 1-10\% of pharmaceuticals on the patient floor go unused. Another 16\% of respondents noted that 11-25\% of pharmaceuticals go unused on the patient floor, and 4\% noted that 26-50\% of pharmaceuticals go unused on the patient floor; some (20\%) did not know what proportion goes unused and 4\% reported that no pharmaceuticals ever go unused on the patient floor. No respondents stated that over half of the unused pharmaceuticals on the patient floor go unused. From an outreach meeting with a waste management vendor, EPA, in their Health Care Industry (HCI) study, gathered some general statistics on the disposal of unused pharmaceuticals from health care facilities. Specifically, data show that the total amount of unused pharmaceuticals at a hospital ranges from 10–20 pounds per bed/per month total.\textsuperscript{281}

Hospital/medical representatives involved in the Advisory Group meetings stated that the types of pharmaceuticals that are most commonly flushed or poured down the drain on the patient floor in hospitals are liquids, usually from pre-filled containers. The disposal survey results supported this but also suggested that portions of solid dose pills that are not returnable to the pharmacy also commonly go unused in a hospital setting. Regarding the most common type of pharmaceutical media that goes unused (partially or completely) on the patient floor, the surveys indicated that liquid from IV bags and solid dose pills were significant, each garnering 32\% of the responses. Liquid from syringes was also a fairly common response, with 20\% noting them as the most common type of unused pharmaceutical on the patient floor. Some respondents (12\%) did not know what the most common type of unused pharmaceutical was on the patient floor, while one respondent (4\%) thought that topical substances were the most common unused pharmaceutical on the patient floor. Therefore 84\% of the survey respondents\textsuperscript{282} reported that the most common type of pharmaceutical substance that goes unused on the patient floor is either liquid from IV bags or syringes or solid dose pills.

In cases where a pharmaceutical cannot be returned to the hospital pharmacy for redistribution, hospital staff has a few options. Generally, hospital/medical representatives that participated in the Advisory Group meetings noted that unused liquid pharmaceuticals on the patient floor will usually be disposed of down the drain. Stakeholders reported that, many times, liquids contained in syringes and IV bags will be spent in the sink, then the empty containers will be disposed of in a biohazard box (or “red-bag” or “sharps” container managed as medical waste). Sometimes, the entire container containing the liquid, usually in a syringe, will be disposed of in the biohazard box. Based on information gathered from the Advisory Group, unused solid doses on the hospital’s patient floor will usually be disposed of in the biohazard box too. Hospitals usually contract with a medical waste disposal company to remove the biohazard.

\textsuperscript{280} Asking nursing/hospital staff to track volumes or weights of unused pharmaceuticals in the hospital was considered too burdensome on staff so instead the survey asked staff for the proportion of drugs that go unused as opposed to used, based on their daily experiences on the patient floor.


\textsuperscript{282} Noting that a small handful of respondents were staff in clinics.
container wastes periodically, which are ultimately treated and disposed of in a MSW landfill or occasionally processed in a medical waste incinerator, whereby the incinerator ash is disposed of in a MSW landfill.

When asked how health-care providers on the patient floor manage or dispose of controlled substances, non-controlled RCRA hazardous pharmaceuticals and non-controlled non-hazardous (special waste) pharmaceuticals, survey respondents reported some fairly consistent disposal methods across each of the three waste groupings. Unused controlled substances are usually returned to the pharmacy/drug storage area (46% of respondents) or deposited in a “sharps” container or “red-bag/biohazard” container and a waste disposal service disposes of them (21% of respondents). Due to the limited number of options for disposing of the unused controlled substances on the patient floor when they cannot be returned to the hospital pharmacy, some hospitals have a policy of wasting the controlled substances (with a witness) down the drain, or on gauze which is then disposed of in the biohazard/medical waste container. The disposal surveys supported the feedback from Advisory Group discussions about the use of flushing as a method for disposing of unused controlled liquids. A small but identifiable proportion (12.5%) of survey respondents reported that they flush unused controlled substances on the patient floor down the sink or drain. About 8.5% of respondents reported that they either commingle controlled substances with other unused pharmaceuticals then arrange for a waste management service to collect and dispose of all unused pharmaceuticals (unsorted), or dispose of them in the regular trash. Another 12.5% reported that the question was not applicable; that is, there are never unused controlled substances on the patient floor at the facility that would require disposal or transfer.

Data from the EPA HCI study indicate that about 10–20 % of unused pharmaceuticals generated in hospitals are RCRA hazardous waste. The disposal survey respondents stated that unused pharmaceuticals on the patient floor in a hospital (or physician office) setting that would be designated RCRA hazardous waste are usually deposited in a “sharps” container or “red-bag/biohazard” container and disposed of by a waste disposal service (32% of survey respondents); returned to the pharmacy/drug storage area (24%), or segregated from other unused pharmaceuticals and dispose only of that portion as RCRA hazardous waste (20%). Only 12% of the respondents commingle unused hazardous pharmaceuticals with all other unused pharmaceuticals and arrange for a waste management service to collect and dispose of them all as RCRA hazardous waste. No survey respondents reported that they usually dispose of RCRA hazardous waste down the drain.

The disposal surveys indicated that hospitals (and the few physician offices who also responded) mainly return unused non-controlled, non-hazardous pharmaceuticals from the patient floor to the pharmacy or hospital’s drug storage/sorting area (40%). Though non-controlled, non-hazardous pharmaceuticals (special waste) are not required to be managed as medical waste, 28% of respondents noted that they co-mingle all unused pharmaceuticals

Comment made in an Advisory Group meeting by staff of a medical center in central Texas.
(including non-hazardous) in a “sharps/red-bag/biohazard” container which would be collected by a waste management service, and another 16% choose to arrange for non-hazardous pharmaceuticals (special waste) to be disposed of by a waste management company as medical waste. A smaller portion of the respondents (8%) reported that they dispose of unused non-hazardous non-controlled pharmaceuticals from the patient floor onsite in the toilet, sink, or drain. The Advisory Group was unsure about how best to dispose of unused non-controlled, non-hazardous pharmaceuticals, compared with the general awareness many had related to hazardous pharmaceuticals. The EPA HCI study reported that, most of the time (approximately 90%), unused nonhazardous pharmaceuticals in IV bags are poured down the drain in health-care settings. Another small proportion (8%, or 2 respondents) stated that they co-mingle all unused pharmaceuticals and have the waste disposed of as hazardous waste, presumably for convenience and as a precautionary measure. One respondent (4%), most likely a private physician’s office, as opposed to a hospital, stated that they disposed of unused non-hazardous, non-controlled pharmaceuticals on the patient floor in the municipal trash. Interestingly, one respondent stated that they take all of their unused non-hazardous, non-controlled to their “local pharmacy for disposal”.

Summary of Disposal on the Patient Floor. Through the Advisory Group meetings and the disposal surveys it is clear that the most common and convenient disposal method for unused pharmaceuticals on the patient floor in hospitals is to dispose of them all in the biohazard container, ultimately managing pharmaceuticals as medical waste. While pharmaceuticals are not regulated medical waste in the TCEQ waste rules, the commingling of liquid and solid pharmaceuticals with true medical waste such as sharps and infectious materials, makes the entire contents of the biohazard container medical waste, under the “mixture rule” explained earlier. Most times, medical waste at a hospital is sent offsite for treatment to an auto-clave or steam sterilizer; very few hospitals have their own autoclave. The TCEQ did not come across any hospitals in Texas throughout this study that noted they had an onsite auto-clave, though some probably exist.

The disposal survey found that few hospital staff on the patient floor that dispose of unused pharmaceuticals themselves separate the waste into hazardous, medical and special waste streams. In many cases, it seems even hazardous waste is being managed as medical waste on the patient floor in some hospitals in Texas. In general, information gathered from the health-care provider survey and from Advisory Group meetings indicates that some hospitals and other healthcare providers may not always be aware of best practices for disposing of unused pharmaceuticals and sometimes are not aware of the regulatory requirements related to hazardous, medical and special waste.

The survey respondents revealed that of most concern to hospital staff in terms of managing and disposing of unused pharmaceuticals are the CSA rules, followed by meeting RCRA hazardous waste rules and performing functions under the facility’s standard operating procedures. The surveys indicated that perceived environmental outcomes, staff safety, ease of disposal, and cost of disposal were the next most important factors for choosing the adopted disposal
methods in hospitals. No survey respondents noted that their unused pharmaceutical disposal practices were impacted by wastewater permit requirements.

It is more likely that controlled substances are the most common types of unused pharmaceutical flushed or poured down a drain on a hospital’s patient floor because of the lack of acceptable methods for destruction under the CSA. Liquids in partially used IV bags or syringes, whether controlled or non-controlled, seem to be a common problem among hospital staff on the patient floor and tend to be the main items disposed of into the wastewater stream.

Additionally, the study showed that where nursing staff or other staff on the patient floor may return unused pharmaceuticals to the pharmacy or to the hospital’s drug storage/sorting area for ultimate disposal, they will. However, many dispose of unused drugs that cannot be sent to the pharmacy on the patient floor since, presumably, it is convenient, time efficient and may be part of the facility’s standard operating procedure.

**Hospital Pharmacies and Drug Storage/Sorting areas.** Limited information is available for hospitals in Texas that have drug storage/sorting areas separate to the hospital pharmacy. Information related to hospital in-house pharmacies was requested through the disposal surveys. Seven in-house hospital pharmacies responded to the survey. As with retail pharmacies, the survey results that pharmaceuticals generated in the in-house hospital pharmacy go unused is usually due to expiration. The surveys also indicated that in many cases in-house hospital pharmacies in Texas send most unused pharmaceuticals (creditable and non-creditable items) to reverse distributors (and ultimate disposal by the reverse distributor or the manufacturer) and dispose of a small amount of unused pharmaceuticals themselves or arrange for a waste disposal service to dispose of the remaining waste. The findings of the EPA HCI Study support this. It was stated in the Advisory Group meetings that hospitals may send all drugs back to a reverse distributor even if the substances does not qualify to be returned, using the reverse distribution process as their disposal method rather than disposing of true waste pharmaceuticals (non-returnable items) themselves.

As indicated in the EPA’s HCI study, many large hospital pharmacies have arrangements with waste management collection/disposal services for the proportion of unused pharmaceuticals that they can’t redistribute or send to a reverse distributor. Controlled substances that fall into that category would be inventoried and managed through the pharmacy as required by the CSA rules. It is likely that these arrangements are also made by in-house hospital pharmacies in Texas.

In general, the EPA HCI Study found that some hospitals segregate pharmaceutical waste into hazardous waste, medical waste and non-hazardous pharmaceuticals (special waste in Texas), while others do not. Based on feedback from the hospital representatives and waste management companies on the Advisory Group, this also holds true in Texas. Some hospitals separate out drugs and dispose of them according to State/Federal waste regulations related to each type of waste, while others commingle waste and manage it as either
medical waste or hazardous waste. Stakeholders suggested that commingling is a preferred option in hospitals because separating waste is time consumptive and requires trained staff. The EPA HCI Study also noted that a few hospitals have the waste management company dispose of all unused pharmaceuticals as hazardous waste, despite only 10%-12% of waste in hospitals being RCRA hazardous waste.284

The EPA, when they visited hospitals as part of their HCI study, identified many hospitals that treated all their unused pharmaceuticals solely as medical waste; they identified only one hospital that sent hazardous waste to a hazardous waste landfill and one that sent hazardous waste to a hazardous waste incinerator. It is not common for hospitals in Texas to manage all of their waste as hazardous waste, due to the expense associated with disposal at a facility permitted to accept hazardous waste.

As with liquids and controlled substances disposed of on the patient floor, hospital representatives in the Advisory Group noted that it is likely that some liquids and controlled substances are disposed of by hospital preparation areas down the drain, because it is convenient and complies with the CSA.

Finally, this study found that there is an obvious need for information about drug disposal regulations and best management practices to be relayed to hospitals, physician’s offices and educational institutions that train nurses and physicians. Throughout this study many health-care providers expressed the need for clear information to be provided from the State to health-care facilities and their employees regarding drug disposal, especially related to non-hazardous pharmaceuticals and how the different waste rules may apply when they commingle or separate pharmaceutical waste. In fact, when asked in the disposal survey about their preferred methods of disposing or managing drugs in the health-care setting, 31% noted they would prefer training/education of patient floor staff on the best management disposal practices and another 15% noted that brochures/posters/other materials should be provided to facilities by the State of Texas regarding the best management disposal practices.

In summary, the TCEQ found that, in general, that there is a clear need for guidance to help staff in physician’s offices, dental offices, and hospitals better understand current waste rules, identify an acceptable method for disposal of controlled substances and better manage pharmaceuticals, thereby reducing the generation of unused pharmaceuticals requiring disposal.

**Long Term Care Facilities**

Very rarely do nursing homes in Texas have their own in-house/onsite pharmacy; those are limited to a few very large nursing home operations. Most nursing homes in Texas contract out pharmacy services and employ a consultant pharmacist to meet the pharmaceutical ordering, storage, administration, and disposal requirements of the rules.

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284 Hoboy, S. 2010. Written comments to the TCEQ TCEQ received from Ms. Selin Hoboy, VP Legislative and Government Affairs on behalf of Stericycle, 1 July 2010.
At nursing homes, the patient typically owns the medication. Once the off-site contracted pharmacy fills the prescription for patients, the pharmaceutical has technically been dispensed and is under the ownership of the patient, even though the nursing home stores and manages the medications onsite. As a result, any unused medications within a nursing home cannot be redistributed by the nursing home staff because the home itself does not own the medications. Additionally, since medications are already dispensed by the off-site pharmacy and owned by the patients, nursing home facilities cannot return any unused pharmaceuticals to reverse distributors (unless they have a permit to dispose of the waste and conduct waste disposal services for the nursing home, as opposed to a reverse distribution service).

An option for nursing homes is for the consultant pharmacist, under the State Board of Pharmacy rule, to return non-controlled pharmaceuticals to the dispensing pharmacy for re-sale.\textsuperscript{285} The contracted dispensing pharmacy is not required to accept returned drugs from consultant pharmacists;\textsuperscript{286} though typically they will if the unused drugs meet certain requirements for distribution/re-sale of the pharmaceuticals (they must be unused, unopened, unadulterated and have 120 days or more of shelf life).\textsuperscript{287} If the pharmacy accepts the unused unopened non-controlled pharmaceuticals back from the nursing home’s consultant pharmacist for re-sale, the pharmacy could credit the cost for the unused medication to the patient, if allowable under Medicare laws.\textsuperscript{288} If the pharmacy decides not to accept non-controlled drugs for re-sale, or if the drug containers have been opened, spilled/dropped or otherwise adulterated, or are expired (or have less than 120 days on their expiration date) then the nursing home’s consultant pharmacists have no other option but to arrange for disposal of those non-controlled drugs.

Limited options are available for the transfer of controlled pharmaceuticals from the consultant pharmacists at a nursing home to another entity. Even if the controlled substances from the nursing home were unopened, unadulterated, never in the possession of the patient and maintain 120 days or more of shelf life, controlled substances not intended to be used by the patient must be destroyed.

The Advisory Group discussions indicated that most nursing homes currently deal with unused pharmaceuticals as follows: at skilled nursing facilities, unused drugs that must be destroyed are stored in a double-locked box under the control of the administrator or the director of nurses at the facility. Unused drugs that can be returned for re-sale (and credit to the patient, or Medicare) may be returned by the consultant pharmacist to the pharmacy that dispensed the medication. Consultant pharmacists visit the facility periodically to oversee boxing of the pharmaceutical waste. The consulting pharmacist verifies the inventory of unused controlled substances. Controlled substances are then placed in a box, usually with dangerous drugs that also require disposal. Usually, the controlled substances are rendered unusable by being mixed with

\textsuperscript{285} 22 TAC § 291.8(a) and 22 TAC § 291.8(b).
\textsuperscript{286} 22 TAC § 291.8(b)(1).
\textsuperscript{287} 22 TAC § 291.8(b)(3)(A) and 22 TAC § 291.8(b)(3)(B).
\textsuperscript{288} Or credit would be provided to Medicaid, whoever paid for the pharmaceutical.
some undesirable liquid prior to being boxed up, in order to meet the CSA rules. The box is then sealed with tamperproof tape and signed by the consultant pharmacist. A registered biohazard company periodically visits the nursing home to pick up the box of unused pharmaceuticals, send them to an incinerator and returns proof of incineration to the nursing home. It is not known whether the nursing home’s disposal service sends the unused pharmaceuticals to a hazardous waste incinerator or a medical waste incinerator. 289

The long-term care facility disposal survey, of which there were 149 respondents, was designed for both nursing homes and assisted living facilities. However, the functions of the two facilities are different; the main difference is that nursing homes must employ a consultant pharmacist and usually patients do not have access to drugs, whereas in assisted living facilities, some residents may store and dispose of their own pharmaceuticals. As a result, limited information specific to each group could be obtained from the survey results. The vast majority (92.6%) of the respondents were from nursing homes where consultant pharmacists and facility staff are responsible for administering and disposing of resident’s unused pharmaceuticals. Most survey respondents reported that between one and ten pharmaceutical bottles/containers, containing some amount of unused pharmaceuticals, are collected and disposed of per week by the facility staff or a consultant pharmacist. Facilities that employ a consultant pharmacist to manage and dispose of some or all unused pharmaceuticals that have already been dispensed to residents, expressed that they usually commingle all unused pharmaceuticals and arrange for a waste management company to dispose of at a hazardous waste incinerator/hazardous waste landfill. This information coincided with what was suggested by the Advisory Group.

Assisted Living Facilities

While assisted living facilities are not required to employ or contract a consultant pharmacist to provide information on obtaining, storing or administering pharmaceuticals, the regulations do require that unused drugs at assisted living facilities must be disposed of by a pharmacist. Information obtained from the Advisory Group suggests that it is difficult for assisted living facilities to contract a pharmacist simply for drug disposal purposes. 290 Based on input from the Advisory Group, many assisted living facilities use waste management services to dispose of unused medications or render them unusable and dispose of them in the trash. It is not known how the waste management companies that collect waste pharmaceuticals from an assisted living facility manage and dispose of the substances.

In the long-term care provider survey, for those facilities that do not handle or dispose of resident’s unused pharmaceuticals, 62% did not know how residents usually dispose of their unused pharmaceuticals. Almost half of the facilities

289 Gruber, E., 2010. Comment provided by Ed Gruber at Advisory Group meeting on behalf of the Texas Health Care Association.
290 Skelton, E. 2010. Comment at Advisory Group meeting, made by from Elizabeth Skelton, Nursing Facility Policy Specialist, on behalf of the Texas Department of Aging and Disability Services.
that do not handle or dispose of resident’s unused pharmaceuticals report that there is no necessity to collect unused pharmaceuticals because residents do not request staff to dispose of their unused pharmaceuticals contained within their room. For these same facilities, 71% reported that they do not know what advice is given to patients on how to dispose of their controlled substances.

**Home Health and Community Support Services**

Ten responses were received for the home and community support services disposal survey; half of those were hospice service providers at an out-patient hospice facility while the other half were services provided in the in-home setting. No in-patient (hospital setting) hospice service providers responded to the survey.

A majority of the disposal survey respondents (70%, or 7 respondents) reported that they witness clients/patients dispose of less than 10 partially filled or full containers or packages per week. One respondent (10%) said they witnessed their clients’ dispose of 10-25 full or partially-full containers of unused pharmaceuticals per week, while two respondents (20%) noted that their clients/patients never have unused pharmaceuticals that require disposal.

The three most common types of pharmaceuticals that go unused in a hospice facility or in a home visited by a hospice or home-health/support service are 1) solid dose pills (controlled substances); 2) solid dose pills (prescription non-controlled pharmaceuticals); and 3) liquid controlled substances contained within unused (or partially used) syringes.

Information collected throughout this study\(^{291}\) suggests that prescriptions for hospice patients and others that require in-home care change often and, when a patient dies, the families are often left with a significant amount of medications they need to dispose of. The prescribing of controlled substances is common in the elderly and in terminal patients, to ease pain during end-of-life care. In the in-home setting, hospice service staff most times only advise patients or their families how to dispose of controlled substances and other unused pharmaceuticals, while occasionally hospice service staff assist patients in the act of disposal of unused pharmaceuticals if they cannot do it themselves. The Advisory Group noted that some hospice or home health services that provide assistance in patient homes will provide the FDA guidance or similar information to the patient or their family for how to dispose of unused pharmaceuticals, as opposed to assisting with disposal.

In a hospice facility (not an in-home setting), medications are stored in locked compartments, which can only be accessed by authorized personnel.\(^{292}\) Controlled medications that are no longer needed by the client/patient must be disposed of in compliance with state requirements; the pharmacist and registered nurse must dispose of medications and prepare a record of the disposal. The Advisory Group suggested that when patients own the drugs

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\(^{291}\) From Advisory Group stakeholders, from phone calls from in-home care providers and from reviewed literature.  
\(^{292}\) In accordance with 40 TAC § 97.403(w)(12)(H).
administered to them in a home or residential unit, there are limited disposal options for the patient or their family; typically, only disposal down the drain or in the trash are utilized in that situation. While non-controlled pharmaceuticals that go unused in the patient’s home could be returned to a pharmacy for disposal, it may not be a common option adopted due to patient mobility issues. Additionally, even if families of patients who received in-home care took the unused pharmaceuticals to a pharmacy, the pharmacy would not be able to accept controlled substances dispensed to the patient and, as such, the patient is responsible for disposing of controlled substances.

The surveys revealed that in-home care or hospice service providers in Texas direct a significant proportion of unused pharmaceuticals to the wastewater stream. Over a third of survey respondents said that they usually advise patients to dispose of unused pharmaceuticals in the sink or drain. One respondent stated that they recommend that the patient take their unused pharmaceuticals back to their local pharmacy, while others (50% of the respondents for this survey question) offered other solutions to patients, such as: suggesting (and facilitating) disposal of any unused controlled substances by using kitty litter, adding water to make it a non-desirable substance and then disposing of it in the municipal trash; and suggesting patients place unused pharmaceuticals in plastic bottle that contains bleach.

Most (66% of survey respondents) hospice providers noted that they do not store any medications at their office and so disposal in their profession only occurs at the facility itself where patients are housed and in the patient’s home/residential unit. For those that do store some pharmaceutical at their facility respondents said they usually disposed of those, when required, either in a biohazard bag or they separate controlled substances out and dispose of those in the sink/drain and send the rest to either a medical waste treatment facility or hazardous waste disposal facility.

The main factors that impact how hospice and in-home care service providers advise patients to dispose of their unused pharmaceuticals were evenly split between ensuring compliance with the Texas Health and Safety Code or Texas Administrative Code, compliance with the CSA as well as ease of disposal/convenience, concerns with drug-diversion for illicit purposes, and accidental poisoning concerns. The surveys suggested that as with assisted living facilities, staff involved in hospice and in-home care services seem to desire guidance regarding how unused pharmaceuticals should be disposed of in the hospice facility and how they should advise their clients/patients to dispose of unused pharmaceuticals. Five survey respondents stated that their preferred option for assisting clients/patients would be to continue to advise patients to dispose of unused pharmaceutical down the drain. Some of the surveys suggested that some in-home care and hospice stakeholders were not aware of the FDA/ONDCP guidance for consumer disposal of unused medications; those that were aware of the federal guidance suggested that guidance to their clients.
**Veterinary Providers**

The Texas Veterinary Medical Association (TVMA) explained to the Advisory Group that veterinarians in Texas face unique challenges with respect to waste disposal. Veterinarians have to deal with the disposal of a wide array of waste, from dead animals to sharps to unused topical, liquid and solid pharmaceuticals. Since veterinarians also have to act as their own pharmacists they tend to keep quantities of pharmaceuticals on site in case a patient needs it on short notice.

The TVMA stated that there are only three general options for pharmaceutical disposal for veterinarians. First, veterinarians can return pharmaceuticals to pharmaceutical manufacturers, but not all manufacturers willfully take back pharmaceuticals from veterinarians, especially controlled substances. Second, veterinarians can also use reverse distributors, but this is difficult because there are so few reverse distributors in Texas, which may make out-of-state disposal necessary. This method is also costly and can range from $30 to $750 for disposal, and there is often a per pill charge. The third method is controlled burning under the authority of the DEA.

There were 203 respondents for the veterinarian survey, most of whom (77%) work in routine care veterinary clinics in urban settings (76%). A vast majority (85%) of the respondents reported that a small proportion (between 1 and 10%) of pharmaceuticals go unused at the veterinary clinic. The most common type of pharmaceutical that goes unused in the respondent's veterinary clinics are solid dose pills (33.7% of responses), liquid from IV bags (27% of responses), liquid from bottles, jugs, or buckets (15% of responses), and liquid from syringes (10.4%). Veterinarians reported that pharmaceuticals most commonly go unused in a veterinary clinic either because (1) the pharmaceuticals became expired; (2) the veterinarian decided to stop administering the pharmaceuticals to patient (patient experienced reaction or condition changed); (3) excess liquid pharmaceuticals leftover in pre-manufactured/pre-filled syringes or IV bags; or (4) the patient only required a portion of a solid dose drug.

Survey responses to how unused controlled substances are disposed of in veterinary clinics in Texas varied widely. Some (16%) veterinarians reported that they place them in a "sharps" container or "red-bag/biohazard" container and arrange for medical waste disposal service to dispose of them; 13% of respondents reported they usually dispose of controlled substances in the drain. Other respondents (15%) reported that they return them to the pharmacy/drug storage area for future use and 14% stated that they usually return controlled substances to the manufacturer, reverse distributor or third party returns processor. A large number reported under the category of "other." Comments under "other" included destroying the substances with law enforcement or DEA supervision, encasing in concrete and arranging for animal control to incinerate them, however, many comments related to storing controlled substances in a locked box on site for a long period of time or indefinitely because it is too expensive to dispose of them or they feel there is no safe or adequate disposal option currently available.

Hazardous pharmaceutical waste generated in veterinary clinics is often deposited in a “sharps” container or “red-bag/biohazard” container which is
disposed of by a waste disposal service. Over 27% of the respondents reported that they manage them as medical waste. Many veterinarians (21%) reported that there are never unused hazardous substances at their clinic that would require disposal or transfer and 10% reported that they do not know what happens with hazardous waste pharmaceuticals. Only 4% dispose of hazardous waste pharmaceuticals in the regular trash (municipal solid waste), 2.5% commingle with all unused pharmaceuticals and arrange for collection and disposal by a waste disposal service (but do not know the final disposal destination) and only 2% (or four veterinarian clinics) reported that they dispose of unused hazardous waste pharmaceuticals in the drain.

Non-controlled, non-hazardous pharmaceuticals are generally disposed of in the regular trash (municipal solid waste). About 45% of the respondents reported that they usually dispose of non-controlled non-hazardous unused pharmaceuticals in the regular trash (municipal solid waste). About 11% (just less than the statistic on drain disposal for controlled substances) place them in a “sharps” container or “red-bag/biohazard” container and arrange for medical waste disposal service to dispose of them, 10.3% return them to the manufacturer, reverse distributor or third party returns processor, and 8.9% dispose of them on site in the sink/toilet.

The most significant factors impacting the choices that facilities employ for disposing of or transferring unused pharmaceuticals were DEA policy (Controlled Substances Act), ease and cost of disposal, not understanding waste disposal regulations and compliance with hazardous waste regulations (RCRA). One respondent commented that certain disposal methods are employed because limited options are available in rural areas.

When asked about preferred methods of managing or disposing of unused pharmaceuticals in veterinary clinics, many considered the “training/education of staff regarding best management disposal practices” to be a key approach. “Brochures/posters/other materials provided to facility regarding the best management disposal practices” was also selected as a preferred method by 28% of respondents. Others were split (31% of respondents each) between managing all as medical waste in a biohazard box, segregating wastes into their different waste categories and disposing of those separately according to TCEQ rules, and sending back to a reverse distributor or other third party returns company.

Pharmacies

This section will focus on retail pharmacies, institutional pharmacies were discussed earlier under the “hospitals” section. Two broad types of pharmaceutical waste occur in many pharmacies, differentiated by the source of the waste; that is, there are those wastes generated by the pharmacy as part of their dispensing operations (non-dispensed pharmaceuticals), and those dispensed pharmaceuticals returned to the pharmacy by customers specifically for disposal purposes, allowable under 22 TAC § 303.1(b)(1).

Since licensed retail pharmacies are within the secure “closed” pharmaceutical distribution chain, non-dispensed unused unopened but expired
pharmaceuticals in a pharmacy can be returned to the manufacturer for credit. Both controlled and non-controlled pharmaceuticals meeting those criteria could be returned since both the pharmacy and the service that returns pharmaceuticals to the manufacturer (“reverse distributors”) are DEA registrants. On some occasions, pharmaceuticals go unused but cannot be returned to the manufacturer, such as unused pharmaceuticals generated during compounding or when a pharmaceutical is dropped or spilled in the pharmacy. However, this is usually a less common reason why pharmaceuticals go unused and require disposal in a pharmacy than waste generated by the expiration of medications.

There were 70 respondents for the survey and some of those surveys were completed once on behalf of a number of mainly chain-pharmacies (one survey response represented 10 stores, one survey response represented 14 stores, one survey response represented 108 stores, one survey response represented 212 stores). Most of the respondents were in retail chain or retail independent pharmacies in urban settings.

Feedback from the disposal surveys regarding what pharmaceuticals go unused in a pharmacy as a result of their dispensing operations was consistent with the information received from pharmacy stakeholders who participated in the Advisory Group. A vast majority (90%) of the pharmacy survey respondents reported that the most common reason pharmaceuticals went unused in their pharmacy was because they expired on the shelves. Most (88%) reported that the proportion of pharmaceuticals that go unused in the pharmacy is between 1-10% of their stock. The survey suggested that at least some pharmaceuticals will go unused, or become unsalable, in a pharmacy; none of the 70 respondents reported that no pharmaceuticals ever go unused. A little over a third of pharmacies reported that they dispose of less than one cubic foot of pharmaceutical waste per month. Another third reported they have no such waste.

Most pharmacies (over 70%) that responded to the survey reported that they return all unused pharmaceuticals generated at the pharmacy as part of their operations to the manufacturer, reverse distributor or a third party returns processor. Most of the remainder of the pharmacy respondents (21%) reported that they return some unused pharmaceuticals to the manufacturer, reverse distributor or a third party returns processor and dispose of some unused pharmaceuticals themselves. For that portion of unused pharmaceuticals requiring disposal by the pharmacy itself, in most cases, a number of approaches are adopted. The most common response received was that most unused pharmaceuticals are commingled and the pharmacy arranges for a waste management/disposal company to collect and dispose of the pharmaceuticals. A few pharmacies stated in the survey that they separate unused drugs requiring disposal into hazardous and non-hazardous waste categories, and for those that employed those methods they reported that hazardous waste was sent to a hazardous waste incinerator/landfill and the non-hazardous waste is disposed of in the municipal trash. Some (almost 20% respondents) stated that they disposed of unused pharmaceutical waste in a biohazard box and arranged for a medical waste management/disposal service to treat and dispose of those. Very few stated that they disposed of all the waste in the municipal trash and no pharmacy
reported that they dispose of the unused pharmaceuticals requiring disposal into the wastewater by means of the toilet or sink.

Pharmacies seem to have no standard method of disposing of dispensed unused pharmaceuticals. Many pharmacies reported that they do not accept pharmaceuticals from customers; for those that do not accept them, some pharmacy staff provided guidance to consumers for how they may dispose of the unused drugs themselves including: disposal in the sink/toilet, disposal in the municipal trash and disposal following the federal guidance documents, while others did not offer disposal guidance to the customer. For those that do accept dispensed returned unused pharmaceuticals from customers, there were no pharmacies that reportedflushing those and only one reported they dispose of them in the municipal trash. Other pharmacies that accept non-controlled pharmaceuticals from customers choose to dispose of those as either hazardous waste, as medical waste, or arrange for a disposal company to dispose of, but are unaware of the final disposal method. At least five respondents specifically noted that they accept and dispose of "both non-controlled and "controlled" or "all/any" pharmaceuticals returned to the pharmacy by customers. One respondent reported that they "accept returned non-controlled substances from customers and dispose of those in the county’s home hazardous waste collection twice a year."

The most preferred options for aiding customers with disposal or management of unused pharmaceuticals were: not to accept any unused pharmaceuticals that customers want to return (45% of responses did not want to accept drugs from consumers) but be able to provide customers with disposal guidance (verbally or through a brochure or information packet); and to provide mail-back envelopes for customers so that they can mail their unused pharmaceuticals to a central location for disposal (25% of responses). Almost 20% of the survey responses for this question noted that they would like to provide a secure drop box in the pharmacy for customers to drop off their unused non-controlled pharmaceuticals and arrange for disposal via incineration.

**Pharmaceutical Manufacturers**

"Pharmaceutical manufacturers" is a broad term used in this study to include entities that engage in the chemical manufacturing of active pharmaceutical ingredient (API), formulation of finished drugs, packaging of finished drugs, storing drugs prior to sale, processing/disposing of returns from reverse distribution, and processing/disposing of returns from clinical trials/research.

Two pharmaceutical companies responded to the pharmaceutical manufacturer disposal survey. Many manufacturers on the Advisory Group showed willingness to respond to the survey but they had no facilities in Texas so it was not appropriate for them to respond. Neither of the two survey respondents actually manufacturer API in Texas but instead engage in formulation of finished product, or have a pharmaceutical packaging or distribution/warehousing role in Texas. The bulk of the information below was provided by members of
pharmaceutical companies represented on the Advisory Group,\textsuperscript{293} and information from the disposal surveys.

Some chemical manufacturing plants located in Texas produce active pharmaceutical ingredients. The factories use chemical processes and can also use biological processes (e.g., fermentation) to manufacture product. Wastes that are generated at these plants are likely typical of wastes generated in other chemical manufacturing plants and may include spent solvents, solid wastes, filter agents, and wastewater. It is unusual at these plants to produce unused pharmaceuticals because APIs that do not meet specifications are reworked and converted to a final product. However, it is possible that the wastewater generated by an API production plant contains some amount of pharmaceutical compound. Process wastewater destined for discharge to a publicly owned wastewater treatment system or to receiving waters would be regulated by the TPDES permitting process or the Industrial Pretreatment program. The TCEQ reviewed several individual Industrial Wastewater Permits issued to pharmaceutical manufacturing facilities in Texas and found that one treats their wastewater onsite (utilizing anaerobic and aerobic treatment tanks, clarifiers and sand filters) before directly discharging to a surface water body, while another treats wastewater from their processes in a septic tank and ultimately disposes of the water through a subsurface drain field. Other API manufacturing plants may send process water or pretreated wastewater directly to a publicly or privately owned treatment works. No pharmaceuticals except lindane are included in the typical list of constituents analyzed in wastewater discharges under the TPDES process.

These types of factories manufacture pills and other patient dosage forms by blending the API with other ingredients or package the medicines for distribution to customers. Wastes at these types of facilities include unused packaging materials, off-spec product and wastewater. The vast majority of unused packaging materials are recycled. The off-spec product is incinerated to destroy the products because of the concerns regarding counterfeiting and diversion for illicit uses. It is not known whether the off-spec product is sent to a medical waste incinerator or a hazardous waste incinerator. For the one company, involved in formulation of final pharmaceutical products who responded to the disposal survey, unused pharmaceuticals were reported to be transferred to another facility for processing or disposal, so the ultimate disposal method is unknown. Final manufactured product is distributed to customers through a distribution system that includes a network of warehouses. For the survey respondent that reported having warehousing/storage facilities in Texas or finished and packaged pharmaceutical products, it was found that drugs that become unsalable in the warehousing/storage phase are transferred off site to another facility for ultimate disposal; they are not disposed of on site through the trash, wastewater or any other means.

The distribution system usually includes a “reverse distribution” component. Products that are sold by prescription pharmaceutical manufacturers to

pharmacies, hospitals or other institutions that have not been dispensed to an individual patient/customer (overstocked products or expired medications) can be returned to the manufacturer for a credit through the “reverse distribution” system. This system is in place to assure that unsold products are not diverted from the normal distribution system. Products that are returned to the manufacturer can be returned to stock, but are often incinerated by the manufacturer. Additionally, some items sent to the manufacturer through a reverse distributor are disposed of by the reverse distributor (who maintain a waste disposal permit) or their contracted waste disposal service without ever being returned to the manufacturer for review. Inmar, a reverse distributor represented on the Advisory Group, noted that about 14% of the products scheduled to be returned to the manufacturer are destroyed and not returned to the manufacturer, at the manufacturer’s request.\textsuperscript{294} One of the two pharmaceutical companies that responded to the disposal survey noted that they did not provide a reverse distribution mechanism; for the one that does engage in reverse distribution it was noted that returned drugs are transferred to another facility for processing or disposal, instead of being disposed of onsite.

Pharmaceutical companies will sometimes distribute product samples to physicians. Samples are intended to provide the physician and the patient an adequate supply to evaluate the effectiveness of a new medicine. Samples are tracked by the manufacturing company and physicians are usually provided with procedures for returning any used samples to the manufacturer, though there is no requirement for physician’s to do so. One of the two companies that responded to the survey stated they do not have a program in place for physicians to return unused product samples to the manufacturer. The one company that does have that process in place reported that they send returned samples to another location for processing and disposal, and will not dispose of those on site via trash, wastewater or other means.

Pharmaceutical companies also produce medicines that are used only for research in clinical trials. Medicines used in clinical trials are distributed directly to patients under closely controlled conditions. Unused medicines are returned to the clinics where the trial is being administered and then returned to the manufacturer to be destroyed after the trial concludes. Those returned trial medicines are usually incinerated. Neither of the pharmaceutical companies that responded to the disposal survey was involved in clinical trials, so no further information is known regarding disposal of clinical trial substances in Texas.

\textit{Research Institutions}

Research institutions that may handle and dispose of pharmaceuticals include the research facilities associated with hospitals, educational institutions, governmental and private analytical laboratories, private research institutions including research and development sectors of pharmaceutical companies. From the five entities in Texas that responded to the research institution disposal

\textsuperscript{294} Bias, R., 2010. Information provided by Rodney Bias, formerly with Inmar, CLS Reverse Logistics, email communication 6 April 2010.
survey, three were educational institutions, one was a private analytical laboratory and one was a state agency laboratory. Two research institutions reported that wastewater generated at the facility does not contain API, while three did not know, and none apply any treatment to wastewater generated at the institution. Four research institutions noted that they usually dispose of unused pharmaceutical products at a facility that can accept hazardous waste, either at a hazardous waste landfill or hazardous waste incinerator. One institution reported that they dispose of unused pharmaceuticals in the sink/drain. Another institution reported that formulated pharmaceuticals are separated into hazardous and non-hazardous pharmaceuticals; hazardous substances are disposed of at a hazardous waste landfill/incinerator and non-hazardous pharmaceuticals are disposed of in a MSW landfill. Pharmaceuticals tend to go unused in research institutions, according to the survey results, either as a result of the pharmaceutical no longer under investigation, or because environmental samples (soil or water) contained API and those were required to be disposed of following analysis. The research institutions who responded to the survey, requested that they be provided information regarding the requirements for unused pharmaceutical disposal through guidance documents.

**Waste Management/Disposal Service Providers**

Most of the respondents reported that they were involved with waste collection/transfer, though they also reported waste processing/treatment by means of incineration. The waste management/disposal survey respondents usually collect from hospitals, clinics, law enforcement, though a couple of respondents reported that they also provide services to veterinary clinics, assisted living and nursing home settings, HHW collection events and community pharmaceutical collection events. One survey respondent noted that their company does not collect any pharmaceuticals. In terms of disposing of unused controlled substances, one respondent reported that they will accept controlled substances for disposal only from law enforcement. Another stated they recommend their clients dispose of those in the municipal trash and another reported that controlled pharmaceuticals might be commingled with other pharmaceutical waste and processed in a permitted medical waste incinerator.

Waste management/disposal providers involved in the Advisory Group noted that most segregated pharmaceuticals in Texas are transferred to an incinerator for processing. Pharmaceuticals that are commingled with and managed as medical waste (biohazard/red bag waste) are usually treated in an autoclave then disposed of in a MSW landfill. Two survey respondents noted that when waste has been segregated by the generator, collected waste containing RCRA hazardous pharmaceuticals are sent to a hazardous waste incinerator while waste containing non-hazardous pharmaceuticals is directed to a medical waste incinerator. Survey respondents reported that some of their clients, the generators of pharmaceutical waste, request superior disposal practices; that is,

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295 The process of encapsulating medical waste in concrete was tried in the past, but was not successful.
they request pharmaceutical waste to be processed or disposed of at a higher level than that required by federal or state regulations. Those generators that requested superior disposal practices include some law enforcement offices, some hospitals, some pharmacies, some community pharmaceutical collection events and some research institutions.

Few waste management/disposal service providers who responded to the survey (2 out of 7) are involved with the collection and disposal of pharmaceuticals from ultimate user/consumers. Three companies noted that they have not been involved in community pharmaceutical collection activities to date, but they would like to be involved in the future, while another two do not wish to be involved in community pharmaceutical collection activities, either because the company does not wish to explore that market or because of the “confusing rules” and “logistical difficulty” involved with such an event. For the two waste management/disposal companies responding to the survey, who have already been involved in community collection activities, one has provided the disposal/processing service for irregular/semi-regular community collection events and one has provided the materials and disposal services for “mail-back” envelopes that consumers can use to dispose of their unused non-controlled pharmaceuticals.

While no survey respondents indicated that they participate in reverse distribution activities, the Advisory Group did comment on the reverse distribution process as it occurs in Texas and elsewhere. Reverse distributors, acting as agents for the manufacturers or pharmacies, can transfer unused unopened pharmaceuticals from an entity to a reverse distributor and from one reverse distributor to another, if they are permitted. Reverse distributors that represent the specific manufacturer take unused pharmaceuticals to the pharmaceutical manufacturing location for destruction, or are taken to be destroyed without being returned to the manufacturer. Reverse distributor are not waste handlers, they are generators, so they only take products that have return value. However, if reverse distributor has a permit to accept waste (not returnables) they may do so. It’s important to remember that a reverse distributor cannot take back pharmaceuticals that have been dispensed to an end user, so they cannot be involved in any community pharmaceutical collection programs. As mentioned earlier, some of the products returned to a reverse distributor are disposed of immediately, at the request of the manufacturer and that portion are usually incinerated. A significant amount of pharmaceuticals go through reverse distributors prior to disposal. Inmar noted in the Advisory Group meetings that they estimate receiving approximately 20 million pieces in 2010. The Advisory Group also noted that reverse distributors are commonly mistaken for waste disposal companies by health-care providers and pharmacies who tend to send back all wastes to the reverse distributor, even when they are not returnable items. As a result, more unused pharmaceuticals may be incinerated through the reverse distribution process than intended.
Law Enforcement

The information in this section was provided during the Advisory Group meetings as well as information from the disposal survey directed at law enforcement agencies in Texas. A total of 81 responses were received, most of which (93%) were completed by city police department staff in addition to a response from the Texas DPS crime lab, a county sheriff’s office and four educational law enforcement groups.

As discussed in the “current rules” part of this section, there is a distinction between the management of drugs collected by law enforcement for evidentiary purposes versus those that are voluntarily surrendered. Drugs collected as a part of law enforcement property seizures are held until the conclusion of the prosecution at which point they are disposed of under a destruction order issued by the judge. They are usually incinerated, often with the help of local agencies or the DPS laboratory. The disposal survey results indicate that most drugs that end up in the hands of law enforcement are a result of property seizures during investigations involving criminal acts such as arrests and search warrant activities. A few law enforcement officers indicated that they dispose of prescription drugs as a result of a request from the Justice of the Peace.

Drugs surrendered to law enforcement may come from hospices and in-home health service, other elderly care facilities, unattended deaths or the general public. The disposal surveys indicated that, in Texas, drugs are more commonly surrendered to law enforcement from families or licensed care-givers, who do not know what to do with leftover medications following a person’s death, as opposed to individuals simply dropping their own unwanted pharmaceuticals off with law enforcement.

Almost 25% of survey respondents reported that they do not dispose of any pharmaceuticals, possibly a result of utilizing the transfer to other offices, the crime lab or to other entities. Most (54%) survey respondents reported that less than 10 partially-filled or full containers/packages are disposed of by the law enforcement office per month. A few law enforcement agencies need to dispose of more pharmaceuticals; 12%, 5% and 5% of survey respondents reported that they dispose of 10-25, 26-50 and >50 partially-filled or full containers/packages of pharmaceuticals per month, respectively.

In practice, surrendered drugs are often destroyed at the same time and in the same manner as drugs collected as evidence. However, the ultimate disposal method for pharmaceuticals at a law enforcement office is not uniform throughout the state and was noted in the Advisory Group meetings and supported by the disposal survey results. Just over 30% of the law enforcement staff who responded to the disposal survey reported that they arrange for disposal of all drugs at a permitted hazardous waste Incinerator. About 10% have all drugs sent to a permitted medical waste incinerator. Disposing of drugs in the regular municipal trash does not seem to be a used disposal approach by law enforcement in Texas; none reported adopting that method, which may be a result of the law enforcement office’s standard operating procedures and drug diversion concerns. One respondent reported that they dispose of pharmaceuticals that they obtained in an animal waste incinerator. Drain
disposal of pharmaceuticals in the possession of law enforcement offices in Texas does occur; about 7%, or six respondents, stated that they dispose of all pharmaceuticals down the sink or toilet. Another noted that illegal controlled substances are incinerated while other pharmaceuticals are flushed in the toilet. A few (4%) law enforcement agencies dispose of pharmaceuticals in biohazard boxes and arrange for a medical waste disposal service to manage and dispose of those. Some police departments also coordinate with local fire departments for disposal, since fire departments often have contracts with biohazard disposal companies and sometimes on site incinerators. While not identified in the surveys, some police departments in Texas have purchased small portable incinerators for the destruction of confiscated drugs and documents. It is not known whether or not those are being used for pharmaceuticals in Texas, though the manufacturer markets them for that purpose.\textsuperscript{296} In general, law enforcement officers in Texas do not separate controlled substances from non-controlled pharmaceuticals before disposing of them or arranging for another entity to dispose of them; only 3 survey respondents selected any of the 4 disposal options provided in the survey that involved separating out controlled substances from other pharmaceuticals before employing a number of different disposal options. The surveys indicated that cost and ease of disposal were key factors impacting how law enforcement agencies choose the methods they employ to dispose of unused pharmaceuticals. However, those factors were secondary to following the law enforcement office’s standard operating procedure and compliance with the federal and Texas CSAs.

The DPS has 13 crime labs and 12 incinerators in Texas. All 13 of the DPS Crime Laboratories dispose of pharmaceuticals, however, they may do so in different manners. All DPS drug seizures are first sent to a crime lab and then ultimately disposed of. The labs also receive drug evidence from cities, counties and other agencies, but following analysis they are returned to those agencies. The DPS incinerators are dual chambered gas fired types and are permitted by TCEQ. Those incinerators burn all seized marijuana, cocaine, heroin, and methamphetamines, but are not allowed to incinerate pharmaceuticals. However, based on discussions with stakeholders, it is very unlikely that law enforcement would classify waste into hazardous, medical or special waste; it is simply impractical to expect law enforcement to have the skills and time to segregate their waste.

Finally, many of the law enforcement agencies that responded to the disposal survey (47%) never receive inquiries from residents about how to dispose of their unused pharmaceuticals. For the other half of respondents who do receive inquiries, law enforcement agencies in Texas provide varied guidance; some tell the resident to drop it off with the policy department, some advise residents to contact the fire department, the TCEQ, their doctor or their hospital, and some recommend taking their unused pharmaceuticals to the resident’s pharmacy or a HHW event. Six survey respondents usually advise resident’s to dispose of their

\textsuperscript{296} For example, the webpage for “Drug Terminator” notes its possible use for pharmaceuticals. Elastec Inc./American Marine Inc., 2010. Drug Terminator. http://www.drugterminator.com/portableincinerators/drugterminator/ Webpage also provides a list of police departments who have purchased the Drug Terminator, some of which are in Texas. Accessed 15 September 2010.
unused pharmaceuticals in the toilet/sink and only one reported providing the
FDA/ONDCP guidance about mixing the substance with kitty litter or coffee
grounds and disposing of the container in the household trash. Some surveyed
specifically noted that their police department has no policy on what advice they
should provide residents on this subject.

Most (87.5%) of the respondents reported that their law enforcement office has
not been involved in any type of community pharmaceutical collection
activities. Those that have chose to be involved mainly did so to either show
community support/solidarity or because they are concerned about the possible
negative impacts of storing unused medications in the household (such as
accidental poisonings and drug abuse/misuse). One respondent reported they
were involved in the community pharmaceutical collection activity due to
concerns over pharmaceuticals in waterways or drinking water. When asked
about preferred approaches, some law enforcement agencies (around 20% of
respondents) supported their involvement in community pharmaceuticals
collection events. A larger proportion (34%) preferred that law enforcement
agencies not be involved in the collection of resident's unused pharmaceuticals,
but instead provide/promote disposal guidance. Some (11%) even preferred to
refrain from providing residents with guidance with best disposal practices for
their unused pharmaceuticals. In terms of the preferred options for law
enforcement agencies to dispose of unused pharmaceuticals, many (60%)
supported sending all seized and surrendered pharmaceuticals to an incinerator.

Local Governments (Solid Waste and HHW)

The information below was gathered through communication with the TCEQ's
MSW Section and the Advisory Group, and from disposal surveys completed by
74 rural and urban local governments involved in solid waste collection/disposal
(47% and 53% of survey respondents were from rural and urban counties,
respectively).297

When local governments or their waste hauler engage in municipal solid waste
collection activities (“curbside pick-up”), they are very likely collecting,
transporting and disposing of unused pharmaceuticals that consumers
intentionally placed in their household trash bin. That municipal waste is
disposed of in permitted MSW landfills in Texas. Those landfills comply with
Subtitle D (federal) requirements of a leachate-collection system, single clay or
gemembrane liner, among other precautions, to prevent contamination of the
groundwater or soil.

In most cases in Texas, the municipal waste curbside collection is the only way
that local governments collect and dispose of unused pharmaceuticals; over 40%
of survey respondents reported this. Many survey respondents reported that
there is little to no demand for information regarding disposal of unused
pharmaceuticals from residents/customers. For those that do receive requests

297 Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than
50,000. Rural County definition map:
from residents regarding how to dispose of unused pharmaceuticals, no survey respondents reported recommending that residents dispose of their unused pharmaceuticals in the toilet/sink. Instead, local governments either recommend residents dispose of them in their household trash, many times with mention of FDA/ONDCP guidance (almost 25% of survey respondents reported this), or they direct residents to dispose of their unused pharmaceuticals at a HHW event (12%) or pharmaceutical-only community collection event (4%). When asked for guidance, 3% of survey respondents usually choose to not provide any to residents on how to dispose of unused pharmaceuticals.

Household hazardous waste (HHW) programs are another way that unused pharmaceuticals are currently managed or disposed of by local governments. They are usually held in dedicated permanent facilities and are either continuously accepting HHW (that is, open during normal office hours and sometimes weekends), or accepting waste on designated days of the month. During the Advisory Group meetings, HHW managers wanted clarification on the regulatory requirements of accepting and disposing of household-generated pharmaceutical waste through a HHW facility. Currently, some continuously-operating HHW programs do accept all unused pharmaceuticals (usually without advertising that they will accept them). While three local governments specifically noted that they reject controlled substances when they accept pharmaceuticals from residents, it was also revealed in the Advisory Group meetings that HHW facilities do not screen for controlled substances in the waste brought to them by residents and therefore do not have a way of rejecting them. This is generally not the case when a HHW facility conducts a dedicated event for pharmaceuticals because they will employ a law enforcement officer for those one-day events. It is often very difficult for the average person or an untrained eye (i.e. not a physician or pharmacist) to identify a controlled substance. Most current HHW events that accept pharmaceuticals from residents do not separate out hazardous waste (if not generated by a household) from MSW waste. Consequently, all commingled pharmaceuticals are sent to a facility that accepts hazardous waste.

The majority of local government survey respondents indicated that they would prefer not to handle and dispose of unused pharmaceuticals. Local government survey respondents (41%) reported that their local government prefer not to collect any unused pharmaceuticals from residents/customers (outside of what may be collected during the regular household trash collection), but would prefer to provide guidance to residents based on federal or state best practices and guidance. Another 12% did not want to provide disposal options or guidance. Over 17% of survey respondents reported that their local government would prefer to host or support a regular, semi-regular or irregular pharmaceutical take-back event to be run in conjunction with HHW collection events, and 5% would prefer to collect unused pharmaceuticals from residents/customers (for disposal) at the local government’s permanent HHW facility.
Ranchers/Farmers

In general, most large animal feeding operations in Texas use antibiotics and other pharmaceuticals on an ‘as needed’ basis and these are usually administered by a veterinarian or trained animal health specialist. The cost associated with the purchase and administration (e.g. the costs of a veterinarian to come onsite) of antibiotics and other pharmaceuticals in the agriculture industry is a major determining factor for the amount of unused and expired material subject to return or disposal. Due to the expense involved, very little is available for disposal or allowed to go beyond the expiration date.

Smaller agriculture operations, which include the handling of livestock of any kind, generally will purchase only the amount recommended for a particular application or will use the services of a veterinarian to administer the medication. This reduces the likelihood of accumulating expired and unused medical supplies that require disposal or return. The visiting veterinarian will usually take unused pharmaceuticals with them for disposal.

In larger operations, with large numbers of animals in concentrated areas, the cost of using pharmaceuticals for preventative measures has also reduced the incidence of mass inoculations. As with the smaller operations, the larger facilities generally dispense medicines and other pharmaceuticals on an “as needed” basis. The administration of these pharmaceuticals is generally accomplished by a veterinarian or other trained specialist, except in the case of aquaculture and poultry raising which usually administers antibiotics and other medications, as well as non-drug products such as supplements, through feed or spray irrigation. Unused material is handled by that professional. In some of the larger animal feeding operations, animal health specialist companies provide the pharmaceuticals and pick up any unused or expired material for disposal.

A disposal survey was developed for ranchers and farmers in Texas to determine how they dispose of unused pharmaceuticals and how much goes unused. There were six rancher/farmer disposal surveys completed, though some were completed on behalf of a number of different operations that followed the same procedures as each other for disposal of unused pharmaceuticals: one survey response represented 19 livestock members, one poultry survey represented 20 poultry (agribusiness) companies and one cattle survey represented about 200 cattle ranchers). Most of the respondents reported that they were involved in the cattle business, and all respondents reported that they were in rural areas and used pharmaceuticals in their operations. Over half of the respondents reported that between 1-10% of their pharmaceuticals go unused, while over a third said that no pharmaceuticals ever go unused. One survey respondent reported that 11-25% of pharmaceuticals go unused. Survey respondents reported that pharmaceuticals usually went unused at the ranch/farm because they became expired (83% of respondents); very rarely is it because pharmaceuticals were dropped/spilled, because the veterinarians stopped prescribing a pharmaceutical or because an animal only required a portion of a solid dose drug. All

298 Although some pork and poultry feeding facilities include some antibiotics in feed and water as a treatment for certain diseases or as a preventative, the growing concerns about antimicrobial resistance has led to limitations on this practice.
respondents reported that less than 10 partially filled or full containers or packages of unused pharmaceuticals are disposed of per month at their ranching/farming operation. Methods employed at the survey respondent’s ranching/farming operations for managing or disposing of unused pharmaceuticals were varied and included: storing them onsite without choosing a disposal method, returning them to the veterinarian or supplier for disposal, disposal in the municipal trash, disposal in the sink/toilet and arrangement with a waste disposal company. The poultry and cattle farmers who responded to this survey noted that convenience, cost and availability of options were the main factors that impact the disposal methods employed.

**Drinking Water and Wastewater Utilities**

Drinking water and wastewater utilities, unless involved in community pharmaceutical collection programs, do not dispose of unused pharmaceuticals. Through the Advisory Group, several utilities expressed the desire to have a disposal survey developed. As such, a survey was developed and questions related to their treatment technologies, sludge disposal, pharmaceutical sampling employed and how they may be involved in consumer collection programs and why. There were 85 respondents to the drinking water and wastewater utility survey. Most of the respondents were in urban areas and 90.5% reported that they do not request any dischargers to pre-treat their wastewater for the purpose of removing pharmaceutical compounds. Less than half (45.6%) of the respondents reported that they transfer bio-solids to a municipal solid waste landfill, while almost a third (28%) applied the bio-solids to land either owned by the utility or another entity. Almost all (except one) of the respondents reported that they had not changed treatment techniques specifically due to concerns or difficulties removing pharmaceutical compounds from wastewater or water. About three quarters of survey respondents reported that the utility will wait for the EPA or the State of Texas to require treatment for pharmaceutical compounds or to regulate pharmaceuticals in drinking water or wastewater before considering treatment change decisions.

A majority of the respondents (82%) reported that they had not collected samples and had them analyzed for the presence of pharmaceutical compounds. Just five, three and seven utilities, reported that they have collected wastewater-only, drinking water-only and both drinking water and wastewater samples, respectively, and had them analyzed for pharmaceuticals.

Most utilities (80%) had not participated in pharmaceutical take-back events. For those that have, many were either involved in a pharmaceuticals-only collection event or the utility hosted or supported a pharmaceutical take-back event in conjunction with a HHW facility. Additionally, one utility also reported hosting or supporting drop-box/kiosk at pharmacies, one supported kiosks at another location, one utility is involved in encouraging residents to drop off unused pharmaceuticals at a fire station to be disposed of with other medical waste by the contracted disposal company.
Those utilities involved in community pharmaceutical collection programs were involved for a wide range of reasons: a number of utilities reported supporting a pollution prevention approach because treatment can not remove all pharmaceuticals (so the utility has fewer pharmaceuticals to remove in the treatment process); some utilities were concerned about the occurrence of pharmaceuticals in drinking water supplies and waterways; some supported programs as a community service and some were asked to provide financial support; and other supported collection programs because of they were made aware of customers concerns about disposing of unused pharmaceuticals in landfills and in the drain. Those involved in collecting unused pharmaceuticals disposed of them in MSW landfills, with or without prior treatment (medical waste treatment), or processed them in a hazardous waste incinerator or medical waste incinerator.

About 44% of those involved in pharmaceutical collection program did not know the final destination of the waste. Limitations for participating in take-back events included monetary cost (43 responses), complicated pharmaceutical disposal/handling regulations/requirements (41 responses), lack of staff time (38 responses), little demand from residents (31 responses), pharmaceutical waste disposal not being a core function of the utility (27 responses) and the organization and effort required (26 responses).

Consumers

The consumer disposal survey questions mainly related to the proportion of pharmaceuticals that go unused in Texas households, why pharmaceuticals usually go unused, how they are disposed of and why residents choose to employ their adopted methods of disposal. There were 860 respondents for the consumer disposal survey. Most of the respondents lived in an urban county (84%) at the time of the survey. Over half (58%) reported that their household (people or pets) usually uses five or less different pharmaceuticals at one time. Over a third (39%) reported that their household usually uses more than five different types of pharmaceuticals at one time. Only 3.5% reported that their household does not normally use pharmaceuticals.

A little over half of the respondents (56%) in the TCEQ's survey reported that between 1-10% of their pharmaceuticals go unused. Another 23% reported that 11-25% of pharmaceuticals in the household usually go unused. Therefore, over three quarters (79%) of the respondents reported that between 1-25% of their pharmaceuticals usually go unused. Approximately 6% and 2% of respondents reported that 26-50% and >50% of the pharmaceuticals in their household usually go unused. However, about 9% of those who use pharmaceuticals in their household reported that no pharmaceuticals go unused; that is 9% of those surveyed would not need to dispose of any unused pharmaceuticals.

In the TCEQ's survey, respondents who normally have unused pharmaceuticals in their household acknowledged a number of reasons for pharmaceuticals going unused. One standout reason was drug expiration: a little less than half (41%) of the respondents reported that pharmaceuticals usually went unused in their
household because they expired. Additionally, almost a quarter (22.4%) of respondents noted that pharmaceuticals went unused and unwanted because the physician (or veterinarian, if it was a pet’s medication) changed the patient’s prescription to something else so the original pharmaceuticals purchased were no longer needed. A number of survey respondents who selected “other” as the reason for pharmaceuticals going unused noted that they did not need any or all of the pain medication prescribed to them following a surgery. Almost all (98%) of the question respondents reported that they dispose of less than 10 partially filled or full containers or packages containing unused pharmaceuticals per month.

Approximately 50% of households in survey reported that they usually dispose of their unused pharmaceuticals in the regular municipal trash (curbside pick-up). Over a quarter (26%) of survey respondents reported that they usually just store/keep unused pharmaceuticals in the house. Ten percent of survey respondents reported that they usually dispose of their unused pharmaceuticals into the wastewater, either in the sink or toilet drain. Based on information obtained in the surveys, very few take their unused pharmaceuticals to a pharmacy or HHW facility or other community collection event.

**Pharmaceutical Wastes and the Environment and Public Health**

This section discusses the impact of those current management, processing and disposal methods on both the environment and public health. When the intentional use and ultimate excretion of pharmaceuticals is excluded, only direct drain disposal of unused pharmaceuticals, and possibly treatment of pharmaceuticals in an autoclave (through the generation of a wastewater stream) may release pharmaceuticals to the environment. It is unlikely that landfills play a significant part in environmental release of pharmaceuticals.

**Detection of Pharmaceutical Wastes Associated with Current Disposal Methods**

**Sewer/Direct Drain Disposal**

Intentional disposal of unused pharmaceuticals down sink drains or flushing them down toilets has been a historically recommended practice, especially by the health-care industry and by poison centers across the country. Sewer disposal appears to be a practice still used in Texas by health-care providers as well as consumers. While it is becoming less common a disposal method in health-care settings (including physician’s offices, hospitals, pharmacies, nursing homes, veterinarian offices, assisted living, hospice, in-home care, etc.) it is still a practice used for controlled substances due the issues involved with deeming those drugs non-recoverable or non-retrievable.

The result of direct drain disposal and flushing of pharmaceuticals is that they are conveyed in wastewater collection systems to wastewater treatment plants where they are subject to treatment along with other wastes. Studies have shown
that some pharmaceuticals and other emerging contaminants present in the influent of wastewater treatment plants pass through the treatment systems to receiving waters, which in turn may become a source of raw water for drinking water. While exposure to pharmaceuticals has been found to have some adverse effects on aquatic life in experimental settings, notably in the fish populations, a similar link has yet to be established between ingestion of these compounds through drinking water and human health. The EPA continues to report that the consumption of the low concentrations of pharmaceuticals found in drinking water do not represent a human health risk, based on current knowledge. The impacts of release of pharmaceuticals to the environment on aquatic life and human health are presented in a subsequent section of the report.

Discharge to Surface Waters

A discussion was provided earlier regarding the extent to which API is removed from wastewater under currently available wastewater treatment processes. As discussed, publicly owned treatment works (POTWs) may not effectively remove all API through treatment; some pharmaceuticals present in the influent may remain at ppb concentrations following wastewater treatment. As a result, API can pass-through the POTWs and be discharged to surface waters. Most of these compounds have removals greater than 50 percent. However, among the published studies, removals for these compounds often range from negative removals to close to 100 percent removals (i.e., compound not detected in effluent). The removals (actual removal or the perception of removal using analytical chemistry methods) are dependent on the operation of the treatment plant (such as retention times, GAC reactivation/regeneration, among others) and the characteristics of the influent (such as organic matter content which can cause interferences during analysis for pharmaceutical compounds, or the polar nature of the pharmaceuticals in the wastewater, which may impact how easily parent pharmaceuticals reform during wastewater treatment processes). It is also possible that some pharmaceuticals volatilize to the air during the wastewater treatment process.

The results of discharging low concentrations of API to surface waters are aquatic life exposure to pharmaceuticals and the potential for detection in sources of drinking water. While exposure to pharmaceuticals has been found to have some adverse effects on aquatic life in experimental settings, notably in the fish populations, a similar link has yet to be established between ingestion of these compounds through drinking water and human health. The EPA continues to report that the consumption of the low concentrations of pharmaceuticals found in drinking water do not represent a human health risk, based on current knowledge. The impacts of release of pharmaceuticals to the environment on aquatic life and human health are presented in a subsequent section of the report.

Wastewater Treatment Sludge

As mentioned earlier, wastewater treatment sludge (“biosolids”) can contain pharmaceutical compounds removed from the wastewater during treatment.
Air Emissions from Sewer Disposal

Mechanisms for air emissions from sewer disposal include API volatilization from sewage conveyance systems and from POTW units which are open to the atmosphere. The common APIs studied by the USGS and others have low volatility (as indicated by low Henry’s law coefficients, \( K_H \)), which suggests that air emissions of pharmaceutical compounds are negligible. Air emissions from sewer disposal of pharmaceuticals are much less likely for the proportion of Texans whose wastewater is directed to a septic system.

Municipal Trash and Disposal in MSW Landfill

Based on the TCEQs’ statewide disposal survey as well as the localized surveys undertaken in Amarillo and Austin, about half of Texans dispose of their unused pharmaceuticals in the municipal trash. Some health-care providers also dispose of unused pharmaceuticals in the trash after mixing them with an undesirable substances and making them “unfit for human consumption.” MSW landfills are regulated under RCRA Subtitle D, which requires that the landfill have a liner and a leachate collection. The TCEQ adopts the RCRA Subtitle D requirements for MSW landfills in Texas. Unlike Subtitle C (hazardous waste) landfills, Subtitle D/MSW landfills do not require waste to be treated prior to disposal. In addition, Subtitle D requires MSW landfills to have only a single lining with a geomembrane and compacted clay liner.

Releases to the environment from MSW landfills could occur from landfill leachate and landfill gas emissions.

Landfill Leachate to Surface Waters (through a POTW)

In Texas, no MSW landfills treat the collected leachate to a point where they can directly discharge it to surface water. Most Type I landfills (excluding Type I-AE landfills) send leachate to a POTW or WWTP. Type I-AE landfills do not have a leachate collection system so these facilities will not be contributing API to a WWTP. There are three other options that have been noted in permits for managing landfill leachate: re-circulation, solidification and evaporation in a lined surface impoundment. Out of 36 Type I landfill permits that the TCEQ reviewed, all were authorized to discharge leachate to a WWTP, 22 were authorized to recirculate leachate, two landfills had leachate evaporation surface impoundments, and one was authorized to solidify the leachate in a lined liquid waste solidification unit.

Little information is available regarding the impact that landfill leachate has on pharmaceuticals in the environment. As noted earlier, the Maine Department of Environmental Protection (DEP) found very low concentrations of pharmaceuticals in leachate from three lined MSW landfills, however the human health or environmental relevance of those detections was not covered in that

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299 See ERG, 2009a.
One notable leachate study, undertaken by PhRMA in 2007, evaluated the potential for 24 APIs to leach from MSW landfills and their potential releases to surface water (Tischler, 2007). Since MSW landfills (Subtitle D) have less stringent controls than hazardous waste (Subtitle C), MSW landfills were evaluated as a worst case scenario for API releases to surface water. Subtitle D landfills are required to have a leachate collection system, monitor for methane, and conduct groundwater monitoring. Subtitle C landfills are required to be lined and to conduct groundwater monitoring. A corrective action plan is required for Subtitle C facilities if hazardous constituents are detected. PhRMA selected the 24 example pharmaceutical ingredients to represent a range of sales per year in the United States (i.e., high quantities and low quantities) and a range of physical-chemical properties. They were also pharmaceuticals that were included in the USGS National Stream Reconnaissance Study. A number of assumptions related to mass transfer within the landfill were built into the study to help estimate pharmaceutical concentrations in landfill leachate. Some of the assumptions included:302

- That the range of 5 to 15 percent of the total quantity of APIs sold, is disposed of in landfills.
- That APIs disposed in landfills are unpackaged and immediately available for dissolution in the liquid phase.
- The use of solids/liquid adsorption coefficients (K_p) to predict partitioning of each API between the solid and leachate phases in the landfill.
- Sorption efficiencies of 10, 50 and 100 percent were applied to partitioning to account for the lack of homogeneity and leachate saturation in landfills as compared to wastewater in a POTW.
- API loss due to hydrolysis and anaerobic degradation was assumed to be zero for those APIs lacking hydrolysis and biodegradation factors (the case for most of APIs included in the study).
- That API loss due to volatilization is zero.
- That 10 to 100 percent efficiency in solids sorption occurs (to account for varying organic content in the solids).
- That maximum leachate volume generated during the landfill active phase occurred, based on leachate rates in the northeast and southeast.
- That this is zero leachate volume after landfill closure.
- Landfill disposal rates and compaction density were obtained from EPA and literature sources.
- That all leachate is recovered and treated at a POTW.

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- POTW removals from PhRMA’s Pharmaceutical Assessment and Transport Evaluation (PhATEs) model were applied.

- Leachate transfer to groundwater is zero.

In that study PhRMA estimated API concentrations in landfill leachate for nine different scenarios – three different API disposal rates (5, 10, and 15 percent) and three different sorption efficiency factors (10, 50 and 100 percent).

PhRMA compared the modeled landfill leachate releases to estimates of surface water releases from disposal of unused pharmaceuticals to sewer. The PhRMA study found that the landfill disposal pathway to surface water (i.e. API in landfill leachate that gets released to surface water) accounted for an average of 0.03% to 0.10% of the estimated aggregate annual surface water releases for the 24 APIs. Therefore, the study estimated that over 99.9% of the releases of API in surface water would be due to patient excretion, not landfill disposal of unused pharmaceuticals, assuming that landfill disposal were used for all unused pharmaceutical disposal. In comparison, the study suggested that if all unused medicines were disposed of by flushing to the sewer, then unused medicine disposal would constitute approximately 6.1%, 12.0% and 17.8% of the total surface water discharges of those 24 APIs at 5%, 10%, and 15% rates of unused medicine disposal (as a function of annual sales), respectively.

The concentrations of API in Maine DEP's MSW landfill leachate study are generally consistent with predicted leachate concentrations developed in PhRMA’s research (PhRMA’s predicted concentrations are either higher or mostly similar to what was measured in Maine) and corroborate that the disposal in unused drugs in household trash that is then directed to a permitted MSW landfill effectively removes unused medicine component of pharmaceuticals in surface water.

The PhRMA study did not consider the impact of the addition of API that POTW/WWTP sewage sludge disposed of in a landfill may contribute. However, landfilled biosolids contributions are probably not germane to a discussion of the impact of unused pharmaceutical disposal because API in biosolids are mostly attributed (80-90%) to the intended use and excretion of pharmaceuticals. Based on the current information available, MSW landfill leachate (directed through a POTW) probably does not contribute a significant amount of API to surface waters.

**Landfill Leachate to Groundwater**

As discussed earlier, some pharmaceutical compounds were detected at micrograms per liter concentrations in groundwater below and down gradient of...
unlined landfills in Elkhart, Indiana, and Norman, Oklahoma. It is important to keep in mind that those are unlined landfills and therefore do not meet the current landfill construction requirements for Subtitle D (MSW) landfills. As mentioned earlier, there are no landfills in Texas that are still operating unlined pre-subtitle D cells.

The EPA assessed the performance of landfills and evaluated liquids management data for 187 double lined cells at 54 landfills (double-lined cells are only required for hazardous waste landfills, however, the results of this study indicate relevance to MSW landfills which are required to have a geomembrane and compacted clay liner). The goal of EPA’s study was to better understand the field performance of landfill primary liners, leachate generation rates, and leachate chemistry. The following study findings are relevant to characterizing the permeability of landfill liners and the potential for pollutant transfer to groundwater:

- Geomembrane liners alone can achieve true hydraulic efficiencies in the 90 to 99% range, with higher efficiencies occasionally being achievable.
- Composite liners (geomembrane on top of compacted or geosynthetic clay) can achieve true hydraulic efficiencies of 99 percent to more than 99.9%.
- Composite liners are capable of substantially preventing leachate migration over the entire period of significant leachate generation for typical landfill operations scenarios without leachate recirculation or disposal or liquid wastes of sludges.
- Leachate collection and removal system flow rates were highest at the beginning of cell operations and decreased as waste thickness increased and daily and intermediate covers were applied to the waste; leachate generation rates decreased on average by a factor of four within one year after closure and by one order of magnitude two to four years after closure; within nine years of closure, leachate generation rates were negligible for the landfill cells evaluated in the study.

The findings of this EPA study suggest that API transfer to groundwater from landfills is negligible.

Recently, those who have wished to convey that landfills are potential sources of contamination often quote a Federal Registry notice that states “even the best liner and leachate collection system will ultimately fail due to natural deterioration, and recent improvements in MSWLF [municipal solid waste landfill facilities] containment technologies suggest that releases may be delayed by many decades at some landfills.” The focus should be on the amount of time that structures will remain intact. Current landfill liner systems are anticipated to be effective long after the life of the facility and 30 years of post closure care maintenance. It is known that pre-subtitle D cells (unlined cells) do

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leak but there is little evidence that a pre-subtitle D landfill cell routinely leaks. There is also little evidence that suggests current permitted Subtitle D landfills cells leak. If leachate was to impact groundwater, it is likely that this will occur after the landfill has closed and conducted 30 years of post closure care maintenance. While the landfill is active, the operator is required to remove leachate from the collection system so that no greater than 30 centimeters of leachate is on the liner at any one time.\(^{308}\) Also, the current rules require landfills to install and conduct groundwater monitoring and in the case of a release of hazardous constituents above the ground water protection standards, the operator is required to conduct corrective action.\(^ {309}\) These requirements help ensure that groundwater contamination does not occur. Additionally, if an area of land occupied by a closed landfill (following 30 year post-closure care) is to be purchased, the purchasing entity usually conducts a due diligence assessment (“Environmental Site Assessment”, commonly a “Phase 1” or “Phase 2” assessment) prior to purchasing the site. It is usually during that property assessment phase that previously unidentified contaminations become identified, triggering remedial action. It should also be noted that this was EPA’s position in 1988 and industry construction standards and techniques have advanced since this position was published. At this time, there is little information to dispute EPA’s current scientific knowledge that API transfer to groundwater from landfills is negligible.

**Air Emissions from Landfills**

Landfill gas is the natural byproduct of the decomposition of solid waste in landfills and is comprised primarily of carbon dioxide and methane. As with the current knowledge about air emissions from sewer disposal of unused pharmaceuticals, the common APIs studied by USGS and others have low volatility suggesting that air emissions are negligible.\(^ {310}\)

**Processing in Autoclave and Disposal in MSW Landfill**

Many health-care facilities in Texas manage their unused pharmaceuticals as medical waste, and treat that waste in either own autoclave or arrange to send their medical waste to another facility for autoclaving. When unused pharmaceuticals are placed in biohazard/sharps boxes or red-bags in health-care facilities, the unused pharmaceuticals in liquid or solid form will likely be commingled with syringes, devices that contain blood, microbiological waste, pathological waste and other types of medical waste.

An autoclave is a pressure vessel that sterilizes equipment and wastes by subjecting them to high pressure steam.\(^ {311}\) Bacteria, viruses, fungi, and spores are inactivated at typical autoclave operating conditions of 134° C for more than three minutes or 121° C for more than 15 minutes. In addition to high

\(^{308}\) 30 TAC § 330.331(a)(2)

\(^{309}\) 30 TAC Chapter 330, Subchapter J.


\(^{311}\) See ERG, 2009a. All information describing autoclaves in this paragraph is directly quoted from ERG, 2009a.
temperature, air must be completely evacuated from the chamber because it is a poor sterilizing medium. The steam must be saturated so that it quickly releases heat through condensation upon contact with the equipment or waste. The packaging and loading of waste in the chamber are also important as the steam must flow freely to all surfaces of the waste. The “Rotoclave” ® is a type of autoclave that uses a grinder and rotating internal drum rather than a stationary chamber to provide size reduction and agitation to improve the interaction of the materials or waste with the sterilizing steam. Another attribute of the Rotoclave is that it renders the waste unrecognizable. Some landfill operators do not accept medical waste that is not ground up. The TCEQ is not aware if Rotoclaves are used in Texas.

An autoclave disinfects waste by destroying possible pathogens but does not destroy the waste. Therefore, the waste that has been disinfected or sterilized (“treated”) in an autoclave must then be disposed of in a landfill. Most times, the treated waste will be disposed of in a MSW landfill. Additionally, autoclaving is highly effective for inactivating biohazards and other waste disinfection needs, however it does not destroy or inactivate APIs since they are not biological products.

A number of wastes may be generated through the autoclaving process, including: air emissions (volatilization of chemicals during heating), wastewater discharged to the sewer (from air pollution control systems and steam condensate), and municipal waste (disinfected solid medical waste).

**Wastewater Discharge from Autoclaving**

Wastewater can be generated during autoclaving as a result of steam condensate (generated at the end of the autoclave cycle), as well as from air pollution control devices. Compounds that are extracted from the autoclaved waste and that are condensable will be retained in the steam condensate rather than emitted to the air. That condensate is usually discharged to a POTW. Consequently, there is a route for chemicals in an autoclave to be discharged to wastewater. However, it is unlikely that most pharmaceuticals commingled with the medical waste in an autoclave would react during the steam and pressure treatment nor find their way to the condensate. It is more likely that most pharmaceuticals in an autoclave will remain in the same form as when they entered the autoclave. However, there is certainly the possibility that by disposing of unused pharmaceuticals with medical waste and treating that in an autoclave, some API is released to the wastewater system as a result of the condensate generation and air pollution control.

In addition, if medical waste is ground before, during, or after autoclaving (such as with the Rotoclave), there is the potential for further reaction with steam or other media (such as landfill leachate). Therefore, pharmaceuticals disposed of as medical waste that is ground up before, during or after autoclaving, may contribute more API to the wastewater.
Air Emissions from Autoclaving

Steam exits the autoclave through a condenser at the end of the treatment cycle. Uncondensed steam vapor exits through the emissions vent, which sometimes contains a high-efficiency filter or a water spray scrubber. Air emissions from steam treatment would include any compounds volatilized from the waste during the autoclave cycle. EPA is not aware of any testing of APIs in autoclave emissions; however, autoclave emissions are not believed to carry significant quantities of pollutants including pharmaceutical compounds.312

Treated/Autoclaved Waste Disposed of in MSW Landfill

Following the autoclaving processing, treated medical waste is packaged and sent for disposal at a MSW landfill. Pharmaceuticals in the waste are not expected to have been impacted by the autoclave process significantly (except perhaps in the case that the medical waste is ground up). As highlighted earlier, it is unlikely that MSW landfills contribute a significant amount of API to the environment. Since most pharmaceuticals are not expected to be affected by autoclave treatment, autoclaved materials are not expected to contribute a significant amount of API to the environment.

Processing in Incinerator and Disposal in Landfill

Some health-care facilities in Texas send all unused pharmaceuticals to an incinerator (either a medical waste incinerator or hazardous waste incinerator) and some others segregate their waste and send hazardous waste to a hazardous waste incinerator. Additionally, HHW facilities in Texas are required to send the collected waste to a facility that can accept hazardous waste, and this is many times a hazardous waste incinerator.

Incineration provides near complete destruction of organic waste, however inorganic components of the waste and byproducts of incineration may be: (1) released to the atmosphere through the incinerator exhaust; (2) discharged to wastewater via wet air pollution control technologies (e.g., scrubbers); or (3) disposed of in landfills with the incinerator ash.

Incinerator Air Emissions

Little information is available about pharmaceuticals contained in incinerator emissions, partly because those types of chemicals are not routinely monitored for as part of a permittee’s responsibilities. However, continuous emissions monitoring for other compounds of known concern to human health are monitored for. Incinerators, especially hazardous waste incinerators, are optimized for virtually complete destruction of organic compounds, including the organic components of pharmaceuticals, the air emissions of pharmaceuticals associated with incinerators are likely negligible. Of possibly greater importance (i.e. likely a larger environmental footprint) are the emissions generated as a result of the transport of hazardous waste to the few facilities in Texas permitted to dispose of hazardous waste. This is also the case for medical

312 See ERG, 2009a. All information related to air emissions from autoclaves was obtained from ERG, 2009a.
waste incinerators; there are only a couple of these in Texas, so generally long- hauls are required to transport waste to incinerators in Texas.

**Wastewater Resulting from the Incineration Process**

Incinerators use a variety of air pollution controls, wet and dry scrubbers, bag house filters, and electrostatic precipitators to reduce air emissions. Wet scrubbers generate a wastewater stream. However, since the organic component of pharmaceuticals is destroyed in an incinerator, the slurry generated by wet scrubbing is not expected to result in negligible amounts of API in the wastewater (though it may contain other inorganic compounds such as metals). It is possible, but unlikely, that wastewater from the incineration process contributes significant amounts of pharmaceuticals to the environment or wastewater stream.

**Incinerator Ash Disposal to Landfills**

The incineration process creates a solid waste (“ash”) which can include the bottom ash removed from the kiln or hearth and fly ash separated from the combustion gases. While incinerator ash is not tested for pharmaceutical compounds, the complete destruction of organic materials in a well-operating high temperature incinerator suggests that pharmaceuticals will likely be destroyed completely and probably would not be contained in significant quantities in incinerator ash.

The ash generated by hazardous waste incinerators in Texas is either disposed of at hazardous waste landfills or at a MSW landfill, depending on its properties. Ash generated by medical waste incinerators is typically disposed of in municipal landfills, provided it does not exhibit any toxicity characteristics.

If incinerator ash is disposed of in a permitted hazardous waste landfill (RCRA Subtitle C), the landfill’s construction (per RCRA design requirements) isolates wastes from contact with moisture to avoid leachate generation. The top of the landfill has a low-permeability cover and the sides and bottom are lined with a double-liner system. The outer lining consists of compacted clay and a geomembrane liner. Leachate at hazardous waste landfills is collected in a sump and treated or recirculated to the landfill. Even if incinerator ash is directed to a MSW landfill (RCRA Subtitle D), information provided earlier suggests that it will contribute negligible amounts of API to surface water and groundwater (that is if there were any APIs in the incinerator ash to begin with, which is unlikely).

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313 “Scrubber water” is a slurry that results from the operation of wet scrubbers and contains salts, excess caustic or lime, and contaminants (particles and condensed organic vapors) scrubbed from the flue gas. From ERG, 2009a.
314 See ERG, 2009a.
315 Holderread, J., 2010. Information provided by Jeff Holderread, TCEQ Waste Permits Division, email communication 14 September 2010.
Potential Impacts of the Release of Pharmaceuticals to the Environment on Aquatic Life and Human Health

Studies have identified low concentrations (micrograms per liter and nanograms per liter levels) of various pharmaceuticals in surface waters within Texas and within the United States. Research suggests this is a result of the poor removal of API during wastewater treatment. This section considers the impact of the occurrence of pharmaceuticals in surface water on aquatic life and on human health.

Impact on Aquatic Life

The majority of the reviewed published literature shows that little is known about long-term effects of pharmaceuticals in waterways on aquatic organisms. However, there seems to be a sufficient body of evidence to suggest that trace environmental concentrations of sex steroids and antidepressants may have adverse effects on aquatic organisms in experimental situations.

Probably the most quoted study is the whole-lake experiment conducted over 7-years at the Experimental Lakes Area in northwestern Ontario, Canada which concluded that the concentrations of estrogens observed in freshwaters can impact the sustainability of wild fish populations after their research showed that chronic exposure of fathead minnow (Pimephales promelas) to low concentrations (5–6 ng/L) of 17α-ethinyl estradiol (EE2 - the synthetic estrogen used in birth-control pills), led to feminization of male fish and, ultimately, a near extinction of this species from the lake. The “feminization” of the male fish was identified by the production of vitellogenin (VTG) (a protein normally synthesized by females during oocyte maturation) by male fish and early-stage egg development in male fish testes.

Another study evaluated the effects of embryonic and larval exposure to environmentally relevant (ng/L) concentrations of common antidepressants, fluoxetine, sertraline, venlafaxine, and bupropion (singularly and in mixture) on C-start escape behavior in fathead minnows. “C-starts” are reflex behaviors that begin with a short latency period during which the threat stimulus is being perceived by the animal, are followed by a dramatic bending of the body into a C-shape, and end with an explosive burst of high-velocity locomotion away from the threat stimulus. When tested 12 days posthatch, exposure to fluoxetine and venlafaxine adversely affected C-start performance of larvae exposed as embryos. On the other hand, larvae exposed for 12 days posthatch did not exhibit altered escape responses when exposed to fluoxetine but were affected

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by venlafaxine and bupropion exposure. Mixtures of these four antidepressant pharmaceuticals slowed predator avoidance behaviors in larval fathead minnows regardless of the exposure window. The impact of antidepressant exposure on larval fathead minnows has been shown to reduce predator avoidance behavior as reflected by C-start performances, which may ultimately impact survival and possibly reproductive fitness.

A recent study\textsuperscript{319} tested the hypotheses that (1) larval fathead minnows exposed to estrogens, a primary class of endocrine disrupting compounds, singularly or in mixture, suffer a reduced ability to perform an innate predator avoidance behavior when faced with a threat stimulus; (2) additive effects will cause greater reductions in predator avoidance behavior; and (3) effects will differ among developmental stages. In this study, four experiments were conducted, each with embryos and with larval fish, and the predator avoidance behavior of all exposed animals 12 days post-hatch was assessed. Embryos (post-fertilization until hatching) were exposed for 5 days to environmentally relevant concentrations of estrone (E1 – naturally occurring estrogen), 17β-estradiol (E2 – also naturally occurring), and 17α-Ethinyl Estradiol (EE2 - synthetic estrogen), singularly and in mixture. When tested 12 days post-hatch, only E1 adversely affected predator avoidance performance of larvae exposed as embryos. Conversely, larvae exposed for 12 days post-hatch did not exhibit altered escape responses when exposed to E1, while adverse responses were seen in E2 and the estrogen mixture. Interestingly, anticipated to be the most potent estrogen compounds in the group, EE2 exposure did not elicit changes in escape behaviors at either developmental stage.

Due to the concerns of the impact of pharmaceuticals in surface water on aquatic life, scientists of PhRMA members have undertaken work to validate those impacts and consider how data collected in experimental settings may transfer to real world aquatic environments. The PhRMA research predicts that the vast majority of pharmaceuticals do not present a significant risk from chronic exposure at the concentrations that exist in the environment. In a few extraordinary circumstances pharmaceuticals in conjunction with other compounds have been suspected to contribute to aquatic life impacts. An example of one of these few compounds is EE2. PhRMA research on EE2 has found that analytical methods can affect the reported concentrations of EE2 in waterways.\textsuperscript{320} Single mass spectrometry (MS) measurement can lead to an overestimation of the concentration of EE2 due to an overlap of the EE2 peak in the chromatogram with an unknown impurity of similar mass-to-charge ratio. \textsuperscript{321} PhRMA researchers have also developed a Predicted No Effect Concentration for EE2 and compared that with environmental concentrations to determine if


concentrations of EE2 that would harm aquatic species actually occur at those levels in the environment. Their findings indicate that for EE2, the predicted environmental concentration (PEC - what is expected to be found in the environment) is less than the predicted no effect level concentrations (what would adversely impact aquatic species) at low, average and high stream flow situations.\(^{322}\) In summary, the EE2 work done by PhRMA suggests that the concentrations of pharmaceuticals that are typical in environmental settings are not high enough to cause the types of aquatic life effects you may see in experimental settings.

Some observed aquatic life impacts have been attributed to endocrine modulating chemicals. However, the PhRMA research shows that it is unlikely that EE2 concentrations alone are causing these impacts. Based on current research, it may be necessary to conduct further research to better understand the impact and relative contribution of pharmaceutical compounds on observed impacts on aquatic species.

**Impact of Pharmaceuticals in Finished Drinking Water on Human Health**

Limited data show that human pharmaceuticals have only occasionally been detected in finished drinking water, with concentrations generally being in the ng/L (ppt) range.

While exposure to pharmaceuticals has been found to have some adverse effects on aquatic life in experimental settings, notably in the fish population as documented earlier, a similar link has yet to be established between ingestion of these compounds through drinking water and human health. The EPA continues to report that the consumption of the low concentrations of pharmaceuticals found in drinking water do not represent a human health risk, based on current knowledge.

Current research has determined that the long-term risk to humans from any single pharmaceutical at sub-μg/L levels is negligible\(^{323, 324}\) and it is unlikely that pharmaceutical compounds are present in the environment at concentrations high enough to cause significant harm.\(^{325}\) Researchers presented human risk assessments for 26 active pharmaceutical ingredients (APIs) or their metabolites, representing 14 different drug classes, for which environmental monitoring data were available for the United States.\(^{326}\) Acceptable daily intakes (ADIs), representing a level of daily intake that should not result in an adverse health


\(^{325}\) See U.S. EPA, 2010d.

\(^{326}\) See Schwab et al., 2005.
effect from direct exposure to a population, were derived using available data for APIs; the resulting ADIs were designed to protect potentially exposed populations, including sensitive sub-populations such as the elderly and children. The ADIs were then used to estimate predicted no effect concentrations (PNECs). The PNEC is defined as a concentration in water at or below which no adverse human health effects are expected. The author derived three categories of PNECs; one for drinking water, the second for water from which potential exposures are limited to fish consumption, and a third for water used both as a drinking water source and as a source of fish consumption. The PNECs were derived both for adults and children using equations that are consistent with those used by the EPA for developing concentration limits to protect against threshold-type effects. The PNECs were compared to measured environmental concentrations from the published literature and to maximum predicted environmental concentrations (PECs) generated using the PhATE model. Ratios of measured environmental concentrations to PNECs were typically found to be very low and consistent with maximum PECs to PNEC ratios. The authors concluded that for all 26 compounds, these low ratios indicated that trace concentrations of pharmaceuticals in surface water and drinking water present no appreciable risk to human health.

Researchers conducted an analysis on four pharmaceutical compounds representing different therapeutic classes (acetylsalicylic acid, clofibrate, cyclophosphamide, and indomethacin) to evaluate the presence and potential adverse human health effects of trace levels of pharmaceuticals in aqueous environmental media. An extensive literature search and chemical-specific risk assessments were performed to assess the potential human health significance of each compound’s individual presence in environmental media. Safe water quality limits were estimated for each pharmaceutical by following the U.S. EPA Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health and were compared to the concentrations found in the environment. The calculation of the provisional ambient water quality criteria involved estimation of human exposure to contaminated water, including intake via bioaccumulation in fish, and calculation of cancer risk and non-cancer hazard indices. Parameters detailing the toxicological and pharmacological nature, exposure assessment, and environmental fate and transport of each pharmaceutical were also considered. The overall conclusion was that based on available data, no appreciable risk to humans exists, as the detected concentrations of each of these pharmaceutical compounds found in aqueous media were far below the derived safe limits.

Studies have been performed demonstrating that the odds of any form of acute (short-term) human health risk originating from the presence of low concentrations of pharmaceuticals in drinking water is extremely low. For the pharmaceuticals detected in water, exposure to people through water is

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327 See Schulman et al., 2002.
expected to be small compared to exposures to potentially hazardous compounds through the use of prescription and OTC medications. Researchers compared reported concentrations of pharmaceuticals in German drinking water and therapeutic doses for those compounds and found that the margin between potential indirect daily exposure via drinking water and daily therapeutic dose was at least three orders of magnitude and typically much more.\textsuperscript{331} This comparison of daily or lifetime intake of pharmaceuticals via drinking water (two liters per day over a 70-year time frame) with therapeutic doses indicated that the exposure levels were low and well below the dosages that can cause a pharmacological effect. To illustrate, Ibuprofen was one of the pharmaceuticals assessed in this study. The therapeutic dose for Ibuprofen is 1,200 mg/day for adults. The maximum reported value for Ibuprofen measured in the German drinking water was 3 ng/L. The value for daily drinking water intake was 6 ng/day. This equates to a lifetime intake of 153 µg, equivalent to 0.001 times the daily therapeutic dose. Thus drinking two liters of water containing 6 ng of Ibuprofen every day over a lifetime would not cumulatively deliver the equivalent of a single prescribed dose. Daily and lifetime intake estimates were based on reported maximum measured concentrations in German drinking water\textsuperscript{332} and were calculated using worst case predictions for United Kingdom drinking water concentrations (assuming no human metabolism, no removal during sewage treatment, no surface water effluent dilution and no removal during drinking water treatment). Over 90% of the compounds assessed had lifetime intake estimates less than the daily therapeutic dose (those with greater lifetime intake estimates were all bronchodilators; their resulting lifetime estimates are more of a reflection of the low therapeutic doses of 20-250 µg/day, rather than elevated concentrations in drinking water).

Human health risk-based screening levels for 15 pharmaceutically active ingredients and four metabolites were compared to concentrations detected at 19 drinking water treatment plants across the United States to assess health risks and establish target concentrations for water treatment.\textsuperscript{333} Compounds were selected based on rate of use, likelihood of occurrence, and potential for toxicity. Screening levels were established based on animal toxicity data and adverse effects at therapeutic doses, focusing largely on reproductive and developmental toxicity and carcinogenicity. Calculated drinking water equivalent levels (DWELs), levels where health effects are not expected to occur, ranged from 0.49 µg/L (risperidone) to 20,000 µg/L (naproxen). None of the 10 detected compounds exceeded their DWEL. Ratios of DWELs to maximum detected concentrations ranged from 110 (phenytoin) to 6,000,000 (sulfamethoxazole). Based on this evaluation, the authors concluded that adverse health effects from targeted pharmaceuticals occurring in U.S. drinking water are not expected.

Some believe that it is more important to focus human health risk assessments on compounds that present a “higher risk” to those for whom the drug is not prescribed; many consider “neuropharmaceutical” compounds to be among this

\textsuperscript{331} See Webb et al., 2003.
\textsuperscript{332} See Ternes et al., 1998.
higher risk category. Consequently, recent research\textsuperscript{334} performed human health risk assessments to evaluate the risks from residues of three neuropharmaceuticals which might be found in United States surface waters: atomoxetine (used in the treatment of attention-deficit/hyperactivity disorder), duloxetine (used in the treatment of major depressive disorder, diabetic peripheral neuropathic pain, and generalized anxiety disorder), or olanzapine (used in the treatment of patients with schizophrenia and bipolar disorder). Preclinical safety studies and human clinical data were used to determine an ADI for each compound: atomoxetine, 1.4 µg/kg/day; duloxetine, 1.8 µg/kg/day; and olanzapine, 1.4 µg/kg/day. The calculated PNECs for children were 25.7, 19.1, and 35.9 µg/L for atomoxetine, duloxetine, and olanzapine, respectively. Estimated exposure concentrations determined using FDA guidelines and predicted environmental concentrations (PECs) from the PhATE model were compared with each PNEC to determine margins of safety, which ranged from 147 to 642. This evaluation indicates that predicted levels of atomoxetine, duloxetine, and olanzapine that might be found in surface waters are significantly below PNECs. Based on currently available data used in this assessment, no appreciable human health risks exist from exposure to the highest 99th percentile of predicted residue levels of atomoxetine, duloxetine or olanzapine in surface waters under low-flow conditions.

Researchers have carried out a human health risk assessment for environmental exposures for carbamazepine (CBZ) and its major human metabolites (carbamazepine diol and carbamazepine N-glucuronide).\textsuperscript{335} Carbamazepine is an API used worldwide to treat epileptic seizures and trigeminal neuralgia, and tends to be detected in surface water more frequently, and at relatively higher concentrations, than most other APIs, as evidenced by some of the occurrence studies in the “Background” section of this report. The PNECs for CBZ and its major human metabolites were developed for surface waters to be protective of human health from environmental exposures from drinking water and fish consumption. These PNECs were compared to both measured and predicted environmental concentrations for North America and Europe. The PECs were calculated using the models PhATE for North America and GREAT-ER for Europe. Based on available human data, the authors reported that CBZ and its major metabolites should have no appreciable risk to human health through environmental exposures.

In order to help prioritize future research efforts, researchers estimated risks associated with exposure to human prescription pharmaceutical residues in wastewater using marketing and pharmacological data.\textsuperscript{336} Masses of 371 APIs dispensed in the United States in 2004 were estimated from marketing data, and then divided by therapeutic dose rate to normalize for potency. Comparing maximum likely average wastewater concentrations of pharmaceuticals to


exposure rates that produce therapeutic effects in humans suggests that the threat to healthy human adults from aquatic exposure is low, even when likely mixture effects are considered, as results showed that, under most circumstances, aquatic exposure rates to single APIs and combination of APIs are at least 100 fold lower than those required to produce minimal therapeutic effects. This suggests that significant synergy is unlikely at the low exposure levels predicted.\textsuperscript{337} Synergistic effects occur when the combined effect of two chemicals are much greater than the sum of the effects of each chemical given alone. Presently available data on mixtures of chemicals at doses well below their individual no-effect levels is of no health concern as research has shown synergy is typically seen only at doses of interacting chemicals similar to or above their individual threshold effect doses.\textsuperscript{338} However, there was one study that made a different claim: some researchers reported that combinations of two weak environmental estrogens could cause an estrogenic effect even if each compound was present at a concentration below its no-effect value.\textsuperscript{339} However, this report was later withdrawn because neither the authors nor other workers were able to repeat the results.

Presently, only the individual toxicity of a compound is considered while setting up drinking water guidelines. That is, each chemical currently regulated in public drinking water systems in the United States, such as arsenic, nitrate, volatile organic compounds, among many others, is evaluated individually to determine the maximum concentration of that chemical in finished drinking water that may be consumed every day for 70 years without having adverse health effects associated with it, coupled with some built-in safety factors. We do not develop those maximum allowable levels for each chemical based on knowing whether another chemical is also in the water at the same time; accurately determining the risks associated with multiple compounds at varying concentrations is currently not possible because there is not enough experimental data to adequately evaluate the risks associated with exposure to multiple chemicals. Therefore, although we do not consider the impact that mixtures of pharmaceuticals might have on human health, we do not do it for any currently regulated chemicals because we do not have a sound way of performing that analysis at this time; pharmaceuticals are no different in that way. Despite this, it must be stated, as with the currently regulated chemicals in drinking water, is not is not clear what toxicological implications chronic exposure to multiple trace contaminants may have.\textsuperscript{340} Additionally, not much is known about the environmental or human health hazards that may result from long-term exposure to sub-therapeutic levels of these bioactive substances or their transformation products. Again, as with the currently regulated chemicals, we do not determine risk that way at this time; it is a knowledge gap that stretches far beyond pharmaceuticals.

\textsuperscript{337} See Kostich and Lazorchak, 2008.
\textsuperscript{340} See Daughton, C.G., 2003.
In summary, there is considerable information available at this time that suggests that the low concentrations of pharmaceuticals in drinking water - there as a result of incomplete removal during treatment - do not adversely impact human health. There are still some data gaps that exist in terms of evaluating the impact of mixtures and long-term-low concentration risk, and for chemicals that have yet to be assessed. However, at this time, based on the studies performed on some of the more widely-used pharmaceuticals on the market and some with higher expected toxicology risk, there seems to be no evidence to suggest that exposure to low concentrations of pharmaceuticals via drinking water in the United States would have an adverse human health impact.

**Significance of the Impact of Disposal Methods on the Environment and Human Health**

Data suggests that low concentrations of pharmaceuticals in drinking water present no appreciable risk to humans. Some experimental studies have shown that pharmaceuticals in water, at micrograms per liter (µg/L) concentrations, may impact fathead minnows, both their predator avoidance behavior and their reproduction functions, which may ultimately lead to reduced population numbers and possibly the collapse of the species, where exposed. However, real-world data are required to support those research efforts since current models suggest that concentrations of pharmaceuticals in real environmental settings in the United States are too low to obtain the impacts seen in experimental settings.

The major unanswered question related to unused pharmaceutical disposal and pharmaceutical occurrence in the environment is what proportion of pharmaceuticals in waterways, or at a wastewater treatment plant, is a result of excretion (following the intended use of the drug) versus the intentional flushing of unused pharmaceuticals into the wastewater. While we do not have experimental scientific approaches established to address the question at this time, some estimates based on other data have been established.

PhRMA researchers have investigated the contribution of unused medicine to the trace amounts of pharmaceuticals in water and found that patient excretion is the primary contributor. If all unused medicine were flushed they estimate that about 88% of pharmaceuticals in the water would come from excretion following patient use and 12% would be attributed flushing of unused medicine. However, they also found that the unused medicine contribution to pharmaceuticals can be effectively eliminated if all unused medicine is disposed of in household trash. When compared to flushing unused medicines, disposal of pharmaceuticals in the municipal trash disposal method reduce the unused medicine component of pharmaceuticals in surface waters from around 10% to less than 0.1%. This calculation assumes that 10% of medicine goes unused (which was found to be consistent with the results of the disposal survey in Texas) and that 15% of household trash in the United States is incinerated.

Since excretion is a much more dominant source of pharmaceuticals in wastewater than intentional disposal in the drain, it can be said that any aquatic life impacts that result from the pass-through of pharmaceuticals from...
wastewater into surface water are not significantly impacted by disposal practices; it is as result of their intended use and excretion. While flushing that 10% should be avoided when possible, to remove that source of 10% of API in the environment, we do not currently know if there would be any impact on aquatic life of 10% of unused pharmaceuticals were removed from wastewater discharge to waterways; it is likely minimal but remains unknown at this time.

Enhanced treatment technologies such as reverse osmosis may remove more pharmaceuticals than more conventional treatment processes, but even the most effective technologies may not remove all pharmaceuticals to below detection limits. Additionally, there does not appear to be concrete evidence to justify reductions in pharmaceuticals in wastewater effluent. That is because ecotoxicology has not identified maximum allowable concentrations based on aquatic life exposure (therefore no MCLs are set and pharmaceuticals are not regulated). Ultimately, at this time we do not know the numerical values to which wastewater treatment must reduce concentrations of pharmaceuticals in water in order for there to be any impact on aquatic life. Therefore, it may not be feasible at this time to require wastewater utilities or drinking water utilities to adopt enhanced treatment technologies for the purposes of removing small concentrations of pharmaceuticals.

For health-care providers that dispose of their unused pharmaceuticals as medical waste after being treated in an autoclave, it is unlikely that the autoclave wastewater stream would contribute significant amounts of API to the environment or impact aquatic life. However, since it is a recognized possible source, it may be appropriate to consider eliminating that potential source where possible.

Potential Impacts of Disposal Methods on Public Health and Safety

Potential Impact of municipal trash disposal or MSW landfill disposal

Public health agencies have historically promoted drain disposal of unused drugs primarily to deter drug abuse and misuse as well as diversion for illicit uses and poisonings. This is also why the FDA continues to recommend drain disposal for the most lethal drugs that might be found at home. Some go beyond this observation and assert that disposing of unused pharmaceuticals in the municipal trash can continue to lead to drug diversion issues and wildlife poisonings. Researchers have suggested that scavengers (e.g., human "gleaners") could access drugs discarded to curbside trash or municipal landfills, or that landfill employees could easily reveal and divert dangerous pharmaceutical waste. Some also assert that wildlife may enter a landfill, scavenge for substances, and become poisoned by disposed human pharmaceuticals.

Other comments received assert that by encouraging disposal of unused pharmaceuticals in the trash, more pharmaceuticals will be stored in the
household because consumers and health-care providers do not feel comfortable with landfill disposal.

While drug diversion is an important and legitimate concern, the TCEQ did not receive convincing evidence to support these assertions. The TCEQ considers that the model put forth in the FDA/ONDCP strikes a proper balance between environmental protection and drug diversion control. As with flushing, the FDA/ONDCP guidance proposes a method of disposal that quickly extricates pharmaceutical waste from the household. Furthermore, the TCEQ asserts that modern landfills, when properly engineered and operated, are safe and appropriate to handle pharmaceutical waste from households.

While media outlets (particularly the Associated Press “PharmaWater” series of March 2008) are often effective at informing the public of important environmental issues related to pharmaceutical waste, some fall short of conveying the broader context to the public. For example, when reports identify pharmaceuticals in “drinking water sources,” the public may not be aware that raw sources of drinking water are treated prior to being provided to customers. Additionally, when both the scientific literature and media reports focus on detections of pharmaceuticals in water, they seldom convey information related to the known impacts of those detections on human health.

Alternatively, the reflex to hoard pharmaceuticals in the absence of take-back programs could just as easily be attributed to a lack of known, permissible disposal methods as to a lack of take-back programs. It was apparent to the TCEQ from the consumer, veterinary, hospice/in-home care surveys, and discussions with poison control centers and take-back program coordinators that many consumers in Texas simply do not know how they should dispose of their unused pharmaceuticals and therefore store drugs in their homes. This was even the case for some health-care providers, who admitted to storing drugs on site because they did not know what to do with them.
Alternative Methods for Disposing of Unused Pharmaceuticals

The TCEQ focused on three approaches to identify possible alternative methods for the management and disposal of unused pharmaceuticals: (1) identification of regulatory approaches adopted by other states; (2) identification of the methods used by health-care providers and others to manage, process and dispose of unused pharmaceuticals; and (3) identification of alternative methods that could be adopted for collecting, managing, processing/disposing of consumers’ unused pharmaceuticals.

A number of alternative approaches have been tried in the United States for collecting unused pharmaceuticals from consumers for ultimate disposal. Some of those have been adopted in Texas in isolated situations, but because they are not widely adopted and very few in the consumer surveys reported that they used those methods, they are all considered “alternative methods” compared to the “current methods” of direct drain disposal and direct municipal trash disposal, or storing drugs on site (not a disposal method, but a management method).

Alternative Methods for the Management and Disposal of Unused Pharmaceuticals—Regulatory Approaches

This section focuses on pharmaceutical waste management and disposal methods in other states that differ significantly from those in Texas. Statutes such as RCRA and the Clean Water Act set national standards while allowing states to run permitting programs that “fill in the gaps.” There is a degree of uniformity between state programs. For example, according to a 2009 EPA survey, a majority of states have some form of drug repository or donation program, such as the one authorized by the TSBP at 22 TAC § 291.8.343 All 50 states have approved hazardous waste programs that must meet the minimum standards set forth by the federal government.344 Most state environmental agency websites the TCEQ visited seemed to adopt some version of the White House Office of National Drug Control Policy (ONDCP) guidance for household pharmaceutical waste disposal.

Most alternative methods of pharmaceutical waste disposal fall within four different categories, which are described in more detail below according to the states that implement them. First, several states have amended their waste rules in order to create special requirements for pharmaceutical waste. These rule changes range from the creation of new hazardous waste categories, to adoption

344 See 40 C.F.R. § 272.
of “pharmaceuticals” as a universal waste, to inclusion of pharmaceuticals as a type of medical waste. These states include Arizona, California, Minnesota, and North Carolina. Second, several states have enacted or proposed legislation to establish either community drug take-back events or mail-back programs. These states, which include Maine, Minnesota, Missouri, and Washington, have either funded these programs or amended their pharmacy rules to facilitate private programs. Third, some states/regions (Illinois and King County, Washington) have either banned disposal of pharmaceutical waste into wastewater systems or implemented special wastewater discharge provisions for pharmaceutical waste in particular. Finally, one state, New York, stepped up enforcement of waste rules and used resulting settlement agreements to reduce discharges of pharmaceutical wastes into waterways by requiring that sites cease discharges of pharmaceutical wastes into waterways or divert pharmaceutical waste to proper waste handling facilities for treatment and disposal.

**Arizona**

Arizona is one of a very small handful of states that regulates pharmaceutical waste as a distinct waste stream.345 The Arizona Department of Environmental Quality (ADEQ) promulgated a rule in 1999 that includes “discarded drugs” as a distinct type of waste within the broader category of medical waste.346 The ADEQ rules define “discarded drugs” as the following:

> [A]ny prescription medicine, over-the-counter medicine, or controlled substance, used in the diagnosis, treatment, or immunization of a human being or animal, that the generator intends to abandon. The term does not include hazardous waste or controlled substances regulated by the United States Drug Enforcement Agency.

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The treatment practice for discarded drug disposal is simple. Unless drugs are returned to the manufacturer, generators of discarded drugs must destroy the drugs on site prior to putting the waste out for collection.348 The generator may destroy the drug using any method that prevents the drug’s use, or any specific method approved or prescribed by federal or state law.349

Although Arizona’s rule is fairly unique, it does not dictate a final disposal method for discarded drugs, and the intention of the rulemaking appears to be aimed at reducing drug proliferation rather than water-quality concerns. In the 1999 rulemaking the ADEQ stated the following:

Generators may continue to use a variety of disposal options, except placing discarded drugs directly into the solid waste stream. This rulemaking requires generators to render the drugs unusable prior to disposal in the dumpster. Rendering the drugs unusable could include crushing, grinding, bleaching (using

345 See ERG, 2009c.
346 ARIZ. ADMIN. REG. at 3776 (September 17, 1999).
347 ARIZ. ADMIN. CODE R18-13-1401(12).
348 Id. at R18-13-1401(12).
349 Id. at R18-13-1418(A).
hypochochlorite or iodophors), or diluting prior to disposal. Some generators could be impacted by this requirement, but ADEQ expects the impact to be minimal.  

Evidently, the ADEQ contemplated that generators would continue to dispose of discarded drugs after the new rule, so long as the drugs were rendered unusable. Additionally, the ADEQ created an exemption from the above requirements for generators that intend to flush discarded drugs into a sanitary sewer, if permitted by the wastewater treatment authority.  

California  

California's hazardous waste law framework is based on federal RCRA rules as well as a host of more expansive state rules. California hazardous waste rules, found in Title 22, Division 4.5 of the California Code of Regulations, define hazardous waste to include acutely hazardous waste, extreme hazardous waste, non-RCRA hazardous waste, RCRA hazardous waste, special waste and universal waste.  

Pharmaceutical waste in California may be classified as federal RCRA hazardous waste, California-only (non-RCRA) hazardous waste, or solid waste. In 1996, California passed the Medical Waste Management Act (“MWMA”), which transferred authority over California-only hazardous “medical waste” from its Department of Toxic Substances Control to the Department of Health Services. The three categories (RCRA hazardous, California-only, or solid) created a source of confusion in determining how to classify medical waste. First, pharmaceutical solid waste (non-toxic, non-hazardous) may be flushed down the sewer or thrown away. Second, pharmaceutical hazardous waste is governed by RCRA hazardous waste rules. Third, pharmaceutical medical waste must be incinerated under the MWMA. These rules govern facilities that dispose of pharmaceuticals, but do not govern household waste.  

Household waste is exempt from both medical waste and RCRA hazardous waste requirements. Household pharmaceutical solid waste may be flushed down the toilet or thrown away. In 2007, California passed SB 966, “Reducing Pharmaceuticals in Waste Streams,” which required relevant state agencies to oversee the testing of pharmaceutical take-back programs for future statewide implementation. There are currently 297 home-generated pharmaceutical take-back locations in California. Locations range from pharmacies and drug stores

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350 5 ARIZ. ADMIN. REG. at 3785-86.  
351 See ARIZ. ADMIN. CODE R18-13-1418(B). See also ARIZ. ADMIN. CODE R18-13-1403(B)(3).  
352 22 C.C.R. § 66260.10.  
355 Non-hazardous pharmaceutical solid wastes include saline solutions, dextrose, electrolytes, etc.  
357 Cal. H.S.C. § 117700. Veterinarian, livestock, and animal livestock operations are also exempt from medical waste rules.  
358 22 C.C.R. § 66261.4(b)(2).  
359 Codified at Cal. P.R.C. § 47120.  
to police stations and city halls. Two cities have door-to-door programs, and one take-back program runs out of a coroner’s office.

Under SB 966, the collection facility becomes the “medical waste generator” subject to MWMA requirements for medical waste, including proper storage, transportation, and destruction. If controlled substances are accepted, a law enforcement official must be present to inventory and take control of the substances. The California Department of Resources Recycling and Recovering (“CalRecycle”) must prepare a report on the program for the California legislature by December 2010. A background paper was developed by CalRecycle for a July 10, 2010 workshop which summarizes information about the collection programs currently underway in the State.

**Illinois**

The State of Illinois has arguably taken the boldest step in regulating pharmaceutical waste disposal by enacting an outright ban on disposal via public wastewater collection system or septic system. In August 2009, the governor of Illinois signed into law SB 1919 prohibiting health care institutions from disposing non-liquid (solid) pharmaceutical waste down the drain. The law became effective on January 1, 2010.

**Maine**

In 2003, the Maine legislature passed a unique solution to the household pharmaceutical waste problem. Public Law 2003, chapter 679, “An Act to Encourage the Proper Disposal of Unused Pharmaceuticals” established a program for mailing unused pharmaceuticals to the Maine Drug Enforcement Agency, which destroys the pharmaceuticals in compliance with federal RCRA standards using high-heat incineration. The law remained unfunded until 2007, when the U.S. Environmental Protection Agency awarded a $150,000 grant to the University of Maine Center on Aging to start, implement, and evaluate a trial mail-back program. The Maine Legislature awarded $150,000 in additional funding to continue the program for two years past the EPA’s grant. The “Safe Medicine Disposal for ME” program provides prepaid mailers distributed to pharmacies for citizens to mail back unused pharmaceuticals. The envelopes are sent through the U.S. Post Service and picked up by a Maine Drug

362 Cal. P.R.C. § 47123.
364 See ER, 2009b, supra note 1 at 24.
365 210 ILL. COMP. STAT. 150/10 (2010).
366 Codified at 22 M.R.S.A. c. 604.
Enforcement Agency official. The Maine Drug Enforcement Agency serves as the central agency in coordinating, collecting, and destroying the mailed-back pharmaceuticals, avoiding problems faced by many take-back and other programs regarding the retrieval of controlled substances.

Additionally, Maine attempted to reduce the amount of pharmaceuticals that go unused by instituting a new 15-day limit on initial prescriptions for certain medications that have been identified as having high side effect profiles, high discontinuation rates, or frequent dose adjustments (i.e., those medications that have a high rate of waste quantities). MaineCare, a health insurance program managed by the Maine Department of Health and Human Services implemented the requirements and the limitation went into effect for Suboxone, Subutex, Chantix, and Nicotine replacement products in August 2009. Beginning in September and October 2009, limitations applied to additional medications. Prescriptions at higher dose quantities can be obtained with prior authorization. In addition to reducing wasted medication, the policy aims to control health care costs.

**Minnesota**

In April 2010, Minnesota passed the Safe Drug Disposal Act (SDDA). The law allows specified parties to possess prescription drugs for the purpose of disposing the drug as pharmaceutical waste. Those parties are: law enforcement officers; licensed hazardous waste transporters; licensed Very Small Quantity Generator collection programs; a county or its agent that collects, stores, transports, or disposes of drugs pursuant to a program in compliance with federal law; and legally created sanitation districts. The law also allows for a person with a valid prescription to designate any individual or county with a collection program in compliance with federal law to handle the drug for the purpose of destruction. The law originally made pharmaceutical companies responsible for establishing and maintaining a state-wide collection network, but that provision was removed from the final version, as was a provision prohibiting hospitals from flushing unused drugs. The new law has encouraged local drug take-back efforts. Prior to the SDDA, drug take-back programs were administered by law enforcement, such as at the Chisago County Sheriff’s Office and police stations in Rice County. Since the law passed, collection events have operated at non-law enforcement locations such as local community centers.

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369 U.S. EPA, 2010e.
370 Id.
371 See ERG, 2009b.
373 This is equivalent to the term used in Texas “CESQG”. Minn. R. 7045.0206.
374 Safe Drug Disposal Act, 2010, Minn. Laws Ch. 223.
375 Id.
Minnesota also includes an additional characteristic hazardous waste that includes several categories of pharmaceuticals. In addition to the RCRA hazardous waste characteristics of ignitability, corrosivity, reactivity, and toxicity, the Minnesota Pollution Control Agency (MPCA) includes “lethality” as a characteristic of hazardous waste. \(^{377}\) While “lethality” is a generic characteristic that includes non-pharmaceutical waste that fails specifically-defined thresholds of lethality, MPCA developed an “alternative method” to evaluate pharmaceutical waste for the characteristic. Simply put, generators of pharmaceutical waste should assume lethality if the waste falls within six risk criteria groups: 1) carcinogen, 2) chemotherapy agent, 3) combination U/P-List drug, 4) endocrine disruptor, 5) NIOSH hazardous drug, or 6) OSHA hazardous drug. \(^{378}\) If a specific pharmaceutical waste does not fall into that category, the generator may assume that the waste is not lethal; however, the waste may be hazardous for some other characteristic.\(^{379}\)

**Missouri**

In 2008 the EPA issued a grant of $150,570 to the Area Resources for Community and Human Services (“ARCHS”), a non-profit organization based in St. Louis, Missouri. \(^{380}\) With the EPA funds, ARCHS orchestrated a one year pharmaceutical take-back program in the St. Louis metropolitan area known as the Regional Excess Medication Disposal Service Partnership, or RxMEDS.

**New York**

In January 2010, the State of New York implemented a unique enforcement approach to the issue of pharmaceutical waste. The Attorney General, Mario Cuomo, instituted a broad investigation into pharmaceutical waste management practices at hospitals, nursing homes, and assisted living facilities. \(^{381}\) As a result of the investigation, the state entered into settlement agreements with five hospitals and nursing homes in the New York City watershed. \(^{382}\) The settlement agreement requires the sites to “immediately cease all discharges of pharmaceutical wastes into waterways within New York City’s watershed.”\(^{383}\) As an alternative the sites must divert the pharmaceutical waste to proper waste handling facilities for treatment and disposal. \(^{384}\) The sites also have to pay civil

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\(^{377}\) See MINN. R. 7045.0131.

\(^{378}\) See Alternative Method to Evaluate Pharmaceutical Waste for the Lethality Characteristic, Minnesota Pollution Control Agency (w-hw4-45b), August, 2010.

\(^{379}\) Id.


\(^{382}\) Id.

\(^{383}\) Id.

\(^{384}\) Id.
penalties for prior violations and establish take-back programs for household pharmaceutical waste collection.385

The settlements were the end result of investigations that threatened violations of the state-implemented RCRA rules and, in some instances, the CWA.386 According to the Attorney General’s office, the sites had violations related to improper identification, tracking, and disposal of pharmaceuticals that fell within the definition of RCRA hazardous waste.

North Carolina

In North Carolina, the Division of Waste Management (DWM) regulates solid waste within the North Carolina Department of Environment and Natural Resources. The North Carolina DWM allows generators of pharmaceutical waste to dispose of the waste in the general waste stream unless it is hazardous waste or an endocrine disruptor.387 Endocrine disruptors must be treated as if they are hazardous waste, and must either be offered back to the manufacturer or disposed of in a hazardous waste incinerator or landfill. In short, like Minnesota and California, North Carolina has expanded its definition of hazardous waste to include certain categories of pharmaceutical waste. However, unlike California and Minnesota, North Carolina has not changed its rules to include endocrine disruptors, but merely recommends the above treatment by way of a guidance document. North Carolina waste regulations also state that there should be no disposal of any drug or chemical in a commode or drain (North Carolina, 2009).388

Washington

The State of Washington has supported two take back programs: the Bellingham Pharmaceutical Take-Bake Program and the Pharmaceuticals from Households: A Return Mechanism (PH:ARM) program. The Bellingham Pharmaceutical Take-Back Program, which began in April 2010, was supported by a two-year, $25,780 grant from the EPA intended to cover costs associated with collection, disposal and management of the program.389 PH:ARM was created as a pilot, statewide drug-return program. The program is organized and funded through several private organizations, although it is regulated by the state.390

385 Id.
386 Id.
In King County, Washington (home to Seattle), the King County Industrial Waste Program (KCIW) requires hospitals to obtain discharge authorizations in order to discharge wastewater into the King County sewer system.\textsuperscript{391} This program, which has existed since 2002, requires hospitals in King County to meet county-based pollutant limits before discharging.\textsuperscript{392} Their guidance seems to recommend treating all pharmaceutical waste as hazardous waste and have it all sent to a RCRA-authorized facility for incineration.

**Controlled Substance Act Proposed Rule Changes**

On October 12, 2010, President Obama signed Senate Bill 3397, the “Secure and Responsible Drug Disposal Act of 2010,” into law. This law gives the Attorney General the authority to promulgate new regulations that allow patients to deliver legally acquired, unused controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion. As was noted previously in this report, under current rules, ultimate users are not allowed to distribute a controlled substance to any other person, even for disposal. Regulations have not yet been promulgated pursuant to this Act; however, once regulations are developed, they will likely provide additional disposal options for consumers seeking to reduce the amount of expired or otherwise unwanted prescription drugs in their homes.

**Texas Rule Amendments**

Through stakeholder discussions, the TCEQ has identified alternatives related to amending the Texas rules targeted at impacting the management and disposal of unused pharmaceuticals in a manner that reduces impacts on public health and the environment.

*Develop an MOU between the TCEQ and the Texas State Board of Pharmacy (TSBP):* A Memorandum of Understanding (MOU) or similar agreement could be developed with the Texas Board of Pharmacy to clarify that the TSBP will regulate the collection of pharmaceutical wastes by licensed pharmacies and TCEQ continues to regulate off site transport, processing and disposal in MSW landfills or processing facilities.

*Amend the Texas Dangerous Drug Act:* Another regulatory option that could be employed to manage pharmaceuticals would be to add a category for “consumer unused pharmaceutical collection event staff” as an additional party that may possess another person’s dangerous drugs under the Texas Dangerous Drug Act. This would simply make it legal for all staff at a collection event (whether they be state or local employees or not) to possess a consumer’s unused drugs before they have the waste transferred to a disposal facility.

\textsuperscript{391} See ERG, 2009b., *supra* note 1 at 26.
\textsuperscript{392} *Id.*
Alternative Methods of Disposal and Management of Unused Pharmaceuticals for the Health-Care Industry and Other Businesses

This section discusses some alternative methods of managing and disposing of unused pharmaceuticals that could be adopted by the health-care industry and other regulated entities. These alternative methods could include adoption of best management practices in an effort to reduce the unused pharmaceuticals entering the wastewater. For example, the EPA’s draft guidance document, *Best Management Practices for Unused Pharmaceutical at Health-Care Facilities*, describes best management practices that EPA recommends to health-care facilities when managing and disposing of unused pharmaceuticals. The guidance document presents the steps that the health-care industry can take to identify and properly manage unused pharmaceuticals. The steps include:

- Conduct an inventory of pharmaceuticals and unused pharmaceuticals to quantify the amount of medication the facility is disposing of and determine how often those pharmaceuticals become waste. Once wasted pharmaceuticals are identified, the facility can use a variety of the recommended best management practices to reduce waste.

- Reduce unused pharmaceuticals by reviewing purchasing practices, using limited dose or unit dose dispensing, replacing pharmaceutical samples with vouchers, and performing ongoing inventory control and stock rotation.

- Properly manage unused pharmaceuticals by identifying types of pharmaceuticals and any federal and state requirements; when possible: reusing or donating unused pharmaceuticals, returning them to the pharmacy; sending them to a reverse distributor for credit and proper disposal; and using EPA recommended practices to dispose of pharmaceutical waste at the facility.

- Segregate waste for disposal to ensure regulations are met and to reduce costs (e.g., non-hazardous pharmaceutical waste disposal in a solid waste landfill may be less expensive than disposal via hazardous waste hauler).

- Train staff in proper disposal methods.

Some of the options above are more applicable to hospitals and pharmacies, while others can be applied to all entities that generate (or collect) unused pharmaceuticals with the intent of disposing of them, such as hospitals, hospital pharmacies, nursing staff, physician’s offices, nursing homes, assisted living facilities, hospices, veterinarians, law enforcement, retail pharmacies.

The EPA, as part of their HCI study, believes that facilities should adopt alternatives in the order described above; that is, prevent the generation of waste, re-use items where possible, then dispose of the remainder according to the appropriate waste rules. The TCEQ recognizes that as a sensible approach to take which may ultimately have more of an impact on the amount of
pharmaceuticals that enter the wastewater as well as the added benefit of reducing health-care costs.

**Resources, Training and Outreach to the Regulated Community**

An approach that may be implemented to facilitate hospitals, physicians’ offices, nursing homes, assisted living facilities, hospices, veterinarians, law enforcement, pharmacies and others in meeting the waste generation and disposal requirements for pharmaceuticals, and in deciding whether to commingle or segregate waste, is the development and dissemination of educational information. Information could be provided to regulated entities in the form of factsheets, posters, web pages and training sessions that explain what sorts of drugs are hazardous and non-hazardous, how they must be handled and disposed of, what authorizations and reporting are involved, and what implications there are when waste is commingled.

Training on the management and disposal of unused pharmaceuticals in health-care settings could be incorporated into the curriculum of required continuing education classes and undergraduate courses for nurses, physicians, pharmacists and home health and community support service providers.

Furthermore, the development of a complete list of pharmaceuticals that are listed or characteristically hazardous could be considered. Such a list may improve the ability for time-pressed staff to identify hazardous substances more rapidly, and therefore dispose of those in accordance with the TCEQ rules, reducing the chances that they are disposed of in the wastewater.

By meeting the current TCEQ waste rules, there would be limited cases where drain disposal of pharmaceuticals would be an option; in fact, the waste rules tend to lead entities in the direction of disposing of pharmaceutical waste in the solid waste stream. Therefore, alternative methods for health-care providers and other regulated entities could be focused on providing guidance to enable them to meet the current waste requirements, which should ultimately reduce the amount of pharmaceutical waste disposed of in the drain.
Alternative Methods of Disposal and Management of Unused Pharmaceuticals for Consumers

For the purposes of this report, the alternative approaches for consumers will be evaluated in terms of the impact that the management/processing/disposal methods have on public health and the environment, and the feasibility in meeting applicable regulations (that is, if they are legal) and being safe/secure, accessible, cost effective and successful in terms of collecting unused pharmaceuticals.

Below are some selected consumer pharmaceutical collection/disposal programs (“take-back” programs) that fall into the five categories above. The list is not exhaustive; there are certainly many other “take-back” programs operating that are not included in this section. Other consumer pharmaceutical collection/disposal programs may be found at The Drug Take-Back Network webpage.\(^\text{393}\) The TCEQ does not endorse any of the programs listed in this document or on the Drug Take-Back Network webpage. Much of the information provided below has been obtained from a few excellent sources. The TCEQ acknowledges the resource “Proper Disposal of Unwanted Medicines: A Resource for Action in Your Community” developed by Illinois-Indiana Sea Grant College Program which was a primary source of information below, unless otherwise noted. Additional original information is also provided, which was mainly obtained from direct communication with the take-back program event organizers.

None of the examples establish success measures prior to initiating, or during, their consumer unused pharmaceutical collection program so there is no quantitative way to rank the approaches. Additionally, some programs are generally promoted for environmental reasons and some are primarily concerned with minimizing potential public health/safety issues related to storing drugs in the household.

However, the TCEQ believes that the following aspects should be considered when rating each program for its potential adoption on a statewide basis in Texas: legality (the ease in meeting state and federal rules), accessibility, cost-effectiveness, efficacy (that is, their ability to obtain significant amounts of consumer’s unused pharmaceuticals), and safety/security. Stakeholders recognized the value in these properties through the Advisory Group meetings. In terms of these measures, the five main approaches discussed above vary considerably.

Infrequent Single Day Collection Events

Intermittent collection events for unused pharmaceuticals commonly consist of single day events with drive-through or drive-up daytime operation. For these events to accept controlled substances requires the presence of law enforcement

personnel since they must secure all controlled substances and witness/document their disposal in accordance with current laws. Immediate segregation into controlled/possibly controlled substances and other drugs is required. In order to avoid this complication, some collection events do not accept controlled substances. Various levels of sorting and inventorying are performed on collected pharmaceuticals at these events depending on staffing levels and ultimate disposal methods. Most examples of this type of event commingle all non-controlled, hazardous and non-hazardous pharmaceuticals for disposal at a permitted hazardous waste incinerator. This may increase the cost of disposal, but simplifies the handling and sorting requirements. Several states, cities and counties throughout the United States have organized single-day or annual collection events as described in the following sections. In Texas, the household exemption no longer applies when household waste is collected; collected household waste must be managed and disposed of according to the TCEQ’s rules as though it were generated by a commercial entity.

*Potential advantages* of one time or intermittent collection events may include:

- Removing unused drugs from households to reduce the potential for poisoning or diversion for illicit uses.
- Raising awareness in households about how much goes unused.
- Providing an alternative to flushing and drain disposal.
- Providing opportunities for partnerships.

Controlled substances can be accepted if law enforcement is on site to witness/inventory drug disposal. The decision to accept or refuse certain drugs/waste depends in part on the availability of trained staff to identify those while the customer waits.

*Potential disadvantages* of one time or intermittent single-day collection events may include:

- The costs and availability of funding.
- Advertising to inform consumers of dates, times, locations and other details.
- Arranging for permitted transport and disposal of collected pharmaceuticals.
- Training staff to identify and sort controlled from non-controlled and hazardous from non-hazardous if separate disposal is planned.
- Arranging law enforcement presence if controlled substances are to be accepted.
- Potential for drug diversion or theft activities.

In some instances it may not be feasible to separate hazardous from non-hazardous pharmaceuticals at a collection event. If there is no identification of the collected waste performed, or if the waste is identified and it is determined
that hazardous materials are included, but the waste streams are not segregated, then it should all be considered hazardous and managed as such. That may mean arranging for disposal at a facility permitted to accept hazardous waste which can be a costly disposal method.

While law enforcement presence is needed if controlled substances are to be collected, law enforcement are not required to participate in a drug collection event and it may be burdensome for some offices.

While single-day collection events are effective in raising awareness of the issues related to drugs being stored in households in the local areas where they operate, they may be limited in providing an accessible disposal option for a broader area. They are, however, accessible in their operation, usually providing participants with drive-through or walk-up options. They are commonly held at a location in the community such as a government building, school or health-care facility parking lot.

Currently, the only legal method to accept controlled substances at a single-day collection event is to have law enforcement officials take direct possession of the controlled substance from the ultimate user. Any single-day collection event in Texas must either hire law enforcement to accept controlled substances or have a mechanism to reject controlled substances.

In terms of their efficacy in collecting significant amounts of pharmaceuticals from ultimate users, infrequent single-day collection events can be successful. Many events have collected close to or over a thousand pounds of unused pharmaceuticals from consumers at one time.

The main disadvantage of single-day collection events can be the cost. In general, they require more advertising in order to gain interest, so the majority of the funds that are available may be spent for advertising purposes instead of disposal. Below are some examples of one-day pharmaceutical collection events designed to collect unused drugs from consumers. Emphasis on the intent of the event, success measures, advantages, conflicts and issues meeting regulatory requirements is identified where possible.

Note that some of these events are operated in conjunction with existing HHW programs (i.e. they take advantage of the HHW facility’s location or existing waste disposal hauler contract). There are several examples/case studies of infrequent single-day collection events in the United States in Appendix E.

**Permanent Collection Facilities - Drop Boxes/Kiosks at Pharmacies, Law Enforcement Offices and Other Locations**

A type of permanent collection facility is the drop box/kiosk. These have been placed at pharmacies, assisted living/independent living facilities, police stations/sheriff’s offices or other convenient locations. There are three kinds of drop box/kiosk settings or situations: (1) the drop box/kiosk is usually unattended but located inside a law enforcement office, (2) the drop box is located behind the counter or on top of the counter at a pharmacy (thereby
“attended”), and (3) the unattended drop box/kiosk. Most drop boxes can’t accept controlled substances unless there is law enforcement presence, therefore, controlled substances are usually only allowed to be accepted at drop boxes in law enforcement buildings. Commingling of hazardous and non-hazardous substances will commonly occur at these facilities since those involved (pharmacists, law enforcement etc.) would unlikely have the expertise to identify a listed or characteristically hazardous substance.

Potential advantages of drop box disposal include:

- Removing unused drugs from households to reduce the potential for poisoning or diversion for illicit uses.
- Raising awareness in households about how much goes unused.
- Providing an alternative to flushing and drain disposal.
- Convenience for the public.
- Providing an opportunity to bring new customers into a business where a drop box is located.

The decision to accept or refuse certain drugs depends in part on the availability of trained staff to identify those while the customer waits.

Potential disadvantages of this disposal method include:

- The cost of boxes and disposal services.
- Requiring regulatory authorizations.
- Training staff to identify and sort controlled from non-controlled and hazardous from non-hazardous pharmaceuticals (if separate disposal is planned).
- The inability to accept controlled substances if law enforcement is not on site.
- The limited amount of pharmaceutical waste that can be collected before the box is filled and requires replacement and disposal.
- Unattended boxes may be targeted for diversion for illicit uses and theft.

Stationary collection sites at law enforcement offices can be a safe and legal way for consumers to dispose of their unused pharmaceuticals. Pharmaceutical drop boxes/kiosks inside law enforcement buildings are accessible to most Texans because even rural towns will be near some type of law enforcement agency office. Examples of law enforcement office drop boxes in California suggest that this method of collecting unused pharmaceuticals can be effective in terms of the amount of drugs collected. If a law enforcement office wants to be involved in collecting consumer’s unused pharmaceuticals, including controlled substances, then this may present a safe and accessible option for consumers.
Pharmaceutical drop boxes on or behind pharmacy counters, with some level of oversight over what consumers may place in the box, can be a safe and accessible and can yield a significant amount of pharmaceutical waste.

Unattended drop boxes/kiosks are cost effective and accessible; however, they can present a risk in accepting controlled substances because there may be no screening of the drugs involved and therefore no way to determine if the drop boxes contain controlled substances. The drop/box kiosk examples below present a variety of scenarios; some are contained with law enforcement offices, some are unattended and some involve screening the substances that consumers want to dispose of by trained staff prior to them being placed in the box. Although some drop boxes/kiosks that are not contained within a law enforcement office advertise that no controlled substances may be disposed of in the container (utilizing signs, stickers and other types of labeling), controlled substances may be deposited. Several examples of permanent collection facilities is located in Appendix F.

**Permanent Collection Facilities - Household Hazardous Waste (HHW) Facilities**

Many municipalities in Texas and throughout the nation have permanent household hazardous waste (HHW) collection facilities. The regulatory requirements for these facilities are well defined for collection of household hazardous waste such as paint, oil, antifreeze and batteries. Some permanent municipal HHW events will accept unused pharmaceuticals. Commingled waste collected at a HHW facility must be disposed of as if it were hazardous; that is, at a facility that is permitted to accept hazardous waste.

*Potential advantages* of unused pharmaceutical collection at HHW facilities include:

- Removal of unused drugs from households to reduce the potential for poisoning or diversion for illicit uses.
- Raising awareness in households about how much goes unused.
- Providing an alternative to flushing and drain disposal.
- Disposal facility and transport arrangements are already established.

The decision to accept or refuse certain drugs/waste depends in part on the availability of trained staff to identify those.

*Potential disadvantages* of unused pharmaceutical collection at HHW facilities include:

- Required regulatory authorizations.
- Training staff to identify and sort accepted from not accepted pharmaceuticals.
- The inability to accept controlled substances unless law enforcement is on site.
• The potential for drug diversion or theft activities.
• HHW facilities are not accessible to all consumers.

Below is an example of a consumer pharmaceutical collection program that operates at an existing HHW facility and accepts pharmaceuticals when possible.

La Crosse County, Wisconsin

In La Crosse County, Wisconsin solid waste managers developed an innovative plan for disposing of households’ unneeded medicines, including controlled substances. Four staff members from the solid waste department were conditionally deputized by the county sheriff to receive controlled medicines strictly for the purpose of safe disposal of prescription medicines. The deputation was temporary and could be renewed. It specifically outlined the authority of the staff; they are not authorized to perform other law enforcement activities such as making arrests, and they are not eligible to be called up to serve as law enforcement in emergency situations in the same way as county sheriffs. The intention of this approach was to be able to accept controlled substances from consumers for the purposes of disposal, which would have been illegal under the CSA without DEA or law enforcement presence.

La Crosse County sought and obtained approval for the deputation from the state DEA in order to ensure compliance with the law. Since 2007, La Crosse County residents can drop off all of their unneeded household medicines for free at the county’s hazardous materials facility, including controlled substances. The program is also available with a small fee to residents of other counties and to businesses that qualify as VSQGs (very small quantity generators of hazardous waste). These may include nursing care facilities, public health departments and schools. The facility is open for drop-offs every Wednesday and every other Saturday and by appointment on Tuesdays and Thursdays.

Program participants bring their medicines to the facility where staff inventory the controlled substances and then supervise the residents dropping the medicine through a funnel into a 55-gallon drum of solvent. The drum contains naphtha and ipecac to deter diversion of the discarded drugs as well as water to dissolve the medicines. Program organizers state that within two days the drugs are completely dissolved, leaving a viscous brown residue. When the drums are full, they are transported using a La Crosse County vehicle and accompanied by two deputized staff to a hazardous waste incinerator near St. Louis, Missouri for disposal. Program organizers estimate that this will be necessary approximately once or twice per year.

Collection takes place at the county’s hazardous materials facility, which has served in the past as the drop-off point for other materials such as paints, pesticides and electronics. The program was started due to concerns about the environmental impacts of medicine waste as well as to protect against accidental poisoning and drug abuse. A disposal cost of $650 per drum of medicine waste is incurred, plus an additional cost of $1,800 to destroy them immediately upon receipt. Other costs included $2,000 to print 160,000 flyers publicizing the event. The total annual cost including staffing is estimated to be $12,000-
$15,000. Currently, these costs are being covered by the solid waste department's regular operating budget; they have not received additional operating funds for disposal or for salary to staff the operation. La Crosse County is raising $25,000 to cover startup costs including advertising, printing and additional security at the facility.

In May 2010, La Crosse County learned that its program for accepting all pharmaceuticals at its HHW facility may not be in alignment with federal Drug Enforcement Agency (DEA) interpretations. The law enforcement deputization process may be the issue. As a result, La Crosse County HHW still accepts non-controlled pharmaceuticals from its residents for disposal, however, it can no longer accept controlled substances.

Mail-Back

In this type of program, pre-paid mailing envelopes are offered in pharmacies, clinics, nursing homes and other accessible locations. Consumers take the mailers home, place unused drugs in an envelope and send them back to a predetermined location for sorting and disposal.

Potential advantages of unused pharmaceutical mail-back programs include:

- Removal of the drugs from households to reduce the potential for poisoning or diversion for illicit uses.
- Uniform access to the public.
- Provides an alternative to flushing and drain disposal.
- Adds the element of confidentiality and anonymity compared to in-person collection events.

Mail-back programs may be an option for people with limited access and for rural areas. Mail-back is considered by some to be an attractive option for the disposal of consumer's unused pharmaceuticals because virtually all citizens have access to the mail. This might be particularly important in Texas since collection events may not be practical in rural areas.

Potential disadvantages of this method include:

- The higher costs per pound of waste collected.
- The method is usually limited to disposal from households only.
- The need for a public education campaign so that controlled substances are not introduced.

The USPS federal mailing regulations and policies are in accordance with federal agency regulations and state laws. This provides consumers and state

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organizations secure mail back for disposal of unused pharmaceuticals. The USPS is the only DEA regulatory approved mail-back transport operation for all pharmaceuticals, including controlled substances, originating from residences to law enforcement to prevent illegal or unauthorized drug trafficking through the mail.

At this time the CSA prohibits possession of dispensed controlled substances by anyone other than the person/animal for whom it was prescribed. A concern with mail-back programs is that, although the transfer of controlled substances by means of USPS is legal, the receiving body (the incineration facility, for example) may be out of compliance with the CSA when they receive the mailed controlled substance. Limited controls can be placed on this type of program because it is the consumer that ultimately places the drugs in the envelope. Therefore, they could in fact put any item in the envelope, including a controlled substance, and no one would be aware of that until the envelope reaches the disposal facility. Several examples of mail-back programs are located in Appendix G.

**Render Undesirable and Dispose of in Municipal/Household Trash**

In general, the TCEQ found that about half of the disposal survey respondents usually discard their unused pharmaceuticals in the trash. A few respondents (less than one percent) noted that they mix their pharmaceuticals with an undesirable substance (cat litter or coffee grounds) before discarding in the trash, which is then picked up by a waste hauler who disposes of the waste in a MSW landfill. The FDA/ONDCP guidance of mixing unused/unwanted pharmaceuticals with an undesirable substance before tossing in the trash does not appear to be commonly adopted and, as such, should be considered as an alternative method of disposal.

Advantages of trash disposal after being rendered undesirable or unfit for human consumption include:

- Relative simplicity and convenience.
- Availability to almost all of Texas.
- Consistency with federal and other disposal guidelines.
- Residents already pay for municipal trash collection and disposal and unlike other methods it is not resource-driven.
- Authorizations or rule changes are not required.
- Mixing unused pharmaceuticals with cat litter, coffee grounds or other unpalatable substances, renders it undesirable to those who wish to sort through trash, thereby, addressing the safety and security issues posed by public safety advocates.

Current waste rules in Texas allow households to dispose of pharmaceutical waste with their routine trash as municipal solid waste without obtaining a
permit. Whether a household mixes unused pharmaceuticals with undesirable substances before disposal to make them undesirable or unfit for human consumption does not alter how household waste is regulated. Additionally, the DEA does not regulate end-users since they are not DEA registrants.

Disposing of unused pharmaceuticals in the household trash after rendering them undesirable has a number of advantages and very few disadvantages. The main caution that must be considered with this approach is that success will depend on an effective, consistent and multi-pronged educational campaign, which requires resources. The educational campaign and outreach efforts are required so that the community is aware of the negligible impacts of trash disposal. The educational campaign must convey a consistent message across the state otherwise confusion may continue among the community regarding the impact of disposal practices on the environment and public health. Some possible options that could be explored as part of a statewide educational campaign include:

- Developing a dedicated state-developed web page for information related to the impacts of drug disposal on the environment and how to render drugs unusable and dispose of them in the trash. Other state agencies, local governments, law enforcement and utility web pages could include a link to a pharmaceutical disposal web page.
- Developing posters for display in pharmacies and health-care provider waiting rooms.
- Developing brochures and postcards for distribution at various events within pharmacies. These could also be provided to in-home care providers so that they can be passed on to their clients.
- Establishing an annual Texas Safe Drug Disposal Day to raise awareness about the drugs stored in households, purchasing practices (perhaps a “buy what you need now” campaign) and to encourage disposal in the household trash after rendering undesirable, as opposed to flushing and drain disposal.

White House Office of National Drug Control Policy (ONDCP) Guidance

The ONDCP’s factsheet provides the following guidance to consumers for disposing of their unused prescription drugs in the trash after rendering them undesirable.395

1. Take 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.

The White House ONDCP guidance discourages flushing drugs down the drain except for those items on the FDA’s flush list.


The previous section provided examples of how health-care providers, consumers, and others could prevent the generation of unused pharmaceuticals and how they could alternatively manage or dispose of unused pharmaceuticals to reduce the pharmaceuticals from entering a wastewater system. Additionally, alternative approaches were provided from the regulatory angle that may be considered in attempting to reduce pharmaceuticals entering wastewater.

While there are no chemical methodologies established yet to determine what proportion of pharmaceuticals enter the wastewater due to excretion as opposed to disposal, available research suggests that the majority (80-90%) of pharmaceuticals in wastewater is a result of excretion and significantly less (10-20%) is a result of intentional disposal into the wastewater. Consequently, many of the alternative methods of management and disposal described above can only impact a small source of pharmaceuticals in the environment. Additionally, since pharmaceuticals at the low concentrations found in drinking water show no adverse human health impacts at this time, and limited information exists on the impact of pharmaceuticals on aquatic life in non-experimental settings, and the EPA has not established maximum contaminant levels for pharmaceutical compounds in drinking water or ambient waters, we do not know to what extent we need to reduce inputs of API into the wastewater. Therefore, at this time, the impact of changing how health-care providers, consumers and others manage and dispose of unused pharmaceuticals may be minimal.

Consumer take-back programs will, with good participation rates, achieve the same benefits as a well publicized municipal trash (after rendering drugs undesirable) disposal program. Pursuing an educational information approach may be integral to health-care providers/law enforcement/pharmacies as well as the consumer in order to dispose of unused pharmaceuticals properly. Education of staff may indirectly reduce the amount of pharmaceuticals being disposed of in the drain because they will become aware of other options. Education of consumers may not only reduce the amount of pharmaceuticals disposed of in the drain but may also lead to a reduced potential for accidental poisonings and diversion from the storing of unwanted medications, and may also lead to lower-health care costs in general.
Analysis and Recommendations for Disposal Methods

Pharmaceuticals have been found at very low concentrations in a number of environmental media, most notably in surface waters, some of which are a source for public drinking water. Current research suggests that low concentrations of pharmaceuticals in drinking water present no appreciable risk to humans. Some experimental studies have shown that pharmaceuticals in water, even at micrograms per liter concentrations, may impact aquatic life. Real-world data are required to support those research efforts since current models suggest that concentrations of pharmaceuticals in real environmental settings in the United States are too low to result in the impacts seen in experimental settings.

Current information suggests that compared to excretion, the disposal of unused pharmaceuticals is a minor source of pharmaceuticals found in the environment. Accordingly, efforts to alter disposal habits will not completely prevent pharmaceuticals from being released into wastewater. Most current methods of disposal, such as the use of landfills or incineration, release only a negligible amount of pharmaceuticals into the environment. At present, given that there are no current means of reducing the excretion of pharmaceuticals, reducing the intentional disposal of pharmaceuticals into the wastewater system presents a practicable means of preventing at least a small percentage of pharmaceuticals from ending up in the environment. As pharmaceutical use continues to increase, reducing the generation of unused pharmaceuticals and determining how best to manage and dispose of them may become increasingly important.

The TCEQ has, based on information provided by the Advisory group, literature reviews, and the stakeholder surveys, identified a number of methods for the management and disposal of unused pharmaceuticals. The following proposed methods could be feasibly implemented on a statewide basis in Texas. The TCEQ recommends these as effective and efficient methods to (1) reduce the amount of pharmaceuticals that enter a wastewater system and (2) raise awareness of how to properly dispose of unused pharmaceuticals. Additionally, these recommendations incorporate the concepts of accessibility, legality and cost-effectiveness. The effort for implementation of the recommendations can be scaled depending on the availability of financial resources.

Recommendations for and Feasibility of Disposal Methods

For Consumers

1. Promote municipal trash disposal as the best method for consumers to dispose of their unused pharmaceuticals and develop a strong public education program for consumers: The most effective and feasible approach that the State of Texas could adopt for managing unused pharmaceutical disposal in households in Texas is to combine:
a. Promoting the disposal of consumers’ unused pharmaceuticals into the municipal trash after rendering the drugs undesirable (consistent with the White House Office of National Drug Control Policy guidance), with

b. An educational program designed to provide accurate information to the community about drug disposal, storing drugs in the household, the sources of pharmaceuticals detected in the environment, and the impact of pharmaceuticals in water on human health and aquatic life.

Developing an education program to encourage disposal of unused pharmaceuticals in household trash is both feasible and cost-effective. Disposal of pharmaceuticals by consumers in household trash is consistent with existing federal and state regulations and does not require the consumer to obtain special authorization. Development of any education program would depend on the availability of funding, but costs could be minimized through electronic web site distribution of information and through targeted communications with pharmacies. To reach a greater number of consumers, the state could consider press releases and public service announcements on radio and television broadcasts, all of which are reasonably cost-effective.

Additional educational outreach could include:

- **Development of educational materials for consumers**: Develop clear and consistent message for consumers through a variety of avenues. Develop a series of guidance documents, factsheets, posters and other educational materials.

- **Development of a web page for information dissemination**: This could include all the educational information concerning the impact of pharmaceuticals in drinking water on human health and the environment, the impact of pharmaceuticals in waterways of aquatic life, the impact of landfill disposal on pharmaceutical releases in the environment, and the impact of intentional disposal of pharmaceuticals in the environment, relative to excretion. This web page could be updated periodically as new information becomes available.

2. **Encourage the voluntary use of take-back programs**. The TCEQ recognizes consumer drug take-back programs provide an opportunity for education and outreach to the public on the proper disposal of unused pharmaceuticals. However, the survey information suggests that more residents of Texas may not dispose of the unused drugs while waiting for an event to be established in their area, leading to an accumulation of drugs in many Texas households. Additionally, in terms of safety, security, accessibility, complying with waste disposal rules and legal requirements, and volumes of drugs returned, the TCEQ considers that the most appropriate programs for collecting and disposing of consumer’s unused drugs, are:

   a. Infrequent single-day collection events;

   b. Permanent drop boxes/kiosk inside law enforcement offices; or

   c. Permanent attended drop boxes/kiosk in pharmacies.
The State should not require take-back programs nor prohibit these voluntary activities. Because there is a high degree of public interest in take-back programs, groups interested in conducting take-back events should be allowed to proceed at their own expense, provided they follow applicable federal and state regulations. Because these take-back programs will be self-funded, this approach is more feasible and cost-effective than mandatory take-back programs. Voluntary programs would not impose costs on people or entities that are unwilling or cannot fund such programs.

**For Health-Care Providers and Others**

Determining the feasibility of specific methods for health-care providers to dispose of unused pharmaceuticals is difficult because it varies greatly, based on the facility type, size, resource limitations, as well as the multiple regulatory provisions that apply to the handling and disposal of pharmaceuticals by health-care providers and health-care facilities. The State could encourage the development of educational materials or information sharing programs that would help health-care and other facilities to reduce the amounts of pharmaceuticals that go unused and better address disposal issues related to their unused pharmaceuticals. One approach could be to encourage health-care facilities to review and consider implementing EPA’s *Best Management Practices for Unused Pharmaceuticals at Health Care Facilities* in order to reduce the amount of pharmaceuticals that go unused.

**Conclusion**

Currently, there are no chemical methodologies established to determine what proportion of pharmaceuticals enter the wastewater due to excretion as opposed to intentional disposal. Available research suggests that the majority of pharmaceuticals detected in wastewater is a result of excretion and significantly less is a result of intentional drain disposal into the wastewater system. Consequently, the alternative methods of management and disposal recommended can only impact a small source of pharmaceuticals in the environment. Additionally, since pharmaceuticals at the low concentrations found in drinking water show no adverse human health impacts at this time, and limited information exists on the impact of pharmaceuticals on aquatic life in non-experimental settings, the EPA has not established maximum contaminant levels for pharmaceutical compounds in drinking water or water quality standards for ambient waters. Therefore, at this time, the impact of changing how health-care providers, consumers and others manage and dispose of unused pharmaceuticals will not prevent pharmaceuticals from being released into wastewater. However, minimizing the amount of pharmaceuticals intentionally disposed of into a wastewater system presents an opportunity to reduce and manage a known source of pharmaceuticals being disposed of in the environment.
A statewide education effort could be initiated to begin disseminating accurate information to health-care providers, consumers and others on the topic of unused pharmaceuticals and their proper disposal. The education effort can vary in cost depending on available resources and the desired level of effort.
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Appendices

Appendix A: List of Pharmaceutical Disposal Advisory Group Stakeholders

* denotes TCEQ Pharmaceutical TCEQ member

Table A: Pharmaceutical Disposal Advisory Group Stakeholders/Interested Parties

<table>
<thead>
<tr>
<th>Individual</th>
<th>Stakeholder Group/Association Name</th>
<th>Stakeholder Type</th>
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<tr>
<td>Adam Shapiro</td>
<td>Genentech</td>
<td>Pharmaceutical Manufacturer</td>
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<tr>
<td>Amanda Engledow</td>
<td>Texas Water Resources Institute</td>
<td>Educational Institution</td>
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<tr>
<td>Amber Briggs</td>
<td>Cibolo Creek Municipal Authority</td>
<td>Local Government/Water Utility</td>
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<td>Amber Pearce</td>
<td>Pfizer, Inc.</td>
<td>Pharmaceutical Manufacturer</td>
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<tr>
<td>Andrea McNair</td>
<td>University of Texas System</td>
<td>Educational Institution</td>
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<tr>
<td>Angela Curry*</td>
<td>TCEQ - Toxicology</td>
<td>State Government</td>
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<tr>
<td>Ann Ardis</td>
<td>United States Geological Survey</td>
<td>Federal Government</td>
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<tr>
<td>Anthony E. Bennett</td>
<td>Association of Water Board Directors/AECOM</td>
<td>Represents Water Utilities</td>
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<td>Audra Morse</td>
<td>Texas Tech University, Civil and Environmental Engineering Department</td>
<td>Educational Institution</td>
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<td>Ben Weinheimer</td>
<td>Texas Cattle Feeders Association</td>
<td>Ranchers and Farmers</td>
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<td>Beth Skelton</td>
<td>Department of Aging and Disability Services</td>
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<tr>
<td>Bethany Ansell</td>
<td>TCEQ Clean Rivers Unit</td>
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<tr>
<td>Bill Harrison</td>
<td>TCEQ - Surface Water Quality Monitoring</td>
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<td>Bill Hynan</td>
<td>Independent Cattlemen's Association of Texas</td>
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<td>Ford Bend County Household Hazardous Waste Program</td>
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<td>Bill Turpin</td>
<td>WM Healthcare Solutions</td>
<td>Waste Processing and Handling</td>
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<td>Bob Turner</td>
<td>Texas Poultry Federation</td>
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<td>Brad Castleberry</td>
<td>Water Environment Assn of Texas/Texas Assn of Clean Water Agencies</td>
<td>Water Utility</td>
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<td>Brian N Miller</td>
<td>M. D. Anderson Cancer Center – Pharmacy Operations</td>
<td>Health Care Provider/Pharmacy</td>
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<td>Butch Habeger</td>
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<td>Candie Phipps</td>
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<td>City of Arlington</td>
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<td>Charles Stringer</td>
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<td>Charlotte Smith</td>
<td>PharmEcology (part of WM Healthcare Solutions)</td>
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<td>Cheri Huddleston</td>
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<td>Cheryl Burton-Fentress</td>
<td>Harris County Watershed Protection</td>
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<tr>
<td>Iris Coleman</td>
<td>Carl R. Darnall Army Medical Center (CRDAMC) - Fort Hood</td>
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<tr>
<td>Kristina Mena</td>
<td>University of Texas Health Science Center at Houston School of Public Health</td>
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<td>Kyle Janek</td>
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Appendix B: Pharmaceutical Disposal Advisory Group Meeting Attendees (January – June 2010 Meetings)

Table B-1: Pharmaceutical Disposal Advisory Group Meeting Attendees (January – June 2010 Meetings)

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<tr>
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<th>Association</th>
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<tr>
<td>Amber Briggs</td>
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<tr>
<td>Angela Curry</td>
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<td>Candilyn McLean</td>
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<td>Carol La Breche</td>
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<td>San Antonio Water System - Legislative Affairs</td>
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<tr>
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<tr>
<td>Elston Johnson</td>
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<tr>
<td>Eric Beller</td>
<td>TCEQ - Municipal Solid Waste Permits</td>
</tr>
<tr>
<td>Ernest Gene Cappadonna</td>
<td>University of Texas Medical Branch - Correctional Managed Care</td>
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<tr>
<td>Gail Harmon</td>
<td>Texas Assisted Living Association</td>
</tr>
<tr>
<td>Gay Dodson</td>
<td>Texas State Board of Pharmacy</td>
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<td>Houston-Galveston Area Council</td>
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<td>George Maxey</td>
<td>University of North Texas</td>
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<td>Jack Ranney</td>
<td>Lower Colorado River Authority</td>
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<td>Jaime Rios</td>
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<tr>
<td>Joe Gildersleeve</td>
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<tr>
<td>John Carlo</td>
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<td>John Cowan</td>
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<td>Karen Tannert</td>
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</tr>
<tr>
<td>Kathy Barber</td>
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<td>Individual</td>
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<tr>
<td>Kelly Freeman</td>
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<tr>
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<tr>
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<tr>
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<td>Department of Public Safety of the State of Texas - Crime Lab</td>
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<td>Rajendra Bhattarai</td>
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<tr>
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<td>Randy Palachek</td>
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<tr>
<td>Richard McHale</td>
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<td>Cibolo Creek Municipal Authority</td>
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<td>Rodney Bias</td>
<td>Inmar–Reverse Logistics</td>
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<tr>
<td>Ronald Stried</td>
<td>Texas Veterinary Medical Association</td>
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<tr>
<td>Rose Dunaway</td>
<td>Texas Association for Home Care &amp; Hospice</td>
</tr>
<tr>
<td>Scheleen Walker</td>
<td>Representative Donna Howard's Office</td>
</tr>
<tr>
<td>Shannon Herriott</td>
<td>TCEQ - Pollution Prevention</td>
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<tr>
<td>Sharnett Latimore</td>
<td>U.S. Dept of Justice, Drug Enforcement Administration, Houston Field Division</td>
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<td>Susan Nold</td>
<td>Senator Kirk Watson's Office</td>
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<tr>
<td>Thomas Harrigan</td>
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<tr>
<td>Todd Chenoweth</td>
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</tr>
<tr>
<td>Tracy Herring</td>
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</tr>
<tr>
<td>Victoria Hodge</td>
<td>City of Denton - Household Hazardous Waste</td>
</tr>
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<td>Merial Ltd.</td>
</tr>
<tr>
<td>William Anderson</td>
<td>Curbside Inc.</td>
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Table B-2: Pharmaceutical Disposal Advisory Group Meeting
January 26th 2010 - Attendees via LiveMeeting/Conference Call

<table>
<thead>
<tr>
<th>Individual</th>
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<tbody>
<tr>
<td>Amanda Engledow</td>
<td>Texas Water Resources Institute</td>
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<tr>
<td>Brian N Miller</td>
<td>M. D. Anderson Cancer Center – Pharmacy Operations</td>
</tr>
<tr>
<td>Butch Habeger</td>
<td>Texas Society of Health-System Pharmacists</td>
</tr>
<tr>
<td>David Hunter</td>
<td>City of Denton - Watershed Protection</td>
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<tr>
<td>Diane Rhodes</td>
<td>Texas Dental Association</td>
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<tr>
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</tr>
<tr>
<td>Kati Stoddard</td>
<td>PhD candidate at University of North Texas</td>
</tr>
<tr>
<td>Kevin Wagner</td>
<td>Texas Water Resources Institute</td>
</tr>
<tr>
<td>Latrice Babin</td>
<td>Harris County Public Health and Environmental Services</td>
</tr>
<tr>
<td>Lesley Wood</td>
<td>Pharmaceutical Research and Manufacturers of America (PhRMA)</td>
</tr>
<tr>
<td>Mario Munoz</td>
<td>Eli Lilly USA, LLC</td>
</tr>
<tr>
<td>Patty Ducayet</td>
<td>Department of Aging and Disability Services (DADS)</td>
</tr>
<tr>
<td>Rebecca Waldrop</td>
<td>sanofi-aventis U.S.</td>
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<tr>
<td>Richard Ponder</td>
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<tr>
<td>Robert Nash</td>
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</tr>
<tr>
<td>Sandra Ellis-Barba</td>
<td>North Central Texas Council of Governments</td>
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</tr>
<tr>
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<td>Steve Hupp</td>
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<td>Victoria Ford</td>
<td>K &amp; L Gates</td>
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<tr>
<td>Wesley Duncan</td>
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<td>Yvonne Forrest</td>
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### Table B-3: Pharmaceutical Disposal Advisory Group Meeting

**February 26th 2010 - Attendees in Person**

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<tr>
<td>Angela Curry</td>
<td>TCEQ - Toxicology</td>
</tr>
<tr>
<td>Anthony E. Bennett</td>
<td>AECOM (representing Association of Water Board Directors)</td>
</tr>
<tr>
<td>Ben Weinheimer</td>
<td>Texas Cattle Feeders Association</td>
</tr>
<tr>
<td>Bill Petty</td>
<td>Ford Bend County Household Hazardous Waste Program</td>
</tr>
<tr>
<td>Carol Batterton</td>
<td>Water Environment Assn of Texas/Texas Ass of Clean Water Agencies</td>
</tr>
<tr>
<td>Charlotte Smith</td>
<td>PharmEcology (part of WM Healthcare Solutions)</td>
</tr>
<tr>
<td>Cheri Huddleston</td>
<td>Texas Pharmacy Business Council &amp; Texas Pharmacy Association</td>
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<td>Academy of Compounding Pharmacists</td>
</tr>
<tr>
<td>Clyde Bohmfalk</td>
<td>TCEQ - Water Quality Standards</td>
</tr>
<tr>
<td>Daniel Ingersoll</td>
<td>TCEQ - Environmental Law</td>
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<td>Donald Hardee</td>
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<td>Gilbert Estrada</td>
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<tr>
<td>Irina Cech</td>
<td>The University of Texas School of Public Health</td>
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<td>Karen Tannert</td>
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<td>Texas Federation of Drug Stores</td>
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<td>San Antonio Water System</td>
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<td>Ken Horton</td>
<td>Texas Pork Producers</td>
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<tr>
<td>Matt Wall</td>
<td>Texas Hospitals Association</td>
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<tr>
<td>Mike Smolensky</td>
<td>University of Texas at Austin</td>
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<td><strong>Association</strong></td>
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<tr>
<td>Naila Ahmed</td>
<td>Lower Colorado River Authority</td>
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<tr>
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<tr>
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<td>TCEQ - Pollution Prevention</td>
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<tr>
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<tr>
<td>William Anderson</td>
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Table B-4: Pharmaceutical Disposal Advisory Group Meeting

February 26th 2010 - Attendees via LiveMeeting/Conference Call

<table>
<thead>
<tr>
<th>Individual</th>
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<tbody>
<tr>
<td>Brian N Miller</td>
<td>M. D. Anderson Cancer Center – Pharmacy Operations</td>
</tr>
<tr>
<td>Brittani Bilse</td>
<td>House Public Health Committee</td>
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<tr>
<td>Candelyn McLean</td>
<td>Brazos Valley Council of Governments</td>
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<tr>
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<td>Texas Dental Association</td>
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Table B-5: Pharmaceutical Disposal Advisory Group Meeting
March 24th 2010 - Attendees in Person

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<td>University of Texas System</td>
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<tr>
<td>Anthony E. Bennett</td>
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<tr>
<td>Beth Skelton</td>
<td>Department of Aging and Disability Services</td>
</tr>
<tr>
<td>Bill Harrison</td>
<td>TCEQ - Surface Water Quality Monitoring</td>
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<tr>
<td>Bill Petty</td>
<td>Ford Bend County Household Hazardous Waste Program</td>
</tr>
<tr>
<td>Carol Batterton</td>
<td>Water Environment Assn of Texas/Texas Assn of Clean Water Agencies</td>
</tr>
<tr>
<td>Cheri Huddleston</td>
<td>Texas Pharmacy Association Academy of Compounding Pharmacists &amp;</td>
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<tr>
<td>Chris Geisler</td>
<td>Waste Management Healthcare Solutions</td>
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<tr>
<td>Clyde Bohmfalk</td>
<td>TCEQ - Water Quality Standards</td>
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<td>Daniel Ingersoll</td>
<td>TCEQ - Environmental Law</td>
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<td>Elston Johnson</td>
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<td>Eric Beller</td>
<td>TCEQ - Municipal Solid Waste Permits</td>
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<td>HillCo Partners</td>
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<td>Holly Jacques Turner</td>
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<tr>
<td>Iris Coleman</td>
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<td>Jack Ranney</td>
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<tr>
<td>Jeff Bowman</td>
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<td>National Association of Chain Drug Stores</td>
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<td>Rose Dunaway</td>
<td>Texas Association for Home Care &amp; Hospice</td>
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<tr>
<td>Selin Hoboy</td>
<td>Stericycle, Inc.</td>
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<tr>
<td>Shannon Herriott</td>
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<td>TCEQ - Water Quality Permits</td>
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<tr>
<td>Vincent R. Nathan</td>
<td>Texas A&amp;M Health Science Center</td>
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<tr>
<td>Individual</td>
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<tr>
<td>Ben Weinheimer</td>
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<td>M. D. Anderson Cancer Center – Pharmacy Operations</td>
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<td>James Tompkins</td>
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<td>Kathy Hutto</td>
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<tr>
<td>Kyle Janek</td>
<td>Eisai Pharmaceuticals</td>
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<td>Meg Propes</td>
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<td>Richard McHale</td>
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<td>M. D. Anderson Cancer Center</td>
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<td>Timothy Oden</td>
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<tr>
<td>Wesley Duncan</td>
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</tr>
<tr>
<td>Yvonne Forrest</td>
<td>City of Houston – Drinking Water Operations</td>
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## Table B-7: Pharmaceutical Disposal Advisory Group Meeting

April 22nd 2010 - Attendees in Person

<table>
<thead>
<tr>
<th>Individual</th>
<th>Association</th>
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<tbody>
<tr>
<td>Adam Shapiro</td>
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<tr>
<td>Amber Pearce</td>
<td>Texas Healthcare Bioscience Institute</td>
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<tr>
<td>Andrea McNair</td>
<td>University of Texas System</td>
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<tr>
<td>Angela Curry</td>
<td>TCEQ - Toxicology</td>
</tr>
<tr>
<td>Ann Ardis</td>
<td>United States Geological Survey</td>
</tr>
<tr>
<td>Anthony E. Bennett</td>
<td>AECOM (representing Association of Water Board Directors)</td>
</tr>
<tr>
<td>Beth Skelton</td>
<td>Department of Aging and Disability Services</td>
</tr>
<tr>
<td>Bethany Ansell</td>
<td>TCEQ Clean Rivers Unit</td>
</tr>
<tr>
<td>Bill Harrison</td>
<td>TCEQ - Surface Water Quality Monitoring</td>
</tr>
<tr>
<td>Bill Petty</td>
<td>Ford Bend County Household Hazardous Waste Program</td>
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<tr>
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<td>Sharps Compliance Inc.</td>
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<tr>
<td>Charlotte Smith</td>
<td>PharmEcolgy (part of WM Healthcare Solutions)</td>
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<tr>
<td>Cheri Huddleston</td>
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<tr>
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<td>Waste Management Healthcare Solutions</td>
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<tr>
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<td>Claude A. Dance</td>
<td>Sharps Compliance Inc.</td>
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<tr>
<td>Clyde Bohmfalk</td>
<td>TCEQ - Water Quality Standards</td>
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<tr>
<td>Daniel Ingersoll</td>
<td>TCEQ - Environmental Law</td>
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<tr>
<td>Donovan Burton</td>
<td>San Antonio Water System</td>
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<tr>
<td>Elizabeth Choate</td>
<td>Texas Veterinary Medical Association</td>
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<tr>
<td>Elston Johnson</td>
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<tr>
<td>Eric Beller</td>
<td>TCEQ - Municipal Solid Waste Permits</td>
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<td>Gary Barrett</td>
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<td>James C. Grimm</td>
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<td>Jeff Gloyd</td>
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<tr>
<td>Jessica Huybregts</td>
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<td>Joel Budge</td>
<td>Texas Department of Public Safety</td>
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<tr>
<td>Jon Johnson</td>
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<tr>
<td>Kathy Barber</td>
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<tr>
<td>Loraine Fries</td>
<td>Texas Parks and Wildlife Department</td>
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<tr>
<td>Mario Munoz</td>
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<td>Marsha Jones</td>
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<tr>
<td>Matthew Mireles</td>
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<tr>
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<td>Thomas Harrigan</td>
<td>TCEQ - Water Quality Permits</td>
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<td>Timothy Oden</td>
<td>United States Geological Survey</td>
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<tr>
<td>Tom Kowalski</td>
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<td>K &amp; L Gates</td>
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<tr>
<td>William Anderson</td>
<td>Curbside Inc.</td>
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### Table B-8: Pharmaceutical Disposal Advisory Group Meeting

**April 22nd 2010 - Attendees via LiveMeeting/Conference Call**

<table>
<thead>
<tr>
<th>Individual</th>
<th>Association</th>
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<tbody>
<tr>
<td>Butch Habeger</td>
<td>Texas Society of Health-System Pharmacists</td>
</tr>
<tr>
<td>Carol Batterton</td>
<td>Water Environment Assn of Texas/Texas Assn of Clean Water Agencies</td>
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<tr>
<td>Chad McGowan</td>
<td>City of Arlington</td>
</tr>
<tr>
<td>Chelsea Phillips</td>
<td>Texas Municipal League</td>
</tr>
<tr>
<td>DeAnne Meeh</td>
<td>University of Texas Medical Branch</td>
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<tr>
<td>Derek Mosbarger</td>
<td>Clean Harbors</td>
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<td>Gena McKinley</td>
<td>Houston-Galveston Area Council</td>
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<td>Holly Jacques Turner</td>
<td>Merck &amp; Co., Inc.</td>
</tr>
<tr>
<td>Iris Coleman</td>
<td>Carl R. Darnall Army Medical Center (CRDAMC) - Fort Hood</td>
</tr>
<tr>
<td>Jan Harris</td>
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</tr>
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<td>Jeanie Jaramillo</td>
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<td>Jeff Hollar</td>
<td>PharmWaste Technologies, Inc.</td>
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<td>Jeff Jacoby</td>
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<td>Texas Medical Association</td>
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<td>Latrice Babin</td>
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<td>Mike Howe</td>
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<td>Naila Ahmed</td>
<td>Lower Colorado River Authority</td>
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Table B-9: Pharmaceutical Disposal Advisory Group Meeting
May 27th 2010 - Attendees in Person

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<td>Texas Veterinary Medical Association</td>
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<td>Lower Colorado River Authority</td>
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<td>Julie McEntire</td>
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<td>Lori Woznicki</td>
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<td>Marissa Machado</td>
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<tr>
<td>Yvonne Barton</td>
<td>Abbott Laboratories, Inc.</td>
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Table B-10: Pharmaceutical Disposal Advisory Group Meeting
May 27th 2010 - Attendees via LiveMeeting/Conference Call

<table>
<thead>
<tr>
<th>Individual</th>
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<tbody>
<tr>
<td>Andrea McNair</td>
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<td>Brian N Miller</td>
<td>M. D. Anderson Cancer Center – Pharmacy Operations</td>
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<tr>
<td>Candilyn McLean</td>
<td>Brazos Valley Council of Governments</td>
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<tr>
<td>Cory Handy</td>
<td>Department of State Health Services</td>
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<td>Gena McKinley</td>
<td>Houston-Galveston Area Council</td>
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<td>Holly Jacobs Turner</td>
<td>Merck &amp; Co., Inc.</td>
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<tr>
<td>Iris Coleman</td>
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<td>Texas Panhandle Poison Center</td>
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<td>Tom Clark</td>
<td>Department of State Health Services - Pharmacy Branch</td>
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<td>City of Houston – Drinking Water Operations</td>
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### Table B-11: Pharmaceutical Disposal Advisory Group Meeting

**June 24th 2010 - Attendees in Person**

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<tr>
<td>Angela Curry</td>
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<td>Ann Ardis</td>
<td>United States Geological Survey</td>
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<tr>
<td>Anthony E. Bennett</td>
<td>AECOM (representing Association of Water Board Directors)</td>
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<td>Beth Skelton</td>
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<td>Bill Turpin</td>
<td>WM Healthcare Solutions</td>
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<tr>
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<td>Stericycle Inc.</td>
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<tr>
<td>Don Bowman</td>
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<td>Donald Hardee</td>
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<td>Doug Finan</td>
<td>GlaxoSmithKline</td>
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<tr>
<td>Ed Gruber</td>
<td>Texas Health Care Association</td>
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<tr>
<td>Emily Bickle</td>
<td>University of Texas - School of Nursing</td>
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<tr>
<td>Eric Beller</td>
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<tr>
<td>Frank Jackson</td>
<td>Bristol-Myers Squibb</td>
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<td>Gene Cappadonna</td>
<td>University of Texas Medical Branch - Correctional Managed Care</td>
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<tr>
<td>Gilbert Estrada</td>
<td>Department of Aging and Disability Services</td>
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<tr>
<td>Isaac Jackson</td>
<td>TCEQ Intergovernmental Relations</td>
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<td>Jack Ranney</td>
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<td>Jeff Horvath</td>
<td>TCEQ - Strategic Planning</td>
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<tr>
<td>Jennifer Markley</td>
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<tr>
<td>Jessica Huybregts</td>
<td>TCEQ - Public Drinking Water</td>
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<td>Joel Budge</td>
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<td>Jon Johnson</td>
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<td>Julie McEntire</td>
<td>TCEQ - Water Quality Planning</td>
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<td>Karen Reagan</td>
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<td>Kim Roberson</td>
<td>Texas Pharmacy Association</td>
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<td>Krista Crockett</td>
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<td>Kyle Janek</td>
<td>Eisai Pharmaceuticals</td>
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<tr>
<td>Lilly Mata</td>
<td>TCEQ - Clean Rivers Program</td>
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<td>Loraine Fries</td>
<td>Texas Parks and Wildlife Department</td>
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<tr>
<td>Lori Woznicki</td>
<td>Department of State Health Services</td>
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<td>Individual</td>
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<td>Marla Mathews</td>
<td>ROSS Communications</td>
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<td>Marsha Jones</td>
<td>Hillco Partners</td>
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<td>Mary Staples</td>
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<td>Matt Wall</td>
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<td>MayeBeth Hadfield</td>
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<td>Michelle Bacon</td>
<td>TCEQ - Environmental Law</td>
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<td>Peggy Brand</td>
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<tr>
<td>Pete Martinez</td>
<td>Pharmaceutical Research and Manufacturers of America (PhRMA)</td>
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<tr>
<td>Rajendra Bhattarai</td>
<td>City of Austin – Austin Water Utility</td>
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<tr>
<td>Randy Erben</td>
<td>Genentech</td>
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<tr>
<td>Selin Hoboy</td>
<td>Stericycle, Inc.</td>
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<tr>
<td>Shannon Herriott</td>
<td>TCEQ - Pollution Prevention</td>
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<tr>
<td>Susan Nold</td>
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<tr>
<td>Thomas Harrigan</td>
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<td>Tom Kowalski</td>
<td>Texas Healthcare Bioscience Institute</td>
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<tr>
<td>Trish O'Day</td>
<td>University of Texas - School of Nursing</td>
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<tr>
<td>Victoria Ford</td>
<td>K &amp; L Gates</td>
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<tr>
<td>Victoria Hodge</td>
<td>City of Denton - Household Hazardous Waste Section</td>
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### Table B-12: Pharmaceutical Disposal Advisory Group Meeting

**June 24th 2010 - Attendees via LiveMeeting/Conference Call**

<table>
<thead>
<tr>
<th>Individual</th>
<th>Association</th>
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<tbody>
<tr>
<td>Andrea McNair</td>
<td>University of Texas System</td>
</tr>
<tr>
<td>Bill Petty</td>
<td>Ford Bend County Household Hazardous Waste Program</td>
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<tr>
<td>Brian N Miller</td>
<td>M. D. Anderson Cancer Center – Pharmacy Operations</td>
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<tr>
<td>Bruce Lott</td>
<td>Mylan</td>
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<tr>
<td>Iris Coleman</td>
<td>Carl R. Darnall Army Medical Center (CRDAMC) - Fort Hood</td>
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<tr>
<td>Jan Harris</td>
<td>Sharps Compliance, Inc.</td>
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<tr>
<td>Jeff Hollar</td>
<td>PharmWaste Technologies, Inc.</td>
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<td>Jeff Jacoby</td>
<td>Texas Campaign for the Environment</td>
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<td>John Murphy</td>
<td>Biotechnology Industry Organization</td>
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<tr>
<td>Katie Fleming</td>
<td>Texas Municipal League</td>
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<tr>
<td>Leslie Wood</td>
<td>Pharmaceutical Research and Manufacturers of America (PhRMA)</td>
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<tr>
<td>Lucia Carter</td>
<td>Carl R. Darnall Army Medical Center (CRDAMC) - Fort Hood</td>
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<tr>
<td>Major Rebecca Zinnante</td>
<td>Carl R. Darnall Army Medical Center (CRDAMC) - Fort Hood</td>
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<td>Margaret Mendez</td>
<td>Texas Medical Association</td>
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<td>Naila Ahmed</td>
<td>Lower Colorado River Authority</td>
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<td>Shari Anderson</td>
<td>Greenberg Traurig LLP</td>
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<tr>
<td>Steve Lowe</td>
<td>Texas Association of Healthcare Facilities Management</td>
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<tr>
<td>Susan Spivey</td>
<td>M. D. Anderson Cancer Center</td>
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<td>Vincent R. Nathan</td>
<td>Texas A&amp;M Health Science Center</td>
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Appendix C: Unused Pharmaceutical Disposal Surveys

Surveys were developed to the TCEQ understand how unused pharmaceuticals are disposed of by various groups in Texas. The separate survey groups are listed below.

Group 1: Health-Care Providers - Patient Floor (Hospitals, Clinics, Dentists)
Group 2: Veterinary Providers
Group 3: Pharmacies (including retail and clinical)
Group 4: Waste Disposal/Management Service Providers
Group 5: Pharmaceutical Manufacturers
Group 6: Ranchers/Farmers
Group 7: Consumers (all households in Texas)
Group 8: Home Health and Hospice Providers (In-home and In-patient setting)
Group 9: Drinking Water and Wastewater Utilities
Group 10: Local Governments (solid waste department, including household hazardous waste programs)
Group 11: Law Enforcement
Group 12: Research Institutions
Group 13: Long-Term Care Facilities (Nursing Homes & Assisted Living)

The survey instructions, definitions, questions and response options that were developed for each of the 13 surveys, as they were posted on the TCEQ Pharmaceutical Disposal Advisory Group (PDAG) webpage, are provided in subsequent pages, in ascending group order.
Group 1: Health Care Providers – Patient Floor

Instructions for Completing the Survey

This survey is intended to help the Texas Commission on Environmental Quality (TCEQ) understand how unused pharmaceuticals are disposed of by health-care providers in Texas, and what factors impact the decision to dispose of them in a certain way.

This is part of a study being conducted to fulfill the requirements of Senate Bill 1757 (SB 1757), passed in the Texas 81st Legislative Session.

This survey is intended for the following types of health-care providers located in Texas: ambulance services, hospitals (including emergency room, primary and specialty services), private clinics and dental/oral care offices.

This survey should be completed by the staff member who directs the management and disposal of unused pharmaceuticals in the facility after the pharmaceuticals have been obtained from an in-house pharmacy or centralized storage area (that is, staff who understand how unused pharmaceuticals are disposed of or managed on the patient floor, for example, the Director of Nursing at a hospital or clinic). This survey is NOT for the pharmacies located within health-care provider facilities (refer to the “Group 3: Pharmacy” survey).

Please answer these questions as accurately as possible. There are 10 questions in this survey and it should not take more than 10-15 minutes. One survey should be completed per facility. Surveys are anonymous.

If you have any questions about this survey, please contact Jessica Huybregts at 512-239-4709 or by email at <jhuybreg@tceq.state.tx.us>.

Definitions

Below are definitions for some of the terms used in this survey.

Pharmaceutical: Under the plain and ordinary meaning of the term, a pharmaceutical is considered a “drug”. Plainly stated, pharmaceuticals could be over-the-counter drugs or those that require a prescription to obtain, they can be in the solid, liquid or aerosol form, but they are not foods or nutritional supplements. For more information, see the definition of “drug” in Chapter 431 of the Texas Food, Drug and Cosmetic Act [§431.002(14)].

Facility: This is the type of practice or operation that you work in, such as a clinic or hospital. Answers to survey questions should relate to one facility you work in. If you work in multiple facilities and you are the most appropriate person to complete the survey for each facility, please complete a different survey for each facility.

Patient floor: This is where patients are located during treatment. Whether it is a clinic or hospital or other facility, once the nurse/physician has obtained
pharmaceuticals from the in-house pharmacy or drug storage area and intends to administer them to patients in their care, the pharmaceuticals are considered on the patient floor.

Controlled substance: The term controlled substance has the meaning given in Chapter 481 (Texas Controlled Substances Act) of the Health and Safety Code, which is consistent with the definition in section 802(6) of Title 21, United States Code (U.S.C.).

Prescription drug: The term prescription drug has the meaning given in Chapter 431 (Texas Food, Drug and Cosmetic Act) of the Health and Safety Code, which lists the meaning assigned by section 203.3 of Title 21 Code of Federal Regulations. Under that definition, a prescription drug means any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by Federal law (including Federal regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the act.

Hazardous waste: A solid waste is considered a hazardous waste if it exhibits any of the four characteristics: ignitability, corrosivity, reactivity, or toxicity; or if it is specifically listed as a hazardous waste under Title 40 Code of Federal Regulations Part 61 Rule §261.30.

Unused: The term unused can include partially or completely unused, unwanted, wasted, or expired substances. These are items that are ultimately NOT dispensed to patients and require disposal or transfer to another location.

Rural County: Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than 50,000. Rural County definition map: http://www.tlc.state.tx.us/pubspol/Rural_Definition/Definition_19_and_20.pdf
Group 1: Health Care Providers – Survey Questions

1. What type of facility do you operate?
   - ☐ Ambulance service
   - ☐ Hospital – including emergency room, primary and specialty services
   - ☐ Private Office/Clinic (1-20 practitioners)
   - ☐ Private Office/Clinic (>20 practitioners)
   - ☐ Dental/Oral Care Office
   - ☐ Other (please specify)

2. Is your facility located in a Texas rural county*?
   - ☐ Yes
   - ☐ No

* [Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than 50,000. Rural County definition map: http://www.tlc.state.tx.us/pubspol/Rural_Definition/Definition_19_and_20.pdf]

3. Approximately, what proportion of the pharmaceuticals goes unused on the patient floor*?
   - ☐ No pharmaceuticals on the patient floor ever go unused
   - ☐ 1-10% of pharmaceuticals on the patient floor go unused
   - ☐ 11-25% of pharmaceuticals on the patient floor go unused
   - ☐ 26-50% of pharmaceuticals on the patient floor go unused
   - ☐ >50% of pharmaceuticals on the patient floor go unused
   - ☐ I do not know

* [(1) “Proportion” relates to doses that were brought to the patient floor but were ultimately not administered to patients, compared to the total doses of pharmaceuticals brought to the patient floor. (2) We understand that accurate records of this may not be kept. If it would help, please consider the proportion of pharmaceuticals that go unused on the floor in one section of the facility, or in a one day, or by a select group of nurses, or another measure you deem appropriate that would allow us to gain an approximate understanding of how common it is for pharmaceuticals to go unused on the patient floor.]

4. What is the most common type of pharmaceutical media, dispensed from the facility’s pharmacy, that goes (partially or completely) unused on the patient floor?
   - ☐ Liquid from syringes
   - ☐ Liquid from IV bags
   - ☐ Solid dose pills
   - ☐ Topical substances
   - ☐ I do not know
   - ☐ Not applicable (no pharmaceuticals go unused)

5. What are the most common reasons why pharmaceuticals go unused once on the patient floor or in your facility? (Select up to 3 reasons)
   - ☐ Pharmaceuticals obtained from the in-house pharmacy were expired
Excess samples provided by pharmaceutical manufacturers to physician (expired before these could be offered to patients)
- Physician decided not to administer the pharmaceuticals to patient once obtained from the pharmacy (for example, patient experienced reaction or condition changed)
- Pharmaceuticals dropped/spilled on patient floor
- Excess liquid pharmaceuticals leftover in pre-manufactured/pre-filled syringes or IV bags
- Excess liquid pharmaceuticals drawn up into syringes or manually added to IV bags
- Patient only required a portion of a solid dose drug (excess portion of drug was unwanted/unneeded and cannot be re-used on another patient).
- Patient only required a portion of a topical drug (excess portion of topical drug unwanted/unneeded and cannot be re-used on another patient).
- Not applicable (no pharmaceuticals go unused)

6. **What do nurses/physicians at your facility usually do with the most common unused controlled substances once the pharmaceuticals are on the patient floor?**
   - Return them to the pharmacy/drug storage area
   - Transfer them to the facility’s drug sorting area for sorting and arrange for a waste management service to dispose of as hazardous waste
   - Transfer them to the facility’s drug sorting area for sorting and arrange for a waste management service to dispose of controlled substances via incineration
   - Co-mingle with other unused pharmaceuticals and arrange for a waste management service to collect and dispose of all unused pharmaceuticals (unsorted)
   - Transfer them to the facility’s own autoclave
   - Deposit them in a “sharps” container or “red-bag/biohazard” container and arrange for a waste disposal service to dispose of those
   - Dispose of them in the regular trash (municipal solid waste)
   - Dispose of them onsite in the sink/toilet (drain)
   - I do not know
   - Not applicable; there are never unused controlled substances on the patient floor at our facility that would require disposal or transfer.
   - Not applicable (no pharmaceuticals go unused)
   - Other (please specify)

7. **What do nurses/physicians at your facility usually do with the most common pharmaceuticals that would be considered “hazardous waste” if they go unused on the patient floor?**
   - Return them to the pharmacy/drug storage area
   - Segregate out hazardous pharmaceuticals from other unused pharmaceuticals and arrange for a waste management service to dispose of that portion as hazardous waste
   - Co-mingle unused hazardous pharmaceuticals with all other unused pharmaceuticals and arrange for a waste management service to collect and dispose of them all as hazardous waste
☐ Co-mingle unused hazardous pharmaceuticals with other unused pharmaceuticals and arrange for a waste management service to collect and dispose of them (facility does not define how they will be ultimately disposed of)
☐ Transfer them to the facility’s own autoclave
☐ Deposit them in a “sharps” container or “red-bag/biohazard” container and arrange for a waste disposal service to dispose of those
☐ Dispose of them in the regular trash (municipal solid waste)
☐ Dispose of them onsite in the sink/toilet (drain)
☐ I do not know
☐ Not applicable; there are never unused controlled substances on the patient floor at our facility that would require disposal or transfer.
☐ Not applicable (no pharmaceuticals go unused)
☐ Other (please specify)

8. What do nurses/physicians at your facility usually do with the most common non-controlled, non-hazardous pharmaceuticals that go unused once on the patient floor?

☐ Return them to the pharmacy/drug storage area
☐ Co-mingle all unused pharmaceuticals and arrange for a waste management service to dispose of all unused pharmaceuticals following the company's disposal protocols
☐ Co-mingle all unused pharmaceuticals and arrange for a waste management service to dispose of them all (unsorted) as hazardous waste
☐ Arrange for a waste management service to dispose of non-hazardous pharmaceuticals as medical waste.
☐ Transfer them to the facility’s own autoclave
☐ Deposit them in a “sharps” container or “red-bag/biohazard” container and arrange for a waste disposal service to dispose of those
☐ Dispose of them in the regular trash (municipal solid waste)
☐ Dispose of them onsite in the sink/toilet (drain)
☐ I do not know
☐ Not applicable; there are never unused controlled substances on the patient floor at our facility that would require disposal or transfer.
☐ Not applicable (no pharmaceuticals go unused)
☐ Other (please specify)

9. What are the most significant factors impacting your decision to choose the methods your facility employs for disposing of or transferring unused pharmaceuticals?(Select the top 3 factors)

☐ Drug Enforcement Administration (DEA) Policy (Controlled Substances Act)
☐ Compliance with Hazardous Waste Regulations (RCRA)
☐ Complicated/poorly understood waste disposal regulations
☐ Wastewater permit requirements
☐ Health-care provider permit requirements
☐ Facility Guidelines/Standard Operating Procedures
☐ Drug-diversion concerns
☐ Accidental poisonings
☐ Ease of Disposal
☐ Cost of Disposal
10. What are your preferred options for disposal or management of unused pharmaceuticals? (select up to three)

☐ Nurse/physician transfers pharmaceuticals to centralized sorting area where a different staff member sorts pharmaceuticals into various waste groups and has those waste groups disposed of according to State/Federal requirements.

☐ Nurse/physician sorts pharmaceuticals into various waste groups as they become unused and disposes of those according to State/Federal requirements.

☐ Do not separate unused pharmaceuticals into various waste types – dispose of all unused pharmaceuticals in a “sharps” container or “red-bag/biohazard” container (classify all as medical waste).

☐ Do not separate unused pharmaceuticals into various waste types – classify all unused pharmaceuticals as hazardous waste (and employ disposal service to dispose of as hazardous).

☐ Return all unused pharmaceuticals (including partially used and completely unused) to the pharmacy/drug storage area.

☐ Dispose of pharmaceuticals in the regular trash (municipal solid waste).

☐ Dispose of pharmaceuticals onsite in the sink/toilet (drain).

☐ Focus on waste minimization – do not use pre-filled/manufactured syringes/IV bags.

☐ Focus on waste minimization – do not accept as many pharmaceutical samples.

☐ Training/education of patient floor staff on best management disposal practices.

☐ Brochures/posters/other materials provided to facility by the State of Texas regarding the best management disposal practices.

☐ Other (please specify)
Group 2: Veterinary Providers

Instructions for Completing the Survey

This survey is intended to help the Texas Commission on Environmental Quality (TCEQ) understand how unused pharmaceuticals are disposed of by veterinary providers in Texas, and what factors impact the decision to dispose of them in a certain way.

This is part of a study being conducted to fulfill the requirements of Senate Bill 1757, passed in the Texas 81st Legislative Session.

This survey should be completed by the staff member who directs the management and disposal of unused pharmaceuticals in a veterinary facility in Texas (for example, the Head Veterinarian or Clinic Manager).

Please answer these questions as accurately as possible. There are 10 questions in this survey and it should not take more than 10-15 minutes. One survey should be completed per facility. Surveys are anonymous.

If you have any questions about this survey, please contact Jessica Huybregts at 512-239-4709 or by email at <jhuybreg@tceq.state.tx.us>.

Definitions

Below are definitions for some of the terms used in this survey.

Pharmaceutical: Under the plain and ordinary meaning of the term, a pharmaceutical is considered a “drug”. Plainly stated, pharmaceuticals could be over-the-counter drugs or those that require a prescription to obtain, they can be in the solid, liquid or aerosol form, but they are not foods or nutritional supplements. For more information, see the definition of “drug” in Chapter 431 of the Texas Food, Drug and Cosmetic Act [§431.002(14)].

Facility: This is the type of practice or operation that you work in, such as an emergency veterinary clinic or routine animal care clinic. Answers to survey questions should relate to one facility you work in. If you work in multiple facilities and you are the most appropriate person to complete the survey for each facility, please complete a different survey for each facility.

Controlled substance: The term controlled substance has the meaning given in Chapter 481 (Texas Controlled Substances Act) of the Health and Safety Code, which is consistent with the definition in section 802(6) of Title 21, United States Code (U.S.C.).

Prescription drug: The term prescription drug has the meaning given in Chapter 431 (Texas Food, Drug and Cosmetic Act) of the Health and Safety Code, which lists the meaning assigned by section 203.3 of Title 21 Code of Federal Regulations. Under that definition, a prescription drug means any drug (including any biological product, except for blood and blood components
intended for transfusion or biological products that are also medical devices) required by Federal law (including Federal regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the act.

Hazardous waste: A solid waste is considered a hazardous waste if it exhibits any of the four characteristics: ignitability, corrosivity, reactivity, or toxicity; or if it is specifically listed as a hazardous waste under Title 40 Code of Federal Regulations Part 61 Rule §261.30.

Unused: The term unused can include partially or completely unused, unwanted, wasted, or expired substances. These are items that are ultimately NOT used by patients and require disposal or transfer to another location.

Rural County: Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than 50,000. Rural County definition map:
Group 2: Veterinary Providers - Survey Questions

1. What type of facility do you primarily operate?
   - Veterinary Clinic - Emergency/Critical Care Service
   - Veterinary Clinic - Routine care
   - Veterinary Clinic – Specialized care (including dentistry, radiology, surgery)
   - Mobile Veterinary service
   - Other (please specify)

2. Is your facility located in a rural county*?
   - Yes
   - No

[*Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than 50,000. Rural County definition map: http://www.tlc.state.tx.us/pubspol/Rural_Definition/Definition_19_and_20.pdf]

3. Approximately, what proportion of the pharmaceuticals in your facility go unused?
   - No pharmaceuticals at the veterinary facility go unused
   - 1-10% of pharmaceuticals at the veterinary facility go unused
   - 11-25% of pharmaceuticals at the veterinary facility go unused
   - 26-50% of pharmaceuticals at the veterinary facility go unused
   - >50% of pharmaceuticals at the veterinary facility go unused
   - I do not know

[Notes: (1) “Proportion” relates to doses that were ultimately not administered to patients, compared to the total doses of pharmaceuticals in the facility. (2) We understand that accurate records of this may not be kept. If it would help, please consider the proportion of pharmaceuticals that go unused in a one week, or another measure you deem appropriate that would allow us to gain an approximate understanding of how common it is for pharmaceuticals to go unused in a veterinary facility.]

4. What is the most common type of pharmaceutical that goes (partially or completely) unused at your veterinary facility?
   - Liquid from syringes
   - Liquid from IV bags
   - Liquid from bottles, jugs, or buckets
   - Solid dose pills
   - Topical substances
   - I do not know

5. What are the most common reasons why pharmaceuticals go unused at your veterinary facility? (Select up to 3 reasons)
   - Pharmaceuticals expired
Excess quantities of samples provided by pharmaceutical manufacturers to veterinary practice (expired before being dispensed)
- Physician decided to stop administering the pharmaceuticals to patient (for example, patient experienced reaction or condition changed)
- Pharmaceuticals dropped/spilled
- Excess liquid pharmaceuticals leftover in pre-manufactured/pre-filled syringes or IV bags
- Excess liquid pharmaceuticals drawn up into syringes or manually added to IV bags
- Patient only required a portion of a solid dose drug (excess portion of drug was unwanted/unneeded and cannot be re-used on another patient).
- Patient only required a portion of a topical drug (excess portion of topical drug unwanted/unneeded and cannot be re-used on another patient).
- Therapeutic use is no longer valid or superseded by newer drugs.
- Other (please specify)

6. What do veterinarians/technicians at your facility usually do with the most common unused controlled substances?
- Return them to the pharmacy/drug storage area for future use
- Return them to the manufacturer, reverse distributor or third party returns processor
- Dispose of them in the regular trash (municipal solid waste)
- Arrange for collection and disposal by a waste disposal service (unknown final disposal destination)
- Arrange for a waste disposal service to incinerate them
- Transfer them to the facility’s own autoclave
- Place them in a “sharps” container or “red-bag/biohazard” container and arrange for medical waste disposal service to dispose of them
- Dispose of them onsite in the sink/toilet
- There are never unused controlled substances at our facility that would require disposal or transfer.
- Take them to a local pharmacy for disposal.
- I do not know
- Other (please specify)

7. What do veterinarians/technicians at your facility usually do with unused pharmaceuticals that would be considered “hazardous”?
- Return them to the pharmacy/drug storage area for future use
- Return them to the manufacturer, reverse distributor or third party returns processor
- Dispose of them in the regular trash (municipal solid waste)
- Co-mingle with all unused pharmaceuticals and arrange for collection and disposal by a waste disposal service (unknown final disposal destination)
- Co-mingle with all unused pharmaceuticals and arrange for a waste disposal service to dispose of them all at a hazardous waste landfill/incinerator
- Co-mingle with all unused pharmaceuticals and arrange for a waste disposal service to dispose of them all at a medical waste incinerator
- Separate out hazardous pharmaceuticals and arrange for a waste disposal service to dispose of those at a hazardous waste landfill/incinerator
- Separate out hazardous pharmaceuticals and arrange for a waste disposal service to dispose of those at a medical waste incinerator
Transfer them to the facility’s own autoclave
Place them in a “sharps” container or “red-bag/biohazard” container and arrange for medical waste disposal service to dispose of them
Dispose of them onsite in the sink/toilet
There are never unused hazardous substances at our facility that would require disposal or transfer.
Take them to a local pharmacy for disposal
I do not know
Other (please specify)

8. **What do veterinarians/technicians at your facility usually do with unused non-controlled, non-hazardous pharmaceuticals?**

Return them to the pharmacy/drug storage area for future use
Return them to the manufacturer, reverse distributor or third party returns processor
Dispose of them in the regular trash (municipal solid waste)
Co-mingle all unused pharmaceuticals and arrange for collection and disposal by a waste disposal service (unknown final disposal destination)
Co-mingle all unused pharmaceuticals and arrange for a waste disposal service to dispose of them all at a hazardous waste landfill/incinerator
Co-mingle all unused pharmaceuticals and arrange for a waste disposal service to dispose of them all at a medical waste incinerator
Transfer them to the facility’s own autoclave
Place them in a “sharps” container or “red-bag/biohazard” container and arrange for medical waste disposal service to dispose of them
Dispose of them onsite in the sink/toilet
There are never unused non-hazardous substances at our facility that would require disposal or transfer.
Take them to a local pharmacy for disposal
I do not know
Other (please specify)

9. **What are the most significant factors impacting your decision to choose the methods your facility usually employs for disposing of or transferring unused pharmaceuticals? (Select the top 3 factors)**

Drug Enforcement Administration (DEA) Policy (Controlled Substances Act)
Compliance with Hazardous Waste Regulations (RCRA)
Complicated/poorly understood waste disposal regulations
Wastewater permit requirements
Veterinary-care providers permit requirements
Facility Guidelines/Standard Operating Procedures
Drug-diversion concerns
Accidental Poisonings
Ease of Disposal
Cost of Disposal
Staff Time Constraints
Staff Training Constraints
Staff safety
OSHA compliance
10. What are your preferred options for disposal or management of unused pharmaceuticals? (check all that apply)

- Veterinarian/technician should transfer pharmaceuticals to centralized sorting area where pharmaceuticals are sorted into various waste groups and those are disposed of according to minimum State/Federal requirements.
- Facility should employ a reverse distributor or third party returns processor to return qualifying expired medications back to the manufacturer for credit.
- Facility should not separate unused pharmaceuticals into various waste types – dispose of all unused pharmaceuticals in a “sharps” container or “red-bag/biohazard” container and arrange for waste disposal service to dispose of those.
- Facility should not separate unused pharmaceuticals into various waste types – classify all unused pharmaceuticals as hazardous waste and employ disposal service to dispose of at a hazardous waste landfill/incinerator.
- Veterinarian/technician should dispose of all unused pharmaceuticals in the regular trash (municipal solid waste).
- Veterinarian/technician should dispose of all unused pharmaceuticals onsite in the sink/toilet.
- Focus on waste minimization – do not use pre-filled/manufactured syringes/IV bags.
- Focus on waste minimization – do not accept as many pharmaceutical samples.
- Training/education of staff on best management disposal practices.
- Brochures/posters/other materials provided to facility by the State of Texas regarding the best management disposal practices.
- Other (please specify)
Group 3: Pharmacies

Instructions for Completing the Survey

This survey is intended to help the Texas Commission on Environmental Quality (TCEQ) understand how unused pharmaceuticals are disposed of by pharmacies in Texas, and what factors impact the decision to dispose of them in a certain way.

This is part of a study being conducted to fulfill the requirements of Senate Bill 1757, passed in the Texas 81st Legislative Session.

This survey should be completed by the staff member who directs the management and disposal of unused pharmaceuticals in a pharmacy in Texas, for example, a Pharmacy Manager. This survey should be completed by pharmacies located within health-care facilities as well as retail pharmacies.

Please answer these questions as accurately as possible. There are 10 questions in this survey and it should not take more than 10-15 minutes. One survey should be completed per pharmacy. Surveys are anonymous.

If you have any questions about this survey, please contact Jessica Huybregts at 512-239-4709 or by email at <jhuybreg@tceq.state.tx.us>.

Definitions

Below are definitions for some of the terms used in this survey.

Pharmaceutical: Under the plain and ordinary meaning of the term, a pharmaceutical is considered a “drug”. Plainly stated, pharmaceuticals could be over-the-counter drugs or those that require a prescription to obtain, they can be in the solid, liquid or aerosol form, but they are not foods or nutritional supplements. For more information, see the definition of “drug” in Chapter 431 of the Texas Food, Drug and Cosmetic Act [§431.002(14)].

Controlled substance: The term controlled substance has the meaning given in Chapter 481 (Texas Controlled Substances Act) of the Health and Safety Code, which is consistent with the definition in section 802(6) of Title 21, United States Code (U.S.C.).

Prescription drug: The term prescription drug has the meaning given in Chapter 431 (Texas Food, Drug and Cosmetic Act) of the Health and Safety Code, which lists the meaning assigned by section 203.3 of Title 21 Code of Federal Regulations. Under that definition, a prescription drug means any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by Federal law (including Federal regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the act.
Hazardous waste: A solid waste is considered a hazardous waste if it exhibits any of the four characteristics: ignitability, corrosivity, reactivity, or toxicity; or if it is specifically listed as a hazardous waste under Title 40 Code of Federal Regulations Part 61 Rule §261.30.

Unused: The term unused can include partially or completely unused, unwanted, wasted, or expired substances. These are items that are NOT dispensed to patients/customers and require disposal or transfer to another location.

Rural County: Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than 50,000. Rural County definition map: http://www.tlc.state.tx.us/pubspol/Rural_Definition/Definition_19_and_20.pdf
Group 3: Pharmacies - Survey Questions

1. What type of pharmacy do you operate?
   - Retail chain pharmacy
   - Retail independent pharmacy
   - Retail pharmacy within supermarket (for example, HEB, Walmart, Brookshires)
   - Community clinic pharmacy (retail pharmacy located within a health-care provider setting that dispenses pharmaceuticals to out-patients)
   - Hospital/Clinic In-house Pharmacy (supplies pharmaceuticals to physicians/nurses for dispensing to patients of the health care facility; does not supply pharmaceuticals directly to patients)
   - Long Term Care Facility In-house Pharmacy (supplies pharmaceuticals to consultant pharmacists for dispensing to residents of the long term care facility; does not supply pharmaceuticals directly to patients)
   - Other (please specify)

2. Is your pharmacy located in a rural county*?
   - Yes
   - No

[*Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than 50,000. Rural County definition map: http://www.tlc.state.tx.us/pubspol/Rural_Definition/Definition_19_and_20.pdf]

3. What is the most common reason why pharmaceuticals go unused at the pharmacy (generated by the pharmacy)?
   - Pharmaceuticals became expired in the shelves
   - Pharmaceuticals were re-called by the manufacturer
   - Practitioners discontinued prescribing the pharmaceutical
   - Pharmaceuticals were dropped/spilled
   - Not applicable (pharmaceuticals never go unused at the pharmacy)
   - Other (please specify)

4. Approximately, what proportion of pharmaceuticals goes unused within the pharmacy (generated by the pharmacy as part of their operations; does NOT include those returned by customers)?
   - No pharmaceuticals in the pharmacy ever go unused
   - 1-10% of pharmaceuticals in the pharmacy go unused
   - 11-25% of pharmaceuticals in the pharmacy go unused
   - 26-50% of pharmaceuticals in the pharmacy go unused
   - >50% of pharmaceuticals in the pharmacy go unused
   - I do not know

5. What does the pharmacy usually do with the unused pharmaceuticals generated by the pharmacy (does NOT include those returned by customers)?
Not applicable – there are never unused pharmaceuticals at the pharmacy.

Store unused pharmaceuticals onsite.

Transfer unused pharmaceuticals to another pharmacy.

Return all unused pharmaceuticals to the chain warehouse for handling/disposal.

Return all unused pharmaceuticals to the manufacturer, reverse distributor or a third party returns processor.

Return some unused pharmaceuticals to the manufacturer, reverse distributor or a third party returns processor AND dispose of some unused pharmaceuticals (please provide further detail regarding methods of disposal under question 6).

Dispose of all unused pharmaceuticals (please provide further detail regarding methods of disposal under question 6).

6. **What method does your pharmacy use to dispose of unused pharmaceuticals generated by the pharmacy (does NOT include those returned by customers)?**

Not applicable – we do not dispose of (or specifically arrange for disposal of) any unused pharmaceuticals.

Disposal of unused pharmaceuticals in the sink/toilet.

Disposal of unused pharmaceuticals in the municipal trash.

Arrange for a waste disposal company to collect and dispose of unused pharmaceuticals (no sorting into different waste types).

Sort unused pharmaceuticals into waste types, then dispose of hazardous pharmaceuticals as hazardous waste and dispose of non-hazardous pharmaceuticals in the municipal trash.

Disposal of unused pharmaceuticals in a “sharps” container or “red-bag/biohazard” container and arrange for a medical waste disposal service to collect and dispose of those.

Disposal of unused controlled substances in the sink/toilet and disposal of other unused pharmaceuticals in the municipal trash.

Other (please specify)

7. **What does the pharmacy usually do when customers (“ultimate users”) return their unused pharmaceuticals to the pharmacy for the purpose of disposal?**

Not applicable - the pharmacy does not interact with ultimate users (for example, hospital/clinic in-house pharmacy provides pharmaceuticals to practitioners/consultant pharmacists only).

Not applicable - the pharmacy is never approached by customers to dispose of their unused pharmaceuticals.

The pharmacy does not accept any unused pharmaceuticals from customers for disposal. The pharmacy does not provide guidance about how to dispose of their unused pharmaceuticals.

The pharmacy does not accept any unused pharmaceuticals from customers for disposal. When asked by customers, we advise customers to dispose of their unused pharmaceuticals in the sink/toilet.

The pharmacy does not accept any unused pharmaceuticals from customers for disposal. When asked by customers, we advise customers to dispose of their unused pharmaceuticals in the municipal trash.
☐ The pharmacy does not accept any unused pharmaceuticals from customers for disposal. When asked by customers, we advise the customers consult Federal guidance documents.
☐ The pharmacy accepts only non-controlled pharmaceuticals returned from the customer and disposes of them in the toilet/sink.
☐ The pharmacy accepts only non-controlled pharmaceuticals returned from the customer and disposes of them in the municipal trash.
☐ The pharmacy accepts only non-controlled pharmaceuticals returned from the customer and arranges for them to be disposed of via hazardous waste incineration.
☐ The pharmacy accepts only non-controlled pharmaceuticals returned from the customer and arranges for them to be disposed of via medical waste incineration.
☐ The pharmacy accepts only non-controlled pharmaceuticals returned from the customer and arranges for them to be disposed of in a hazardous waste landfill.
☐ The pharmacy accepts only non-controlled pharmaceuticals returned from the customer and arranges for them to be disposed of in a municipal landfill.
☐ The pharmacy accepts only non-controlled pharmaceuticals returned from the customer and arranges for them to be disposed of by a waste disposal service; however I do not know the disposal method they use.
☐ Other (please specify)

8. Approximately, what quantity/volume of unused pharmaceuticals is disposed of by the pharmacy per month (not returned to a manufacturer, reverse distributor or third party returns processor)?

☐ None
☐ Less than 1 cubic foot box/month
☐ 1-2 cubic foot boxes/month
☐ 3-5 cubic foot boxes/month
☐ 6-10 cubic foot boxes/month
☐ Greater than 10 cubic foot boxes/month

9. What are the most significant factors impacting your decision to choose the methods your facility employs for disposing of or transferring unused pharmaceuticals?(Select the top 3 factors)

☐ Drug Enforcement Administration (DEA) Policy (Controlled Substances Act)
☐ Compliance with Hazardous Waste Regulations (RCRA)
☐ Complicated waste disposal regulations
☐ Wastewater permit requirements
☐ Pharmacy guidelines/Standard Operating Procedures
☐ Ease of disposal
☐ Cost of disposal
☐ Staff time constraints
☐ Staff training constraints
☐ Staff safety
☐ OSHA compliance
☐ Drug-diversion concerns
☐ Accidental poisonings
☐ Public health and safety concerns
10. **What are your preferred options for aiding customers (“ultimate users”) in the disposal or management of their unused pharmaceuticals? (check all that apply)**

- ☐ Not applicable - the pharmacy does not interact with ultimate users (for example, hospital/clinic in-house pharmacy provides pharmaceuticals to practitioners/consultant pharmacists only).
- ☐ The pharmacy does not wish to accept any unused pharmaceuticals that customers return. When asked by customers, the pharmacy prefers to advise customers to dispose of their unused pharmaceuticals in the toilet/sink.
- ☐ The pharmacy does not wish to accept any unused pharmaceuticals that customers return. When asked by customers, the pharmacy prefers to advise customers to dispose of their unused pharmaceuticals in the household trash.
- ☐ The pharmacy does not wish to accept any unused pharmaceuticals that customers return. When asked by customers, the pharmacy prefers to refer customers to Federal or State recommendations/guidelines for how to dispose of their unused pharmaceuticals.
- ☐ The pharmacy does not wish to accept any unused pharmaceuticals that customers return. When asked by customers, the pharmacy prefers to provide customers with a State-approved brochure or information packet for how to dispose of their unused pharmaceuticals.
- ☐ The pharmacy desires to host or support community pharmaceutical collection events.
- ☐ The pharmacy desires to provide mail-back envelopes for customers so that they can mail their unused pharmaceuticals to a central location for disposal.
- ☐ The pharmacy desires to provide a secure drop box in the pharmacy for customers to drop off their unused non-controlled pharmaceuticals and arrange for disposal via landfill.
- ☐ The pharmacy desires to provide a secure drop box in the pharmacy for customers to drop off their unused non-controlled pharmaceuticals and arrange for disposal via incineration.
- ☐ Other (please specify)
Group 4: Waste Disposal/Management Service Providers

Instructions for Completing the Survey

This survey is intended to help the Texas Commission on Environmental Quality (TCEQ) understand how unused pharmaceuticals are disposed of by waste disposal/management service providers in Texas, and what factors impact the decision to dispose of them in a certain way.

This is part of a study being conducted to fulfill the requirements of Senate Bill 1757, passed in the Texas 81st Legislative Session.

Please answer these questions as accurately as possible. There are 10 questions in this survey and it should not take more than 10-15 minutes to complete.

One survey should be completed per operation. However, if a large company operates vastly differently across regions of Texas, then separate surveys should be completed for each distinct operation. Surveys are anonymous.

Local government solid waste departments should not complete this survey; instead they should complete the “Group 10: Local Government” survey.

If you have any questions about this survey, please contact Jessica Huybregts at 512-239-4709 or by email at <jhuybreg@tceq.state.tx.us>.

Definitions

Below are definitions for some of the terms used in this survey.

Pharmaceutical: Under the plain and ordinary meaning of the term, a pharmaceutical is considered a “drug”. Plainly stated, pharmaceuticals could be over-the-counter drugs or those that require a prescription to obtain, they can be in the solid, liquid or aerosol form, but they are not foods or nutritional supplements. For more information, see the definition of “drug” in Chapter 431 of the Texas Food, Drug and Cosmetic Act [§431.002(14)].

Unused: The term unused can include partially or completely unused, unwanted, wasted, or expired substances. These are items that are ultimately not used and require disposal or transfer to another location.

Controlled substance: The term controlled substance has the meaning given in Chapter 481 (Texas Controlled Substances Act) of the Health and Safety Code, which is consistent with the definition in section 802(6) of Title 21, United States Code (U.S.C.).

Prescription drug: The term prescription drug has the meaning given in Chapter 431 (Texas Food, Drug and Cosmetic Act) of the Health and Safety Code, which lists the meaning assigned by §203.3 of Title 21 Code of Federal Regulations. Under that definition, a prescription drug means any drug (including any biological product, except for blood and blood components intended for
transfusion or biological products that are also medical devices) required by Federal law (including Federal regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the act.

Hazardous waste: A solid waste is considered a hazardous waste if it exhibits any of the four characteristics: ignitability, corrosivity, reactivity, or toxicity; or if it is specifically listed as a hazardous waste under Title 40 Code of Federal Regulations Part 61 §261.30.

Special Waste: Since pharmaceuticals are considered “drugs”, they are regulated as “Special Waste” under Title 30 Texas Administrative Code (30 TAC §330.3(148)(J)), which is a sub-group of Municipal Solid Waste. Special waste is defined as: any solid waste or combination of solid wastes that because of its quantity, concentration, physical or chemical characteristics, or biological properties requires special handling and disposal to protect the human health or the environment. If improperly handled, transported, stored, processed, or disposed of or otherwise managed, it may pose a present or potential danger to the human health or the environment.

Medical waste: Treated and untreated special waste from health care-related facilities that is comprised of animal waste, bulk blood, bulk human blood, bulk human body fluids, microbiological waste, pathological waste, and sharps as those terms are defined in 25 TAC §1.132 (relating to Definitions) from the sources specified in 25 TAC §1.134 (relating to Application), as well as regulated medical waste as defined in 49 Code of Federal Regulations §173.134(a)(5), except that the term does not include medical waste produced on a farm or ranch as defined in 34 TAC §3.296(f) (relating to Agriculture, Animal Life, Feed, Seed, Plants, and Fertilizer), nor does the term include artificial, nonhuman materials removed from a patient and requested by the patient, including, but not limited to, orthopedic devices and breast implants. Health care-related facilities do not include: (A) single or multi-family dwellings; and (B) hotels, motels, or other establishments that provide lodging and related services for the public. This medical waste definition is from 30 TAC §330.3(85).

Disposal: The discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste or hazardous waste (whether containerized or uncontainerized) into or on any land or water so that such solid waste or hazardous waste or any constituent thereof may enter the environment or be emitted into the air or discharged into any waters, including groundwater. This definition is from 30 TAC §330.3(44).

Processing: Activities including, but not limited to, the extraction of materials, transfer, volume reduction, conversion to energy, or other separation and preparation of solid waste for reuse or disposal, including the treatment or neutralization of waste, designed to change the physical, chemical, or biological character or composition of any waste to neutralize such waste, or to recover energy or material from the waste, or render the waste safer to transport, store, dispose of, or make it amenable for recovery, amenable for storage, or reduced in volume. This definition is from 30 TAC §330.3(117).
Group 4: Waste Disposal/Management Service Providers - Survey Questions

1. **What services do you provide specifically for pharmaceuticals?**
   - □ Waste collection/transfer
   - □ Waste disposal in a landfill
   - □ Waste processing/treatment - Incineration
   - □ Waste processing/treatment - Autoclave
   - □ Waste processing/treatment - Encapsulation
   - □ Waste processing/treatment - Recycling
   - □ Waste processing/treatment - Reverse Distribution
   - □ Waste processing/treatment - Discharge to waste water treatment plant (WWTP)
   - □ Other (please specify)

2. **What types of facilities does your operation most commonly collect pharmaceuticals from? (select up to 3)**
   - □ Hospitals
   - □ Clinics
   - □ Veterinary practices
   - □ Long term care facilities (assisted living communities or nursing homes)
   - □ Hospices
   - □ Pharmacies
   - □ Pharmaceutical manufacturers
   - □ Pharmaceutical/medical research companies
   - □ Universities/educational institutions
   - □ Hazardous Waste Collection Stations/Events
   - □ Pharmaceutical-only Community Collection Stations/Events
   - □ Law Enforcement
   - □ Individuals/residences (“ultimate users”)
   - □ Farming/ranching operations
   - □ Not applicable – our operation is not engaged in collecting unused pharmaceuticals from generators.
   - □ Other (please specify)

3. **Does your company usually collect pharmaceuticals that have been already sorted into various waste categories?**
   - □ No – the generating facility chooses not to sort various wastes that they generate. Different types of pharmaceuticals are co-mingled and pharmaceuticals may be co-mingled with other substances (such as medical waste).
   - □ No – the generating facility chooses not to sort their unused pharmaceuticals into various waste categories. Different types of pharmaceuticals are co-mingled but pharmaceuticals are not co-mingled with other substances (that is, pharmaceuticals are kept separate from medical waste).
   - □ No – our company provides the service of sorting client’s waste onsite.
   - □ No – our company advises the generating facility to not sort their waste. Different types of pharmaceuticals are co-mingled and pharmaceuticals may be co-mingled with other substances (such as medical waste).
☐ No – our company advises the generating facility to not sort their unused pharmaceuticals. Different types of pharmaceuticals are co-mingled.
☐ No – generators only separate pharmaceutical wastes from medical waste. No further sorting of the pharmaceutical waste takes place.
☐ Yes – pharmaceutical wastes are usually already sorted by the generator into non-hazardous pharmaceutical waste (“special waste”) and hazardous pharmaceutical waste.
☐ Yes – pharmaceutical wastes are sorted into other groups.
☐ I do not know.
☐ Not applicable – our operation is not engaged in the disposal or processing of unused pharmaceuticals.

4. How does your operation manage the disposal or processing of unused pharmaceuticals that would be considered controlled substances?
☐ Not applicable – our operation is not engaged in the disposal or processing of unused pharmaceuticals.
☐ Not applicable – our operation is not a Drug Enforcement Agency (DEA) registrant; therefore we do not handle controlled substances.
☐ Our company provides clients with secure containers to dispose of their controlled pharmaceuticals, which we collect and process in a permitted incinerator.
☐ Our company provides clients with secure containers to dispose of their controlled pharmaceuticals, which we collect and process in an autoclave (and are ultimately disposed of in a landfill).
☐ Controlled pharmaceuticals are may be co-mingled with other pharmaceutical waste and processed in a permitted hazardous waste incinerator.
☐ Controlled pharmaceuticals are may be co-mingled with other pharmaceutical waste and processed in a permitted medical waste incinerator.
☐ Controlled pharmaceuticals are may be co-mingled with other pharmaceutical waste and disposed of in a hazardous waste landfill.
☐ Controlled pharmaceuticals are may be co-mingled with other pharmaceutical waste and disposed of in a municipal solid waste landfill.
☐ Controlled pharmaceuticals are separated out and disposed of in the sink/toilet.
☐ Other (please specify)

5. How does your operation dispose of or process unused pharmaceuticals you collect (Hazardous and non-hazardous [Special Waste])?
☐ Unused pharmaceuticals are co-mingled, are all considered hazardous, and processed in a permitted hazardous waste incinerator.
☐ Unused pharmaceuticals are co-mingled, are all considered hazardous, and processed in a permitted medical waste incinerator.
☐ Unused pharmaceuticals are co-mingled, are all considered hazardous, and transferred for disposal at a permitted hazardous waste landfill.
☐ Unused pharmaceuticals are co-mingled and all processed in an autoclave (then disposed of in a landfill).
☐ Unused pharmaceuticals are co-mingled and all disposed of in the sink/toilet.
☐ Unused pharmaceuticals are co-mingled then transferred to a facility located outside of Texas for processing or disposal.
Hazardous pharmaceuticals are separated from non-hazardous pharmaceuticals; the hazardous pharmaceuticals are processed in a permitted hazardous waste incinerator and the non-hazardous pharmaceuticals are disposed of in a municipal solid waste landfill.

Hazardous pharmaceuticals are separated from non-hazardous pharmaceuticals; the hazardous pharmaceuticals are processed in a permitted hazardous waste incinerator and the non-hazardous pharmaceuticals are disposed of in the sink/toilet.

Hazardous pharmaceuticals are separated from non-hazardous pharmaceuticals; the hazardous pharmaceuticals are processed in a permitted medical waste incinerator and the non-hazardous pharmaceuticals are disposed of in a municipal solid waste landfill.

Hazardous pharmaceuticals are separated from non-hazardous pharmaceuticals; the hazardous pharmaceuticals are disposed of at a permitted hazardous waste landfill and the non-hazardous pharmaceuticals are disposed of in a municipal solid waste landfill.

Not applicable – our operation is not engaged in the disposal or processing of unused pharmaceuticals.

Other (please specify)

6. For reverse distributors, what do you usually do with unused pharmaceuticals that are returned to the manufacturer (via your operation) for credit?

Not applicable – our company does not engage in reverse distribution.

Our company sorts returned pharmaceuticals onsite into eligible and ineligible items, and returns ineligible items to the generator of the waste.

Our company transfers all the returned drugs to the manufacturer who arranges for disposal of the unused pharmaceuticals themselves.

Our company transfers all the returned drugs to the pharmaceutical distributor who then arranges for disposal or works with the manufacturer regarding disposal.

Our company transfers all the returned drugs to the manufacturer who then sorts through eligible returnable substances and contracts our company to dispose of the remaining items.

Pharmaceutical manufacturers require our company to destroy all returned pharmaceuticals at a permitted incinerator.

Pharmaceutical manufacturers require our company to destroy all returned pharmaceuticals in a permitted hazardous waste landfill.

Pharmaceutical manufacturers require our company to destroy all returned pharmaceuticals and our company chooses to send hazardous pharmaceuticals to a permitted hazardous waste incinerator/landfill and special waste (non-hazardous pharmaceuticals) to a municipal solid waste landfill.

Pharmaceutical manufacturers require our company to destroy all returned pharmaceuticals and our company disposes of substances in the sink/toilet.

Other (please specify)
7. **What are the factors impacting your company’s decision to choose the methods you employ for disposal or processing of unused pharmaceuticals? (select up to 3 factors)**

- [ ] Drug Enforcement Administration (DEA) Policy (Controlled Substances Act)
- [ ] Hazardous Waste Regulations (RCRA)
- [ ] State Special Waste Regulations
- [ ] Other State or Local Regulations/Policy
- [ ] Operational permit requirements
- [ ] Company guidelines/Standard Operating Procedures
- [ ] Ease of disposal for customers (for example, sorting or lack of sorting practices)
- [ ] Cost of disposal alternatives
- [ ] Staff time constraints
- [ ] Staff safety
- [ ] OSHA compliance
- [ ] Drug-diversion concerns
- [ ] Accidental poisonings
- [ ] Public health and safety concerns
- [ ] Public perception
- [ ] Customer feedback/input
- [ ] Marketing/promotional/business decisions
- [ ] Waste minimization
- [ ] Perceived better environmental outcomes
- [ ] Other (please specify)

8. **Which of your customers (generators of the pharmaceutical waste) request superior disposal practices (that is, they request pharmaceutical waste to be processed or disposed of at a higher level than that required by Federal or State regulations)?**

- [ ] Hospitals
- [ ] Clinics
- [ ] Veterinary practices
- [ ] Long Term Care Facilities (assisted living communities or nursing homes)
- [ ] Hospices
- [ ] Universities/educational institutions
- [ ] Pharmaceutical/Medical Research companies
- [ ] Pharmacies
- [ ] Pharmaceutical manufacturers
- [ ] Hazardous Waste Collection Stations/Events
- [ ] Pharmaceutical-only Community Collection Stations/Events
- [ ] Law Enforcement
- [ ] Individuals/residences (“end-users”)
- [ ] Farming/ranching operations
- [ ] Not applicable – our customers never request superior disposal practices for the pharmaceutical waste they generate.
- [ ] Not applicable – our operation is not engaged in collecting unused pharmaceuticals from generators.
- [ ] Other (please specify)
9. Has your company engaged in community pharmaceutical collection activities in Texas?

- Yes – we provide the equipment and disposal services for stationary “drop boxes” that end-users can use to dispose of their unused non-controlled pharmaceuticals.
- Yes – we have provided the disposal/processing service for irregular/semi-regular community collection events where end-users can drop off their unused pharmaceuticals.
- Yes – we provide the materials and disposal services for “mail-back” envelopes that end-users can use to dispose of their unused non-controlled pharmaceuticals.
- No – we have not been involved in community pharmaceutical collection activities; however we would like to be involved in the future.
- No – we have not been involved in community pharmaceutical collection activities and we do not wish to be involved in the future.

10. If you answered “No’ to question 9, what is the main reason for not being involved in community pharmaceutical collection activities in Texas?

- Not applicable (answered yes to question 9).
- Unclear or confusing Federal regulations related to accepting and disposing of end-user’s unused pharmaceuticals.
- Unclear or confusing State regulations related to accepting and disposing of end-user’s unused pharmaceuticals.
- Our company does not want to unintentionally/unknowingly be in violation of the Controlled Substances Act as a result of accepting end-user’s unused pharmaceuticals.
- Our company does not wish to explore that market.
- I do not know.
- Other (please specify)
Group 5: Pharmaceutical Manufacturers

Instructions for Completing the Survey

This survey is intended to help the Texas Commission on Environmental Quality (TCEQ) understand how unused pharmaceuticals are disposed of by pharmaceutical manufacturers in Texas.

This is part of a study being conducted to fulfill the requirements of Senate Bill 1757, passed in the Texas 81st Legislative Session.

Please answer these questions as accurately as possible. There are 10 questions in this survey and it should not take more than 10-15 minutes to complete. Surveys are anonymous.

The term “pharmaceutical manufacturer” is used very broadly in this survey and includes: Active Pharmaceutical Ingredient (API) manufacturing plants (chemical manufacturing), finished formulation operations, packaging plants, pharmaceutical distribution centers, collection facilities for returned pharmaceuticals, and research entities that organize pharmaceuticals for clinical trials. Some questions may not apply to your operations; in those cases please select “not applicable”.

ONLY PHARMACEUTICAL MANUFACTURERS LOCATED WITHIN TEXAS SHOULD COMPLETE THIS SURVEY.

One survey should be completed per manufacturing operation. However, if different disposal practices exist for different operational sectors within a pharmaceutical manufacturing company (for example, the packaging group versus the clinical trials group) then a survey may be completed by each distinct operation within the company.

If you have any questions about this survey, please contact Jessica Huybregts at 512-239-4709 or by email at <jhuybreg@tceq.state.tx.us>.

Definitions

Below are definitions for some of the terms used in this survey.

Pharmaceutical: Under the plain and ordinary meaning of the term, a pharmaceutical is considered a “drug”. Plainly stated, pharmaceuticals could be over-the-counter drugs or those that require a prescription to obtain, they can be in the solid, liquid or aerosol form, but they are not foods or nutritional supplements. For more information, see the definition of “drug” in Chapter 431 of the Texas Food, Drug and Cosmetic Act [§431.002(14)].

Hazardous waste: A solid waste is considered a hazardous waste if it exhibits any of the four characteristics: ignitability, corrosivity, reactivity, or toxicity; or if it is specifically listed a as a hazardous waste under Title 40 Code of Federal Regulations Part 61 §261.30.
Disposal: The discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste or hazardous waste (whether containerized or uncontainerized) into or on any land or water so that such solid waste or hazardous waste or any constituent thereof may enter the environment or be emitted into the air or discharged into any waters, including groundwater. This definition is from 30 TAC §330.3(44).

Processing: Activities including, but not limited to, the extraction of materials, transfer, volume reduction, conversion to energy, or other separation and preparation of solid waste for reuse or disposal, including the treatment or neutralization of waste, designed to change the physical, chemical, or biological character or composition of any waste to neutralize such waste, or to recover energy or material from the waste, or render the waste safer to transport, store, dispose of, or make it amenable for recovery, amenable for storage, or reduced in volume. See, e.g., 30 TAC §330.3(117).

Unused: The term unused can include partially or completely unused, unwanted, wasted, or expired substances. These are items that are ultimately not used and require disposal or transfer to another location.
Group 5: Pharmaceutical Manufacturers - Survey Questions

1. What types of activities does your company operate at your facility or facilities in Texas?
   - Active Pharmaceutical Ingredient (API) manufacturing (chemical manufacturing)
   - Finished Formulation
   - Packaging
   - Distribution center for pharmaceuticals
   - Collection facility only for returned pharmaceuticals
   - Research and Development Laboratories (Clinical Trials)
   - Other (please specify)

2. For API (chemical) manufacturing plants and finished formulation operations, does wastewater generated at your facility contain any Active Pharmaceutical Ingredients (API)?
   - Yes
   - No
   - I do not know
   - Not applicable – we do not engage in API manufacturing or formulation

3. For API (chemical) manufacturing plants and finished formulation operations, are there any treatment systems in place to remove Active Pharmaceutical Ingredients (API) from the wastewater?
   - Yes – wastewater is treated via reverse osmosis before being discharged to waters in the State or to an authorized treatment facility (i.e., a privately/publicly owned treatment works or other authorized 3rd party treatment facility).
   - Yes – wastewater is treated using hollow fiber membranes before being discharged to waters in the State or to an authorized treatment facility (i.e., a privately/publicly owned treatment works or other authorized 3rd party treatment facility).
   - Yes – wastewater is treated with other methods before being discharged to waters in the State or to an authorized treatment facility (i.e., a privately/publicly owned treatment works or other authorized 3rd party treatment facility).
   - Yes – wastewater is treated using enhanced treatment methods and land-applied onsite.
   - No
   - Not applicable – there are never API in the wastewater.
   - Not applicable – we do not engage in API manufacturing or formulation.

4. For formulation and packaging activities, how do you usually dispose of off-spec pharmaceutical products (that is, products that are formulated but not able to be sold)?
   - Hazardous waste incineration
   - Medical waste incineration
   - Hazardous waste landfill
   - Municipal Solid Waste landfill (regular trash)
Formulated pharmaceuticals are separated into hazardous and non-hazardous pharmaceuticals; hazardous substances are disposed of at a hazardous waste landfill/incinerator and non-hazardous pharmaceuticals are disposed of in the municipal solid waste landfill/incinerator.

- Treatment in an autoclave then disposal in a landfill
- Transfer to another facility for processing or disposal
- Disposal in the sewer system (sink/toilet)
- Not applicable – there are never off-spec products at the formulation or packaging facilities.
- Not applicable – we do not engage in formulation or packaging

5. **If finished and packaged pharmaceuticals become unusable, expired or can no longer be sold for various reasons when in the distribution center, how are those pharmaceuticals usually managed or disposed of?**

- Hazardous waste incineration
- Medical waste incineration
- Hazardous waste landfill
- Municipal Solid Waste landfill (regular trash)
- Formulated pharmaceuticals are separated into hazardous and non-hazardous pharmaceuticals; hazardous substances are disposed of at a hazardous waste landfill/incinerator and non-hazardous pharmaceuticals are disposed of in the municipal solid waste landfill/incinerator.
- Treatment in an autoclave then disposal in a landfill
- Transfer to another facility for processing or disposal
- Disposal in the sewer system (sink/toilet)
- Not applicable – there are never off-spec products at the distribution center.
- Other (please specify)

6. **How are unused pharmaceutical products that have been collected through reverse distribution usually managed or disposed of? (Select all that apply)**

- Unexpired usable products returned to the manufacturer are returned to stock.
- Hazardous waste incineration
- Medical waste incineration
- Hazardous waste landfill
- Municipal Solid Waste landfill
- Formulated pharmaceuticals are separated into hazardous and non-hazardous pharmaceuticals; hazardous substances are disposed of at a hazardous waste landfill/incinerator and non-hazardous pharmaceuticals are disposed of in the municipal solid waste landfill/incinerator.
- Treatment in an autoclave then disposal in a landfill
- Transfer to another facility for processing or disposal
- Disposal in the sewer system (sink/toilet)
- Not applicable - this company does not participate in the reverse distribution system in Texas.
- Other (please specify)
7. How are unused pharmaceutical product samples that were returned to manufacturer usually managed or disposed of? (Select all that apply)

- Not applicable - this company does not provide product samples.
- Not applicable - this company does not have a program in place for physicians to return unused product samples.
- Unexpired usable product samples returned to the manufacturer are redistributed to other physicians.
- Hazardous waste incineration
- Medical waste incineration
- Hazardous waste landfill
- Municipal Solid Waste landfill
- Formulated pharmaceuticals are separated into hazardous and non-hazardous pharmaceuticals; hazardous substances are disposed of at a hazardous waste landfill/incinerator and non-hazardous pharmaceuticals are disposed of in the municipal solid waste landfill/incinerator.
- Treatment in an autoclave then disposal in a landfill
- Transfer to another facility for processing or disposal
- Disposal in the sewer system (sink/toilet)
- Other (please specify)

8. For facilities engaging in clinical trials/research, how are the unused pharmaceuticals that are returned from clinical trials usually managed or disposed of? (Select all that apply)

- Not applicable - this company does not participate in clinical trials.
- Not applicable - this company does not have a program in place for clinics/physicians conducting the trials to return unused pharmaceuticals to the manufacturer
- Unexpired usable pharmaceuticals from clinical trials that are returned to the manufacturer are redistributed to other clinics/physicians for use.
- Hazardous waste incineration
- Medical waste incineration
- Hazardous waste landfill
- Municipal Solid Waste landfill
- Formulated pharmaceuticals are separated into hazardous and non-hazardous pharmaceuticals; hazardous substances are disposed of at a hazardous waste landfill/incinerator and non-hazardous pharmaceuticals are disposed of in the municipal solid waste landfill/incinerator.
- Treatment in an autoclave then disposal in a landfill
- Transfer to another facility for processing or disposal
- Disposal in the sewer system (sink/toilet)
- Other (please specify)

9. What are the main factors impacting your company’s decision to choose the methods you employ for disposal or processing of unused pharmaceuticals? (select up to 3 factors)

- Drug Enforcement Administration (DEA) Policy (Controlled Substances Act)
- Hazardous Waste Regulations (RCRA)
- State Special Waste Regulations
Other State or Local Regulations/Policy
Operational permit requirements
Company Guidelines/Standard Operating Procedures
Ease of disposal
Cost of disposal alternatives
Staff Time constraints
Staff safety
OSHA compliance
Public perception
Customer feedback/input
Marketing/promotional/business decisions
Waste minimization
Perceived better environmental outcomes
Other (please specify)

10. What is the best way that the State of Texas can provide information to pharmaceutical manufacturers regarding requirements for unused pharmaceutical disposal?

- Guidance documents (e.g. 1-page information sheets)
- Presentations at meetings
- State agency or other dedicated Webpage
- Posters, brochures etc.
- Trade Show Displays
- Information distributed through pharmaceutical manufacture/research associations
- Other (please specify)
Group 6: Ranchers and Farmers

Instructions for Completing the Survey

This survey is intended to help the Texas Commission on Environmental Quality (TCEQ) understand how unused pharmaceuticals approved for use in animals are disposed of by ranchers and farmers in Texas, and what factors impact the decision to dispose of them in a certain way.

This is part of a study being conducted to fulfill the requirements of Senate Bill 1757, passed in the Texas 81st Legislative Session.

This survey should be completed by the person who manages the administration and disposal of unused pharmaceuticals at a farm or ranch in Texas.

Please answer these questions as accurately as possible. There are 10 questions in this survey and it should not take more than 10-15 minutes to complete. One survey should be completed per facility. Surveys are anonymous.

If you have any questions about this survey, please contact Jessica Huybregts at 512-239-4709 or by email at <jhuybreg@tceq.state.tx.us>.

Definitions

Below are definitions for some of the terms used in this survey.

Pharmaceutical: Under the plain and ordinary meaning of the term, a pharmaceutical is considered a “drug”. Basically, pharmaceuticals could be over-the-counter drugs or those that require a prescription to obtain, and they could be solid, aerosol, liquid or a topical (applied externally) substance, but they are not foods or dietary supplements such as a vitamins. Pharmaceuticals, or drugs, also do not include the devices that you may use to administer the drugs, such as syringes. For more information on the definition of a drug, see Chapter 431 of the Texas Food, Drug and Cosmetic Act [§431.002(14)].

Unused: The term unused can include partially or completely unused, unwanted, wasted, or expired substances. These are items that are ultimately NOT dispensed to animals and require disposal or transfer to another location.

Rural County: Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than 50,000. Rural County definition map: http://www.tlc.state.tx.us/pubspol/Rural_Definition/Definition_19_and_20.pdf
Group 6: Ranchers and Farmers - Survey Questions

1. What kind of ranching/farming do you operate?
   - □ Aquaculture
   - □ Cattle
   - □ Equine
   - □ Pork/Swine
   - □ Poultry
   - □ Sheep
   - □ Other (please specify)

2. Is your ranch/farm located in a rural county*?
   [*Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than 50,000. Rural County definition map: http://www.tlc.state.tx.us/pubspol/Rural_Definition/Definition_19_and_20.pdf]
   - □ Yes
   - □ No

3. Do you use pharmaceuticals approved for use in animals (also called drugs or medications, by prescription or over-the-counter; not dietary supplements like vitamins) in your ranching/farming operation?
   - □ Yes
   - □ No – If you answered “No” you have completed the survey. Thank you for your time.

4. Approximately, what proportion of the pharmaceuticals approved for use in animals goes unused at your ranching/farming operation?
   [(1) “Proportion” relates to the amount of pharmaceuticals that were ultimately not administered to your animals, compared to the total amount of pharmaceuticals purchased/onsite for that operation. (2) We understand that you may not keep records of this. If it would help, you could consider the proportion of pharmaceuticals that go unused in a one week or one month.]
   - □ No pharmaceuticals at this ranch/farm operation ever go unused - If you selected “No” you have completed the survey. Thank you for your time.
   - □ 1-10% of pharmaceuticals at this ranch/farm operation go unused
   - □ 11-25% of pharmaceuticals at this ranch/farm operation go unused
   - □ 26-50% of pharmaceuticals at this ranch/farm operation go unused
   - □ >50% of pharmaceuticals at this ranch/farm operation go unused
   - □ I do not know

5. What are the most common reasons why pharmaceuticals approved for use in animals go unused at this ranch/farm operation? (Select up to 3 reasons)
   - □ Pharmaceuticals were expired
Veterinarian changed prescription/dosage (leftover medications)
- Veterinarian discontinued prescribing the pharmaceutical
- Farmer/rancher decided not to continue treatment
- Pharmaceuticals were dropped/spilled
- Excess liquid pharmaceuticals leftover (for example, in pre-filled syringes)
- Animal only required a portion of a solid drug dose (for example, medication was only available in 100 mg dose but only needed 50 mg).
- Other (please specify)

6. **What do you usually do with the unused pharmaceuticals approved for use in animals at this ranch/farm operation? (Select one)**

- Store them onsite
- Return them to the veterinarian/supplier
- Give them to another rancher/farmer
- Dispose of them in the regular trash
- Dispose of them in the sink/toilet
- Arrange for a waste disposal company to pick up the unused pharmaceuticals
- I do not know
- Other (please specify)

7. **Approximately, what quantity of unused pharmaceuticals approved for use in animals do you usually dispose of per month at this ranching/farming operation?**

- Less than 10 partially-filled or full containers/packages
- 10-25 partially-filled or full containers/packages
- 26-50 partially-filled or full containers/packages
- >50 partially-filled or full containers/packages

8. **What are the factors that most impact your decisions about how to dispose of unused pharmaceuticals approved for use in animals generated at this ranch/farm? (Select the top 3 factors)**

- Ease of Disposal/Convenience
- Cost of Disposal
- No other disposal options are available at this location
- Complicated waste disposal regulations
- Compliance with the Standard Operating Procedures or Guidelines of the ranch/farm you operate
- Staff Time Constraints
- Staff Training Constraints
- Staff safety
- Waste minimization
- Perceived environmental outcomes
- Other (please specify)

9. **What are your preferred options for disposal or management of unused pharmaceuticals approved for use in animals? (Select all that apply; answers can be the same as what you currently do with unused pharmaceuticals)**
☐ Dispose of them in the regular trash that goes to a municipal waste landfill.
☐ Dispose of them in the regular trash that stays onsite at the property.
☐ Dispose of them in the sink/toilet.
☐ Return them to the veterinarian/supplier.
☐ Give them to another rancher/farmer.
☐ Arrange for a waste disposal company to pick up the unused pharmaceuticals and dispose of them.
☐ Place unused (non-controlled) pharmaceuticals in special envelopes, available at veterinarians, which you would mail back to a location that would dispose of substances according to best management practices at no cost to me.
☐ Place unused (non-controlled) pharmaceuticals in special envelopes, available at a farm/ranch retail store, which you would mail back to a location that would dispose of substances according to best management practices at no cost to me.
☐ Have a kiosk/box at veterinarian office to be able to drop off unused (non-controlled) pharmaceuticals for disposal according to best management practices at no cost to me.
☐ Have a kiosk/box at a farm/ranch retail store to be able to drop off unused (non-controlled) pharmaceuticals for disposal according to best management practices at no cost to me.
☐ Take (non-controlled) unused pharmaceuticals to a local government household hazardous waste collection facility for disposal according to best management practices at no cost to me.
☐ Take all unused pharmaceuticals to a local community collection event for disposal according to best management practices at no cost to me.
☐ Take all unused pharmaceuticals to an established community or county recycling center that would be able to accept these materials at no cost to me.

10. What is the best way that the State of Texas can provide guidance to ranchers/farmers about how to best dispose of unused pharmaceuticals approved for use in animals?

☐ Provide brochures/posters etc. in veterinarian clinic.
☐ Provide brochures/posters etc. in farm/ranch retail store.
☐ Provide disposal guidelines on pharmaceutical container labels.
☐ Establish a webpage that provides disposal guidelines.
☐ Provide outreach information through current ranch/farmer association resources (such as their newsletters, webpage, meetings, or trade events).
☐ Other (please specify)
Group 7: Consumers

Instructions for Completing the Survey

This survey is intended to help the Texas Commission on Environmental Quality (TCEQ) understand how unused pharmaceuticals are disposed of by consumers or “ultimate users” of over-the-counter and prescription pharmaceuticals in Texas, and what factors impact their decision to dispose of them in a certain way.

This is part of a study being conducted to fulfill the requirements of Senate Bill 1757, passed in the Texas 81st Legislative Session.

THIS SURVEY IS ONLY INTENDED FOR RESIDENTS OF TEXAS.

Please answer these questions as accurately as possible. There are 9 questions in this survey and it should not take more than 10 minutes to complete.

Please complete only one survey per household. Surveys are anonymous.

Definitions

Below are definitions for some of the terms used in this survey.

Pharmaceutical: Simply stated, pharmaceuticals could be over-the-counter drugs or those that require a prescription to obtain, they can be in the solid, liquid or aerosol form, but they are NOT foods or nutritional supplements such as vitamins. For more information, see the definition in Chapter 431 of the Texas Food, Drug and Cosmetic Act [§431.002(14)].

Unused: The term unused can include partially or completely unused, unwanted, wasted, or expired substances. These are items that are NOT used and ultimately require disposal.

Ultimate User: This is the person or animal (for example, the household pet) that the pharmaceutical is intended for.
Group 7: Consumers - Survey Questions

1. Is your household located in a Texas rural county*?
[*Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than 50,000. Rural County definition map: http://www.tlc.state.tx.us/pubspol/Rural_Definition/Definition_19_and_20.pdf]
- Yes
- No

2. Does any person or pet in your household use pharmaceuticals (also called drugs or medications, by prescription or over-the-counter; not dietary supplements like vitamins)?
- Yes – The household usually uses 5 or less different types of pharmaceuticals at one time.
- Yes – The household usually uses more than 5 different types of pharmaceuticals at one time.
- No – If you answered “No” you have completed the survey. Thank you for your time.

3. Approximately, what proportion of the pharmaceuticals go unused in your household?
[Notes: (1) “Proportion” relates to the volume of pharmaceuticals that were ultimately not used, compared to the total volume of pharmaceuticals purchased. (2) We understand that you may not keep records of this. If it would help, please consider the amount of pharmaceuticals that go unused in a one month, or one year.]
- No pharmaceuticals in this household ever go unused - If you selected “No” you have completed the survey. Thank you for your time.
- 1-10% of pharmaceuticals in this household usually go unused
- 11-25% of pharmaceuticals in this household usually go unused
- 26-50% of pharmaceuticals in this household usually go unused
- >50% of pharmaceuticals in this household usually go unused
- I do not know

4. What is the most common reason why pharmaceuticals usually go unused in your household?
- Pharmaceuticals expired (the quantity purchased was not used by the suggested “use-by date”).
- Physician or veterinarian changed prescription/dosage (unused medications leftover).
- Physician or veterinarian advised ultimate user to stop using the pharmaceutical.
- Ultimate user experienced an adverse reaction to the pharmaceutical.
- Ultimate user decided not to continue treatment.
- Ultimate user’s symptoms/illness ceased.
- Pharmaceuticals were dropped/spilled.
Excess liquid pharmaceuticals leftover from pre-filled syringes.
- Ultimate user only required a portion of a solid drug dose (for example, medication was only available in 100 mg dose but only needed 50 mg).
- Unused pharmaceuticals were transferred from deceased or ill family member’s home.
- Other (please specify)

5. **What do you usually do with the unused pharmaceuticals in your household?**

- Store them in the house for potential future use (If you selected this option, please continue to question 7).
- Return them to a pharmacy.
- Return them to a veterinarian.
- Give them to family member or friend.
- Give them to law enforcement.
- Dispose of them in the regular trash (which is collected by disposal service).
- Dispose of them in the regular trash that stays onsite at the property.
- Dispose of them in the sink/toilet.
- Dispose of them at a regular community pharmaceutical collection event.
- Dispose of them at a local household hazardous waste collection facility.
- Other (please specify)

6. **Approximately, what quantity of unused pharmaceuticals in your household do you usually dispose of or transfer to another location per month?**

- Less than 10 partially-filled or full containers/packages
- 10-25 partially-filled or full containers/packages
- 26-50 partially-filled or full containers/packages
- >50 partially-filled or full containers/packages

7. **What factors most impact your decision about how to dispose of or manage unused pharmaceuticals in your household? (Select up to 3 factors)**

- Convenience/ease of disposal.
- Cost.
- Desire to avoid risk of accidental poisoning.
- Desire to avoid risk of drug misuse/abuse.
- Safety (for example, want to avoid handling unused pharmaceuticals).
- Desire to minimize pharmaceuticals in wastewater.
- Desire to minimize pharmaceuticals in surface water.
- Desire to minimize pharmaceuticals in landfills.
- High cost of purchasing pharmaceuticals.
- Lack of other preferable options.
- Other (please specify)

8. **What are your preferred options for disposal or management of unused pharmaceuticals? (Select all that apply; answers can be the same as what you currently do with unused pharmaceuticals.)**

- Store unused pharmaceuticals in the house for potential future use.
☐ Give unused pharmaceuticals to family member or friend.
☐ Give unused pharmaceuticals directly to law enforcement.
☐ Dispose of unused pharmaceuticals in the regular household trash.
☐ Dispose of unused pharmaceuticals in the sink/toilet.
☐ Place unused pharmaceuticals in specialized envelopes, available at some retail pharmacies or physicians/veterinarians office, which would be mailed back to a disposal location.
☐ Drop off unused pharmaceuticals in a kiosk/box at a physician/veterinarian office.
☐ Drop off unused pharmaceuticals in a kiosk/box at a retail pharmacy.
☐ Drop off unused pharmaceuticals in a kiosk/box at a law enforcement office.
☐ Drop off unused pharmaceuticals at a semi-regular community pharmaceutical-only collection event.
☐ Drop off unused pharmaceuticals at a local household hazardous waste collection facility.
☐ Other (please specify)

9. What is the best way that the State can provide guidance to households about how to dispose of their unused pharmaceuticals?

☐ Provide brochures/posters etc. in physician/veterinarian clinic.
☐ Provide brochures/posters etc. in retail pharmacy.
☐ List disposal guidelines on pharmaceutical container labels.
☐ Establish a webpage that provides disposal guidelines.
☐ Provide outreach information through local governments, water/wastewater utility providers or community groups (such as newsletters, meetings, community events).
☐ Radio, TV, social media campaign.
☐ Other (please specify)
Group 8: Home Health and Hospice Service Providers (In-home and In-patient setting)

Instructions for Completing the Survey

This survey is intended to help the Texas Commission on Environmental Quality (TCEQ) understand how unused pharmaceuticals are disposed of by home health and hospice service providers in Texas, how they advise patients to dispose of their unused pharmaceuticals, and what factors impact the decision to dispose of them in a certain way.

This is part of a study being conducted to fulfill the requirements of Senate Bill 1757, passed in the Texas 81st Legislative Session.

This survey should be completed by staff that directs the management and disposal of unused pharmaceuticals by home health service and hospice providers who provide a service in an individual’s home and inpatient settings in Texas.

If your home health service has its own pharmacy, the pharmacy will receive a separate survey. There is also a separate survey for Long Term Care Facilities which is intended for assisted living communities and nursing homes.

Please answer these questions as accurately as possible. There are 10 questions in this survey and it should not take more than 10-15 minutes to complete. One survey should be completed per home health service or hospice provider. Surveys are anonymous.

If you have any questions about this survey, please contact Jessica Huybregts at 512-239-4709 or by email at <jhuybreg@tceq.state.tx.us>.

Definitions

Below are definitions for some of the terms used in this survey.

Pharmaceutical: Under the plain and ordinary meaning of the term, a pharmaceutical is considered a “drug”. Plainly stated, pharmaceuticals could be over-the-counter drugs or those that require a prescription to obtain, they can be in the solid, liquid or aerosol form, but they are not foods or nutritional supplements. For more information, see the definition of “drug” in Chapter 431 of the Texas Food, Drug and Cosmetic Act [§431.002(14)].

Controlled substance: The term controlled substance has the meaning given in Chapter 481 (Texas Controlled Substances Act) of the Health and Safety Code, which is consistent with the definition in section 802(6) of Title 21, United States Code (U.S.C.).

Prescription drug: The term prescription drug has the meaning given in Chapter 431 (Texas Food, Drug and Cosmetic Act) of the Health and Safety Code, which
lists the meaning assigned by section 203.3 of Title 21 Code of Federal Regulations. Under that definition, a prescription drug means any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by Federal law (including Federal regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the act.

Unused: The term unused can include partially or completely unused, unwanted, wasted, or expired substances. These are items that are not ultimately used and require disposal or transfer to another location.

Rural County: Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than 50,000. Rural County definition map: http://www.tlc.state.tx.us/pubspol/Rural_Definition/Definition_19_and_20.pdf

Home and community support services agency (HCSSA): A person who provides home health, hospice, or personal assistance services for pay or other consideration in a client's residence, an independent living environment, or another appropriate location. This definition is from Title 40 Texas Administrative Code Chapter 97 §97.2(42).

Home health service: The provision of one or more of the following health services required by an individual in a residence or independent living environment:

(A) nursing, including blood pressure monitoring and diabetes treatment;
(B) physical, occupational, speech, or respiratory therapy;
(C) medical social service;
(D) intravenous therapy;
(E) dialysis;
(F) service provided by unlicensed personnel under the delegation or supervision of a licensed health professional;
(G) the furnishing of medical equipment and supplies, excluding drugs and medicines; or
(H) nutritional counseling.

This definition is from Title 40 Texas Administrative Code Chapter 97 §97.2(45).

Hospice: A person licensed to provide hospice services, including a person who owns or operates a residential unit or an inpatient unit. This definition is from Title 40 Texas Administrative Code Chapter 97 §97.2(46).

Hospice services: Services, including services provided by unlicensed personnel under the delegation of a registered nurse or physical therapist, provided to a client or a client's family as part of a coordinated program. These services
include palliative care for terminally ill clients and support services for clients and their families that:

(A) are available 24 hours a day, seven days a week, during the last stages of illness, during death, and during bereavement;

(B) are provided by a medically directed interdisciplinary team; and

(C) may be provided in a home, nursing facility, residential unit, or inpatient unit according to need. These services do not include inpatient care normally provided in a licensed hospital to a terminally ill person who has not elected to be a hospice client. This definition is from Title 40 Texas Administrative Code Chapter 97 §97.2(47).
Group 8: Home Health and Hospice Service Providers (In-home and In-patient setting) - Survey Questions

1. What type of service do you provide?
   - [ ] Home and community support services agency (HCSSA) Hospice
   - [ ] HCSSA Home Health Service
   - [ ] Inpatient Hospice

2. Does your operation provide services in a rural county*?
   - [ ] Yes
   - [ ] No

[*Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than 50,000. Rural County definition map: http://www.tlc.state.tx.us/pubspol/Rural_Definition/Definition_19_and_20.pdf]

3. In your profession as an home health and hospice service provider, select the top three most common types of unused pharmaceuticals (within patient’s homes, within the hospice or at your office) that require disposal.
   - [ ] Liquid controlled substances contained within unused (or partially used) syringes
   - [ ] Liquid prescription pharmaceuticals contained within unused (or partially used) syringes
   - [ ] Liquid controlled substances contained within unused (or partially used) IV bags
   - [ ] Liquid prescription pharmaceuticals contained with unused (or partially used) IV bags
   - [ ] Solid dose pills – controlled substances
   - [ ] Solid dose pills – prescription pharmaceuticals
   - [ ] Solid dose pills – over-the-counter pharmaceuticals (no prescription required)
   - [ ] Topicals (administered on the skin surface)
   - [ ] Aerosols
   - [ ] Not applicable – patients never have unused pharmaceuticals.

4. For home health or hospice service providers who do not provide, or carry any ownership of, pharmaceuticals administered to/by patients, what do you usually advise patients do with their unused pharmaceuticals?
   - [ ] We do not advise patients about how they should dispose of their unused pharmaceuticals.
   - [ ] We advise patients to dispose of their unused pharmaceuticals in the toilet/sink.
   - [ ] We advise patients to dispose of their unused pharmaceuticals in the household trash.
   - [ ] We advise patients to contact a State government agency for disposal guidance.
   - [ ] We advise patients to drop off their unused pharmaceuticals with law enforcement.
   - [ ] We advise patients to return their unused pharmaceuticals to their retail pharmacy.
   - [ ] We advise patients to give their unused pharmaceuticals to a family member for disposal.
We advise patients to store their unused pharmaceuticals in their house for possible future use.
☐ I do not know.
☐ Not applicable – patients never have unused pharmaceuticals.
☐ Other (please specify)

5. Approximately (and on average), how many pharmaceutical bottles/containers/full or partial syringes, containing some amount of unused pharmaceuticals, do you witness being disposed of per week by your patients?
☐ Not applicable – patients never have unused pharmaceuticals.
☐ Less than 10 partially-filled or full containers/packages/syringes.
☐ 10-25 partially-filled or full containers/packages/syringes.
☐ 26-50 partially-filled or full containers/packages/syringes.
☐ >50 partially-filled or full containers/packages/syringes.

6. For home health or hospice service providers who store some pharmaceuticals in their offices for administration to patients, how do you usually dispose of the unused pharmaceuticals leftover at your office (for example, those that expire or are re-called)?
☐ Dispose of them all in the regular trash (municipal solid waste).
☐ Dispose of them all in the toilet/sink.
☐ Dispose of them all in a "red-bag” or “bio-hazard” container and arrange for a waste disposal service to collect and dispose of those.
☐ Co-mingle all unused pharmaceuticals and arrange for a waste disposal company to dispose of them all at a Hazardous Waste Landfill/Hazardous Waste Incinerator.
☐ Co-mingle all unused pharmaceuticals and arrange for a waste disposal company to dispose of them but am unaware of the disposal method.
☐ Separate controlled pharmaceuticals from non-controlled pharmaceuticals, dispose of controlled substances in the toilet/sink and dispose of non-controlled substances in municipal trash.
☐ Separate controlled pharmaceuticals from non-controlled pharmaceuticals, dispose of controlled substances in the toilet/sink and dispose of (or arrange for disposal of) non-controlled substances at a Hazardous Waste Landfill/Hazardous Waste Incinerator.
☐ Separate controlled pharmaceuticals from non-controlled pharmaceuticals, dispose of controlled substances in the toilet/sink and dispose of (or arrange for disposal of) non-controlled substances in a permitted Medical Waste Incinerator.
☐ Separate controlled pharmaceuticals from non-controlled pharmaceuticals, dispose of controlled substances in an incinerator and dispose of (or arrange for disposal of) non-controlled substances in municipal trash.
☐ Separate controlled pharmaceuticals from non-controlled pharmaceuticals, dispose of controlled substances in an incinerator and dispose of (or arrange for disposal of) non-controlled substances in toilet/sink.
☐ I do not know
☐ Not applicable – there are never unused pharmaceuticals leftover at the office that require disposal.
☐ Other (please specify)
7. What are the most significant factors that impact how you advise your patients to dispose of their unused pharmaceuticals? (select up to 3 factors)

- Ease of disposal/Convenience
- Cost
- Drug-diversion concerns
- Accidental poisoning concerns
- Staff time constraints
- Staff training constraints
- Drug Enforcement Administration (DEA) Policy (Controlled Substances Act)
- Compliance with Health and Safety Code or Texas Administrative Code
- Unclear about best management/disposal practices
- Home Care Provider Service Guidelines/Standard Operating Procedures
- Perceived better environmental outcomes
- Waste minimization
- Other (please specify)

8. What are the most significant factors that impact your decision to choose the methods your company employs for disposing of unused pharmaceuticals stored at your office? (select up to 3 factors)

- Ease of disposal/Convenience
- Cost of disposal
- Drug-diversion concerns
- Accidental poisoning concerns
- Lack of proximity to disposal service options
- Staff time constraints
- Staff training constraints
- Staff safety concerns
- Drug Enforcement Administration (DEA) Policy (Controlled Substances Act)
- Compliance with Health and Safety Code or Texas Administrative Code
- Unsure about best management/disposal practices
- Home Care Provider Service Guidelines/Standard Operating Procedures
- Perceived better environmental outcomes
- Waste minimization
- Other (please specify)

9. What are your preferred options for advising or helping to manage patient’s unused pharmaceuticals? (select your top 3 preferred options)

- We would prefer not to advise patients about how they should dispose of their unused pharmaceuticals.
- We would prefer to advise patients dispose of their unused pharmaceuticals in the toilet/sink.
- We would prefer to advise patients dispose of their unused pharmaceuticals in the household trash.
- We would prefer to advise patients (or their family members) to contact a State government agency for disposal guidance.
- We would prefer to advise patients to drop off their unused pharmaceuticals with law enforcement.
We would prefer to advise that patients return their unused pharmaceuticals to their retail pharmacy.

We would prefer to advise patients to give their unused pharmaceuticals to a family member for disposal.

We would prefer to advise patients to store their unused pharmaceuticals in their house for possible future use.

We would prefer to provide a mailing envelope to patients so that they can mail their unused pharmaceuticals to an appropriate disposal location/service.

We would prefer to provide patients with a brochure about how they should dispose of their unused pharmaceuticals.

We would prefer to be able to collect the patient’s unused pharmaceuticals and have them disposed of by a disposal service.

I do not know.

Other (please specify)

10. **What are your preferred options for disposal or management of unused pharmaceuticals leftover at your office? (select your top 3 preferred options)**

- Dispose of pharmaceuticals in the regular trash (municipal solid waste).
- Dispose of pharmaceuticals onsite in the sink/toilet.
- Arrange for a waste disposal company to dispose of them according to minimum State/Federal requirements.
- Consider all unused pharmaceuticals as medical waste (red-bag” or “bio-hazard” waste) and arrange for disposal of them as such.
- Focus on waste minimization – do not use pre-filled/manufactured syringes/IV bags.
- Focus on waste minimization – better medication storage practices (for example, better sorting to reduce the possibility of pharmaceuticals becoming expired while on the shelf).
- Brochures/posters/other materials provided to facility by the State of Texas regarding the best management disposal practices.
- Other (please specify)
**Instructions for Completing the Survey**

The survey is intended to help the Texas Commission on Environmental Quality (TCEQ) understand the concerns drinking water and wastewater utilities have related to pharmaceuticals, if and how water and wastewater utilities are (or would like to be) involved in disposal of unused pharmaceuticals.

This survey is part of a study being conducted to fulfill the requirements of Senate Bill 1757, passed in the Texas 81st Legislative Session.

This survey should be completed by a Director, President or another senior staff member at a drinking water or wastewater utility in Texas (including municipalities).

**THIS SURVEY IS ONLY INTENDED FOR DRINKING WATER AND WASTEWATER UTILITIES PHYSICALLY LOCATED WITHIN TEXAS.**

Please answer these questions as accurately as possible. There are 10 questions in this survey and it should not take more than 10-15 minutes to complete. One survey should be completed per utility. Surveys are anonymous.

Some questions relate to wastewater utilities, some to drinking water utilities and some to both. Please answer those questions appropriate to your situation.

If you have any questions about this survey, please contact Jessica Huybregts at 512-239-4709 or by email at <jhuybreg@tceq.state.tx.us>.

**Definitions**

Below are definitions for some of the terms used in this survey.

Pharmaceutical: Under the plain and ordinary meaning of the term, a pharmaceutical is considered a “drug”. Plainly stated, pharmaceuticals could be over-the-counter drugs or those that require a prescription to obtain, they can be in the solid, liquid or aerosol form, but they are not foods or nutritional supplements. For more information, see the definition of “drug” in Chapter 431 of the Texas Food, Drug and Cosmetic Act [§431.002(14)].

Unused: The term unused can include partially or completely unused, unwanted, wasted, or expired substances. These are items that are ultimately NOT used and require disposal or transfer to another location.

Rural County: Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than 50,000. Rural County definition map: http://www.tlc.state.tx.us/pubspol/Rural.Definition/Definition_19_and_20.pdf
Group 9: Drinking Water and Wastewater Utilities - Survey Questions

1. Is your utility located in a Texas rural county*?

[*Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than 50,000. Rural County definition map: http://www.tlc.state.tx.us/pubspol/Rural_Definition/Definition_19_and_20.pdf]

☐ Yes
☐ No

2. Wastewater Utilities Only: Which of the following operations/facilities does your utility require pre-treatment of wastewater discharges, with the intended purpose of removing pharmaceutical compounds?

☐ Not applicable. We do not request any dischargers to pre-treat their wastewater for the purpose of removing pharmaceutical compounds.
☐ Hospitals
☐ Health-care Clinics
☐ Veterinary Practices
☐ Long-Term Care Facilities (Assisted Living/Nursing Homes)
☐ Hospice Providers
☐ Educational Institutions
☐ Pharmaceutical Research Institutions
☐ Pharmaceutical Manufacturers
☐ Law Enforcement Offices
☐ Other (please specify)

3. Wastewater Utilities Only: What do you do with the biosolids (also known as sewage sludge) that result from the wastewater treatment plant processes?

☐ Transfer to municipal solid waste landfill
☐ Land application (on land owned by utility)
☐ Land application (owned by another entity)
☐ Sell/donate biosolids to landscaping company
☐ Sell/donate biosolids to other entity
☐ Other (please specify)

4. Wastewater & Drinking Water Utilities: Have you changed your treatment techniques specifically due to concerns or difficulties removing pharmaceutical compounds from wastewater or water?

☐ Yes
☐ No – however the utility intends to change their treatment techniques within the next 5 years to specifically remove pharmaceuticals and other emerging contaminants.
☐ No – the utility will wait for the United State Environmental Protection Agency or the State of Texas to require treatment for pharmaceutical compounds or to regulate pharmaceuticals in drinking water or wastewater before considering treatment change decisions.
☐ No – the utility is a drinking water utility that does not treat their own water (the utility purchases treated water and re-distributes it without further treatment).

5. **Wastewater & Drinking Water Utilities: Has your utility ever collected samples and had them analyzed for the presence of pharmaceutical compounds?**
   - ☐ Yes – the utility conducted studies related to wastewater only.
   - ☐ Yes – the utility conducted studies related to drinking water only.
   - ☐ Yes – the utility conducted studies related to both wastewater and drinking water.
   - ☐ No

6. **Has your utility ever hosted or supported any kind of pharmaceutical collection or “take-back” event, designed to collect unused pharmaceuticals from residents?**
   - ☐ Yes – the utility hosted or supported an event which was solely for pharmaceutical collection.
   - ☐ Yes – the utility hosted or supported a pharmaceutical take-back event in conjunction with a Household Hazardous Waste event.
   - ☐ Yes – the utility supports an ongoing program involving unused pharmaceutical collection boxes (drop box or “kiosk”) in pharmacies.
   - ☐ Yes – the utility supports an ongoing program involving unused pharmaceutical collection boxes at other types of operations.
   - ☐ No
   - ☐ Other (please specify)

7. **If you answered “yes” in question 6, what is the main reason for being involved in the pharmaceutical take back event?**
   - ☐ Customer concerns related to pharmaceuticals in their drinking water.
   - ☐ Customer concerns related to pharmaceuticals in waterways (rivers/streams).
   - ☐ Customer concerns related to the potential for accidental poisonings.
   - ☐ Customer concerns related to the misuse/abuse of pharmaceuticals.
   - ☐ Customer concerns about disposing of pharmaceuticals in landfills (via household trash collection/disposal).
   - ☐ Customer concerns about disposing of pharmaceuticals in the toilet or sink.
   - ☐ The utility’s concerns about the occurrence of pharmaceuticals in the drinking water supply.
   - ☐ The utility’s concerns about the occurrence of pharmaceuticals in waterways.
   - ☐ The utility’s concerns related to the potential for accidental poisonings.
   - ☐ The utility’s concerns related to the misuse/abuse of pharmaceuticals.
   - ☐ The utility’s concerns about disposing of pharmaceuticals in landfills (via household trash collection/disposal).
   - ☐ As a pollution prevention approach intended to reduce the concentration of pharmaceuticals entering the wastewater, which can be difficult to remove during treatment.
   - ☐ The utility was asked to provide financial support to another entity hosting the event and did so to support the local community.
   - ☐ Other (please specify)
8. If you answered “yes” in question 6 (if the utility was involved in a pharmaceutical collection event/program), how did/does the utility, or waste management company contracted by the utility, dispose of the collected pharmaceuticals?

- All in Municipal Solid Waste Landfill.
- All treated as Medical Waste then disposed of in a Municipal Solid Waste Landfill.
- All in Hazardous Waste Landfill.
- All in Hazardous Waste Incinerator.
- All in Medical Waste Incinerator.
- All in toilet/sink.
- Separated hazardous from non-hazardous wastes, and disposed of hazardous in Hazardous Waste Landfill and non-hazardous in Municipal Solid Waste Landfill.
- Separated hazardous from non-hazardous wastes, and disposed of hazardous in Hazardous Waste Incinerator and non-hazardous in Municipal Solid Waste Landfill.
- Separated hazardous from non-hazardous wastes, and disposed of hazardous in Medical Waste Incinerator and non-hazardous in Municipal Solid Waste Landfill.
- I do not know.
- Other (please specify)

9. What factors limit the feasibility (ability or desire) of your utility from being involved in efforts to collect and dispose of unused pharmaceuticals from residents in the future?

- Monetary Cost.
- Staff time.
- Organization/effort required.
- Complicated pharmaceutical disposal/handling regulations/requirements.
- Little demand from residents.
- Lack of support by utility decision-makers.
- Pharmaceutical take-back events are not core functions of utilities.
- Unsure about the impact that take-back events have on pharmaceuticals in water.
- Unsure about the impact that low concentrations of pharmaceuticals have on aquatic species or other organisms.
- There is no need to prevent pharmaceuticals entering wastewater because pharmaceuticals are not regulated in water or wastewater.
- Other (please specify)

10. What is the best way that the State of Texas can provide information to the utility regarding pharmaceuticals in wastewater, drinking water, other parts of the environment, treatment technologies and recommendations for best practices of disposing of unused pharmaceuticals?

- Posters
- Brochures
- “How to” guidance document for water and wastewater utilities
- Webpage
- Trade Show Displays
- Presentations at utility association meetings
- Information through existing utility association resources (webpage/newsletters)
- Other (please specify)
Group 10: Local Governments (Solid Waste)

Instructions for Completing the Survey

This survey is intended to help the Texas Commission on Environmental Quality (TCEQ) understand what concerns local governments have related to pharmaceuticals, if and how local governments are (or would like to be) involved in efforts to dispose of unused pharmaceuticals.

This is part of a study being conducted to fulfill the requirements of Senate Bill 1757, passed in the Texas 81st Legislative Session (2009).

This survey should be completed by a Solid Waste Manager, another senior staff member of a local government, or at another governmental entity (i.e. utility district) that manages solid waste, including but not limited to household hazardous waste.

THIS SURVEY IS ONLY INTENDED FOR ENTITIES LOCATED WITHIN TEXAS.

Please answer these questions as accurately as possible. There are 10 questions in this survey and it should not take more than 10-15 minutes to complete. One survey should be completed per local government. Surveys are anonymous.

A different survey has been created for the drinking water/wastewater utility aspect within local government operations, thus you may eventually receive and should answer two surveys with different objectives.

If you have any questions about this survey, please contact Jessica Huybregts at 512-239-4709 or by email at <jhuybreg@tceq.state.tx.us>.

Definitions

Below are definitions for some of the terms used in this survey.

Pharmaceutical: Under the plain and ordinary meaning of the term, a pharmaceutical is considered a “drug”. Plainly stated, pharmaceuticals could be over-the-counter drugs or those that require a prescription to obtain, they can be in the solid, liquid or aerosol form, but they are not foods or nutritional supplements. For more information, see the definition of “drug” in Chapter 431 of the Texas Food, Drug and Cosmetic Act [§431.002(14)].

Unused: The term unused can include partially or completely unused, unwanted, wasted, or expired substances. These are also items that are ultimately NOT used and require disposal or transfer to another location.

Rural County: Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than 50,000. Rural County definition map: http://www.tlc.state.tx.us/pubspol/Rural_Definition/Definition_19_and_20.pdf
Controlled Substance: A controlled substance is a substance, including a drug, an adulterant, and a dilutant, listed in Schedules I through V or Penalty Groups 1, 1-A, or 2 through 4 in Chapter 481 (Texas Controlled Substances Act) of the Health and Safety Code, which is consistent with the definition in section 802(6) of Title 21, United States Code (U.S.C.). A prescription is required to obtain a controlled substance and, once obtained from a veterinarian/physician, it must not be transferred to anyone else except law enforcement.
Group 10: Local Governments (Solid Waste) - Survey Questions

1. Is your local government/entity located in a Texas rural county*?

[*Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than 50,000. Rural County definition map: http://www.tlc.state.tx.us/pubspol/Rural_Definition/Definition_19_and_20.pdf]

- [ ] Yes
- [ ] No

2. What guidance does the local government/other entity provide to residents/customers about how to dispose of their unused pharmaceuticals?

- [ ] We do not provide guidance and we never receive inquiries from residents/customers about how they should dispose of their unused pharmaceuticals. (If selected, continue to question 3.)
- [ ] Residents/customers ask for advice about how they should dispose of their unused pharmaceuticals, but we choose to not provide guidance. (If selected, continue to question 3.)
- [ ] We advise residents/customers dispose of their unused pharmaceuticals in the toilet/sink. (If selected, go to question 4.)
- [ ] We advise residents/customers dispose of their unused pharmaceuticals in the household trash. (If selected, go to question 4.)
- [ ] We advise residents/customers dispose of their unused pharmaceuticals in the household trash and follow Federal Guidance when doing so (remove from original container, mix with undesirable substance and conceal). (If selected, go to question 4.)
- [ ] We advise residents/customers contact another government agency (for example Texas Commission on Environmental Quality, or Department of State Health Services). (If selected, go to question 4.)
- [ ] We advise residents/customers dispose of their unused pharmaceuticals at a household hazardous waste collection facility/event. (If selected, go to question 4.)
- [ ] We advise residents/customers dispose of their unused pharmaceuticals at a pharmaceutical-only collection event. (If selected, go to question 4.)
- [ ] We advise residents/customers return unused pharmaceuticals to their pharmacy. (If selected, go to question 4.)
- [ ] We advise residents/customers return unused pharmaceuticals to a law enforcement official. (If selected, go to question 4.)
- [ ] I do not know.
- [ ] Other (please specify)

3. If your local government/other entity chooses to not provide guidance to residents/customers about how to dispose of their unused pharmaceuticals, what is the main reason for that decision?

- [ ] There is little to no demand for that information from residents/customers.
- [ ] We lack information on recommended disposal practices.
We have a lack of understanding/confusion about the regulatory requirements of desired disposal practices.

We lack the staff time to generate/provide the guidance.

It is too expensive to deliver the information to residents/customers.

We do not agree with current disposal guidance and therefore choose not to promote it.

It is not an objective/goal of the local government to provide that information.

I do not know.

Other (please specify)

4. Which unused pharmaceuticals does your local government/other entity collect from residents/customers?

- Not applicable – we do not collect any unused pharmaceuticals from residents/customers. (If selected, go to question 8).
- Anything included in a resident's household trash would be collected as part of the solid waste collection service.
- All unused pharmaceuticals brought to the local government by the resident are collected and disposed of or transferred offsite for disposal.
- All non-controlled pharmaceuticals brought to the local government by the resident are collected and disposed of or transferred offsite for disposal.
- Non-hazardous, non-controlled pharmaceuticals brought to the local government/other entity by the resident are collected and disposed of or transferred offsite for disposal.
- I do not know.
- Other (please specify)

5. How does your local government/other entity collect unused pharmaceuticals from residents/customers (for the purpose of disposal)?

- We only collect unused pharmaceuticals from residents/customers that may be collected during the regular household trash collection.
- We host or support a regular, semi-regular or irregular collection event which is solely for pharmaceutical collection.
- We host or support a regular, semi-regular or irregular pharmaceutical take-back event which is run in conjunction with a Household Hazardous Waste event.
- We collect unused pharmaceuticals for disposal at a permanent Household Hazardous Waste facility.
- We support an ongoing program involving unused pharmaceutical collection boxes (drop box or “kiosk”) in pharmacies or other permanent facilities located within our jurisdictional boundaries.
- We provide mail-back envelopes for residents/customers so that they can mail their unused pharmaceuticals to a central location for disposal.
- I do not know.
- Other (please specify)

6. What does your local government/other entity do with the unused pharmaceuticals that are brought to you by residents/customers?

- Not applicable – we do not accept any unused pharmaceuticals specifically brought to us by residents/customers.
We separate hazardous substances and controlled substances from non-hazardous / non-controlled wastes (or have another entity sort them), and dispose of hazardous in a Hazardous Waste Landfill, controlled substances through law enforcement and non-hazardous / non-controlled substances in a Municipal Solid Waste Landfill.

We separate hazardous and controlled substances from non-hazardous / non-controlled substance wastes (or have another entity sort them), and dispose of hazardous in a Hazardous Waste Incinerator, controlled substances through law enforcement, and non-hazardous / non-controlled substance wastes in a Municipal Solid Waste Landfill.

We arrange for disposal of them all at a Municipal Solid Waste Landfill.

We arrange for them all to be treated as Medical Waste then dispose of them in a permitted Municipal Solid Waste Landfill.

We arrange for disposal of them all at a permitted Hazardous Waste Landfill/Hazardous Waste Incinerator.

We arrange for disposal of them all at a permitted Medical Waste Incinerator.

We reject controlled substances, then dispose of the remainder of the unused pharmaceuticals in the Municipal Solid Waste Landfill.

We reject controlled substances, then dispose of the remainder of the unused pharmaceuticals at a permitted Hazardous Waste Landfill/Hazardous Waste Incinerator.

We identify and reject controlled substances, then dispose of the remainder of the unused pharmaceuticals at a permitted Medical Waste Incinerator.

I do not know.

Other (please specify)

7. **What is the main reason for choosing to be involved in the collection of unused pharmaceuticals from residents/customers (for the purpose of disposal)?**

- Residents'/customers’ concerns related to pharmaceuticals in waterways (rivers/streams/aquatic life).
- Residents'/customers’ concerns related to pharmaceuticals in drinking water.
- Residents'/customers’ concerns related to the potential for accidental poisonings (if unused pharmaceuticals are stored or accumulated in the household).
- Residents'/customers’ concerns related to the misuse/abuse of pharmaceuticals (if unused pharmaceuticals are stored or accumulated in the household).
- Residents'/customers’ concerns about disposing of pharmaceuticals in landfills (via household trash collection/disposal).
- Residents'/customers’ concerns about disposing of pharmaceuticals in the toilet/sink.
- The local government’s concerns about the occurrence of pharmaceuticals in drinking water.
- The local government’s concerns about the occurrence of pharmaceuticals in waterways (rivers/streams/aquatic life).
- The local government’s concerns related to the potential for accidental poisonings (if unused pharmaceuticals are stored or accumulated in the household).
- The local government’s concerns related to the misuse/abuse of pharmaceuticals (if unused pharmaceuticals are stored or accumulated in the household).
- The local government’s concerns about disposing of pharmaceuticals in landfills (via household trash collection/disposal).
As a pollution prevention approach intended to reduce the concentration of pharmaceuticals entering the wastewater, which can be difficult to remove during wastewater treatment.

I do not know.

Other (please specify)

8. What factors limit the feasibility (ability or desire) of a local government or other entity being involved in efforts to collect and dispose of unused pharmaceuticals from residents/customers in the future?

- Monetary Cost.
- Staff time.
- Organization/effort required.
- Lack of understanding/complicated pharmaceutical disposal/handling regulations/requirements.
- Little demand from residents.
- Lack of support by local government decision-makers.
- Pharmaceutical take-back events are not core functions of the solid waste department of local governments.
- Unsure about the impact that take-back events have on pharmaceuticals in water.
- Unsure about the impact that low concentrations of pharmaceuticals have on aquatic species or other organisms.
- There is no need to prevent pharmaceuticals entering wastewater because pharmaceuticals are not regulated in water or wastewater.

Other (please specify)

9. What is your local government's desired approach to manage or dispose of unused pharmaceuticals from residents/customers (your answer can be the same as what is currently undertaken)?

- Our local government desires not to collect any unused pharmaceuticals from residents/customers (outside of what may be collected during the regular household trash collection), and does NOT desire to offer guidance on how residents/customers should dispose of them.
- Our local government desires not to collect any unused pharmaceuticals from residents/customers (outside of what may be collected during the regular household trash collection), BUT desires to provide guidance based on Federal or State best practices and guidance.
- Our local government desires to host or support a regular, semi-regular or irregular collection event which is solely for pharmaceutical collection.
- Our local government desires to host or support a regular, semi-regular or irregular pharmaceutical take-back event which is in conjunction with our Household Hazardous Waste collection events.
- Our local government desires to collect unused pharmaceuticals from residents/customers (for disposal) at our permanent Household Hazardous Waste facility.
- Our local government desires to support an ongoing program involving unused pharmaceutical collection boxes (drop box or “kiosk”) in pharmacies or other permanent facilities located within our jurisdictional boundaries.
Our local government desires to provide mail-back envelopes for residents/customers so that they can mail their unused pharmaceuticals to a central location for disposal.

I do not know.

Other (please specify)

10. What is the best way that the State of Texas can provide information to local governments regarding pharmaceuticals in the environment and best practices of disposing of unused pharmaceuticals?

- Posters
- Brochures
- TCEQ Webpage
- Trade Show Displays
- Guidance documents (e.g. 1-page information sheet)
- Presentations at association meetings
- Information provided via existing webpage/newsletters/other sources available through local government associations or other groups (for example, Texas Municipal League, Council’s of Government, Solid Waste Management Association, Earth 911).

Other (please specify)
Group 11: Law Enforcement

Instructions for Completing the Survey

This survey is intended to help the Texas Commission on Environmental Quality (TCEQ) understand how unused pharmaceuticals are disposed of by law enforcement in Texas, and what factors impact the decision to dispose of them in a certain way.

This is part of a study being conducted to fulfill the requirements of Senate Bill 1757, passed in the Texas 81st Legislative Session.

This survey should be completed by a senior staff person in the law enforcement office who directs the management and disposal of unused pharmaceuticals that come into their possession as part of their law enforcement duties.

THIS SURVEY ONLY APPLIES TO LAW ENFORCEMENT IN TEXAS.

Please answer these questions as accurately as possible. There are 10 questions in this survey and it should not take more than 10-15 minutes to complete. One survey should be completed per law enforcement office. Surveys are anonymous.

If you have any questions about this survey, please contact Jessica Huybregts at 512-239-4709 or by email at <jhuybreg@tceq.state.tx.us>

Definitions

Below are definitions for some of the terms used in this survey.

Pharmaceutical: Under the plain and ordinary meaning of the term, a pharmaceutical is considered a “drug”. Plainly stated, pharmaceuticals could be over-the-counter drugs or those that require a prescription to obtain, they can be in the solid, liquid or aerosol form, but they are not foods or nutritional supplements. For more information, see the definition of “drug” in Chapter 431 of the Texas Food, Drug and Cosmetic Act [§431.002(14)].

Controlled substance: The term controlled substance has the meaning given in Chapter 481 (Texas Controlled Substances Act) of the Health and Safety Code, which is consistent with the definition in section 802(6) of Title 21, United States Code (U.S.C.).

Unused: The term unused can include partially or completely unused, unwanted, wasted, or expired substances that therefore require disposal.

Rural County: Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than 50,000. Rural County definition map: http://www.tlc.state.tx.us/pubspol/Rural_Definition/Definition_19_and_20.pdf
Group 11: Law Enforcement - Survey Questions

1. **Does your office have law enforcement authority within a Texas rural county***?  
   - [ ] Yes  
   - [ ] No

   [*Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than 50,000. Rural County definition map: http://www.tlc.state.tx.us/pubspol/Rural_Definition/Definition_19_and_20.pdf]

2. **What kind of law enforcement group are you associated with?**  
   - [ ] Texas Department of Public Safety  
   - [ ] County Sheriff’s office  
   - [ ] County Constable’s office  
   - [ ] City Police Department  
   - [ ] Texas Parks and Wildlife Department Game Warden  
   - [ ] Educational law enforcement agency  
   - [ ] Federal Law Enforcement  
   - [ ] Other (please specify)

3. **Under what circumstances do you usually receive or obtain unused pharmaceuticals as part of your law enforcement duties?**  
   - [ ] This law enforcement office never receives or obtains any pharmaceuticals as part of their duties.  
   - [ ] Law enforcement staff from other offices transfer seized unused pharmaceuticals to this office for further investigation/analysis.  
   - [ ] Law enforcement staff from other offices transfer seized unused pharmaceuticals to this office for disposal purposes only.  
   - [ ] Law enforcement staff in this office usually obtains unused pharmaceuticals from residents through property seizures.  
   - [ ] Residents of the local community drop off their unused pharmaceuticals at the law enforcement office (forfeiture).  
   - [ ] Law enforcement staff of this office regularly attend a community pharmaceutical collection event/program and they confiscate the controlled pharmaceuticals and arrange for or witness disposal of those.  
   - [ ] Other (please specify)

4. **Approximately, what quantity of unused pharmaceuticals do you usually dispose of per month?**  
   - [ ] None  
   - [ ] Less than 10 partially-filled or full containers/packages  
   - [ ] 10-25 partially-filled or full containers/packages  
   - [ ] 26-50 partially-filled or full containers/packages  
   - [ ] >50 partially-filled or full containers/packages
5. **What do you usually do with unused pharmaceuticals once you obtain them?**

- Not-applicable (this law enforcement office never receives or obtains any pharmaceuticals as part of their duties).
- Store them onsite.
- Transfer them all to another law enforcement office for analysis or disposal.
- Dispose of them all in the regular trash (municipal solid waste).
- Dispose of them all in the toilet/sink.
- Place them in a “red-bag” or “bio-hazard” container and arrange for waste disposal service to collect and dispose of them.
- Arrange for disposal of them all at a permitted Hazardous Waste Landfill.
- Arrange for disposal of them all at a permitted Hazardous Waste Incinerator.
- Arrange for disposal of them all at a permitted Medical Waste Incinerator.
- Dispose of them onsite at the law enforcement incinerator.
- Separate controlled pharmaceuticals from non-controlled pharmaceuticals, dispose of controlled substances in the toilet/sink and dispose of non-controlled substances in the municipal trash.
- Separate controlled pharmaceuticals from non-controlled pharmaceuticals, dispose of controlled substances in the toilet/sink and dispose of (or arrange for disposal of) non-controlled substances at a permitted Hazardous Waste Landfill/Incinerator.
- Separate controlled pharmaceuticals from non-controlled pharmaceuticals, dispose of controlled substances in an incinerator and dispose of (or arrange for disposal of) non-controlled substances in municipal trash.
- Separate controlled pharmaceuticals from non-controlled pharmaceuticals, dispose of controlled substances in an incinerator and dispose of (or arrange for disposal of) non-controlled substances in toilet/sink.
- I do not know
- Other (please specify)

6. **What factors most impact your decision for how you choose to dispose of or manage unused pharmaceuticals? (Select the top 3 factors)**

- Compliance with State/Federal Controlled Substances Acts
- Compliance with Hazardous Waste Regulations (RCRA)
- Complicated/poorly understood waste disposal regulations
- Law enforcement office guidelines/Standard Operating Procedures
- Drug-diversion concerns
- Accidental poisonings
- Ease of Disposal
- Cost of Disposal
- Staff Time Constraints
- Staff Training Constraints
- Staff Safety Concerns
- OSHA compliance
- Waste minimization
- Perceived environmental outcomes
- The pharmaceutical take-back event organizers determined what the ultimate disposal methods would be.
- Other (please specify)
7. **What guidance does your law enforcement office usually provide to residents about how to dispose of their unused pharmaceuticals?**

- We do not provide guidance and we never receive inquiries from residents about how they should dispose of their unused pharmaceuticals.
- Residents ask for advice about how they should dispose of their unused pharmaceuticals, but we choose to not provide guidance on that.
- We advise residents dispose of their unused pharmaceuticals in the toilet/sink.
- We advise residents dispose of their unused pharmaceuticals in the household trash.
- We advise residents contact another government agency (for example Texas Commission on Environmental Quality, or Department of State Health Services).
- We advise residents to drop off their unused pharmaceuticals at our law enforcement office and we will take care of disposal.
- We advise residents dispose of their unused pharmaceuticals at a household hazardous waste collection facility.
- We advise residents dispose of their unused pharmaceuticals at a pharmaceutical-only collection event.
- We advise that residents return their unused pharmaceuticals to their retail pharmacy.
- I do not know
- Other (please specify)

8. **If your law enforcement office is involved in community pharmaceutical collection (“take-back”) events, what is the main reason for choosing to be involved?**

- Not applicable – this law enforcement office has not been involved in community pharmaceutical collection events.
- The law enforcement office participates to show community support/solidarity.
- The law enforcement office is concerned about the potential for accidental poisonings (if unused pharmaceuticals are stored or accumulated in the household).
- The law enforcement office is concerned about the diversion/abuse/misuse of pharmaceuticals (if unused pharmaceuticals are stored or accumulated in the household).
- The law enforcement office is concerned about disposing of pharmaceuticals in landfills.
- The law enforcement office is concerned about the occurrence of pharmaceuticals in waterways/drinking water.
- Residents expressed concern about the potential for accidental poisonings (if unused pharmaceuticals are stored or accumulated in the household).
- Residents expressed concern about diversion/misuse/abuse of pharmaceuticals (if unused pharmaceuticals are stored or accumulated in the household)
- Residents expressed concern about disposing of pharmaceuticals in the household trash.
- Residents expressed concern about disposing of pharmaceuticals in the drain (toilet or sink).
- I do not know
- Other (please specify)
9. What is your law enforcement office’s desired approach to manage or dispose of unused pharmaceuticals that you obtain as part of your law enforcement duties (select all that apply)?

☐ The law enforcement office should not collect any unused pharmaceuticals from residents and does NOT desire to offer guidance on how they should dispose of them.

☐ The law enforcement office should not collect any unused pharmaceuticals from residents BUT desires to provide/promote disposal guidance offered by the relevant State agency/agencies.

☐ All pharmaceuticals obtained by law enforcement officers should be sent to an incinerator.

☐ All pharmaceuticals obtained by law enforcement officers should be disposed of in the household trash.

☐ All pharmaceuticals obtained by law enforcement officers should be disposed of in the toilet/sink.

☐ Non-controlled pharmaceuticals should be disposed of in the trash and controlled substances should be disposed of in the toilet/sink.

☐ The law enforcement office desires to host or support community pharmaceutical collection events.

☐ The law enforcement office desires to host a pharmaceutical drop box/kiosk.

☐ The law enforcement office desires to provide mail-back envelopes for residents so that they can mail their unused pharmaceuticals to a central location for disposal.

☐ I do not know

☐ Other (please specify)

10. What is the best way that the State of Texas can provide information to law enforcement offices regarding pharmaceuticals in the household / community / environment and recommendations for best practices of disposing of unused pharmaceuticals?

☐ Posters

☐ Brochures

☐ State agency or other dedicated Webpage

☐ Trade Show Displays

☐ Guidance documents (e.g. 1-page information sheets)

☐ Presentations at meetings

☐ Information provided via existing webpage/newsletters/other sources available through law enforcement associations

☐ Other (please specify)
Group 12: Research Institutions

Instructions for Completing the Survey

This survey is intended to help the Texas Commission on Environmental Quality (TCEQ) understand how unused pharmaceuticals are disposed of by research institutions in Texas.

This is part of a study being conducted to fulfill the requirements of Senate Bill 1757, passed in the Texas 81st Legislative Session.

Please answer these questions as accurately as possible. There are 8 questions in this survey and it should not take more than 10 minutes to complete. Surveys are anonymous.

Some questions in this survey may not apply to your research activities; in those cases please select “not applicable”.

THIS SURVEY IS ONLY INTENDED FOR RESEARCH FACILITIES LOCATED WITHIN TEXAS AND ONLY THOSE THAT USE ACTIVE PHARMACEUTICAL INGREDIENTS IN THEIR ACTIVITIES.

If you have any questions about this survey, please contact Jessica Huybregts at 512-239-4709 or by email at <jhuybreg@tceq.state.tx.us>.

Definitions

Below are definitions for some of the terms used in this survey.

Pharmaceutical: Under the plain and ordinary meaning of the term, a pharmaceutical is considered a “drug”. Plainly stated, pharmaceuticals could be over-the-counter drugs or those that require a prescription to obtain, they can be in the solid, liquid or aerosol form, but they are not foods or nutritional supplements. For more information, see the definition of “drug” in Chapter 431 of the Texas Food, Drug and Cosmetic Act [§431.002(14)].

Unused: The term unused can include partially or completely unused, unwanted, wasted, or expired substances. These are items that are ultimately NOT used and require disposal or transfer to another location.

Hazardous waste: A solid waste is considered a hazardous waste if it exhibits any of the four characteristics: ignitability, corrosivity, reactivity, or toxicity; or if it is specifically listed as a hazardous waste under Title 40 Code of Federal Regulations Part 61 §261.30.

Disposal: The discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste or hazardous waste (whether containerized or uncontainerized) into or on any land or water so that such solid waste or hazardous waste or any constituent thereof may enter the environment or be
emitted into the air or discharged into any waters, including groundwater. This definition is from 30 TAC §330.3(44).

Processing: Activities including, but not limited to, the extraction of materials, transfer, volume reduction, conversion to energy, or other separation and preparation of solid waste for reuse or disposal, including the treatment or neutralization of waste, designed to change the physical, chemical, or biological character or composition of any waste to neutralize such waste, or to recover energy or material from the waste, or render the waste safer to transport, store, dispose of, or make it amenable for recovery, amenable for storage, or reduced in volume. This definition is from 30 TAC §330.3(117).
Group 12: Research Institutions - Survey Questions

1. Within what types of institutions do you conduct research with pharmaceuticals or active pharmaceutical ingredients (APIs)?
   - Hospital
   - Health Care Clinic
   - Dental office
   - Educational Institution (university/college)
   - Pharmaceutical Manufacturing
   - Analytical Laboratory
   - Independent research institution/company
   - Correctional Setting
   - Long Term Care
   - Retail Pharmacy
   - Other (please specify)

2. Does wastewater generated at your research institution contain any Active Pharmaceutical Ingredients (API) as a direct result of your research activities (not as a result of patient excretion)?
   - Yes
   - No
   - I do not know

3. Are there any treatment systems in place to remove Active Pharmaceutical Ingredients (API) from the wastewater generated at your institution?
   - Yes – wastewater is treated via reverse osmosis before being discharged to waters in the State or to an authorized treatment facility (i.e., a privately/publicly owned treatment works or other authorized 3rd party treatment facility).
   - Yes – wastewater is treated using hollow fiber membranes before being discharged to waters in the State or to an authorized treatment facility (i.e., a privately/publicly owned treatment works or other authorized 3rd party treatment facility).
   - Yes – wastewater is treated with other methods before being discharged to waters in the State or to an authorized treatment facility (i.e., a privately/publicly owned treatment works or other authorized 3rd party treatment facility).
   - Yes – wastewater is treated using enhanced treatment methods and discharged onsite.
   - No
   - Not applicable – there are never API in the wastewater from our research activities.

4. How do you usually dispose of unused pharmaceutical products at your research institution?
   - Hazardous waste incineration.
   - Medical waste incineration.
   - Hazardous waste landfill.
   - Municipal solid waste landfill (regular trash).
Formulated pharmaceuticals are separated into hazardous and non-hazardous pharmaceuticals; hazardous substances are disposed of at a hazardous waste landfill/incinerator and non-hazardous pharmaceuticals are disposed of in a medical waste incinerator.

Formulated pharmaceuticals are separated into hazardous and non-hazardous pharmaceuticals; hazardous substances are disposed of at a hazardous waste landfill/incinerator and non-hazardous pharmaceuticals are disposed of in a municipal solid waste landfill.

Treatment in an autoclave then disposal in a landfill.

Disposal in the sewer system (sink/toilet).

Not applicable - there are never unused pharmaceuticals at the research institution.

Other (please specify)

5. Why do pharmaceuticals go unused at your research institution?

Pharmaceuticals expired.

Pharmaceuticals were no longer under investigation or required for the research activities.

Pharmaceuticals were dropped/spilled.

Environmental (water and or soil) samples contained background levels of active pharmaceutical ingredients and were required to be disposed of following laboratory analysis.

Other (please specify)

6. For research institutions engaging in clinical trials, how are the unused pharmaceuticals that are returned from clinical trials managed or disposed of? (Select all that apply)

Not applicable - this institution does not participate in clinical trials.

Unexpired usable pharmaceuticals from clinical trials are returned to the pharmaceutical manufacturer.

Hazardous waste incineration.

Medical waste incineration.

Hazardous waste landfill.

Municipal Solid Waste landfill.

Formulated pharmaceuticals are separated into hazardous and non-hazardous pharmaceuticals; hazardous substances are disposed of at a hazardous waste landfill/incinerator and non-hazardous pharmaceuticals are disposed of in a medical waste incinerator.

Formulated pharmaceuticals are separated into hazardous and non-hazardous pharmaceuticals; hazardous substances are disposed of at a hazardous waste landfill/incinerator and non-hazardous pharmaceuticals are disposed of in a municipal solid waste landfill.

Treatment in an autoclave then disposal in a landfill.

Transfer to another facility for processing or disposal.

Disposal in the sewer system (sink/toilet).

Other (please specify)
7. What are the main factors impacting your research institution's decision to choose the methods you employ for disposal or processing of unused pharmaceuticals? (select up to 3 factors)

- Drug Enforcement Administration (DEA) Policy (Controlled Substances Act)
- Hazardous Waste Regulations (RCRA)
- State Special Waste Regulations
- Other State or Local Regulations/Policy
- Operational permit requirements
- Company Guidelines/Standard Operating Procedures
- Ease of Disposal
- Limited disposal options for aqueous solutions
- Cost of Disposal Alternatives
- Staff Time Constraints
- Staff safety
- OSHA compliance
- Marketing/promotional/business decisions
- Waste minimization
- Perceived better environmental outcomes
- Other (please specify)

8. What is the best way that the State of Texas can provide information to research institutions regarding requirements for unused pharmaceutical disposal?

- Guidance documents (e.g. 1-page information sheets)
- Presentations at meetings
- State agency or other dedicated Webpage
- Posters, brochures etc.
- Trade Show Displays
- Training classes
- Other (please specify)
Group 13: Long Term Care Facilities (Assisted Living and Nursing Homes)

Instructions for Completing the Survey

This survey is intended to help the Texas Commission on Environmental Quality (TCEQ) understand how unused pharmaceuticals are disposed of within Long-Term Care Facilities (“LTCFs”, including nursing homes and assisted living facilities) in Texas, and what factors impact the decision to dispose of them in a certain way.

This is part of a study being conducted to fulfill the requirements of Senate Bill 1757, passed in the Texas 81st Legislative Session.

This survey should be completed by the staff member who directs the management and disposal of unused pharmaceuticals in the LTCF in Texas, for example, the Director of Nursing, Administrator or Facilities Manager of the LTCF). If your facility has its own in-house pharmacy, the pharmacy itself should complete the “Group 3: Pharmacy” survey.

Please answer these questions as accurately as possible. There are 10 questions in this survey and it should not take more than 10-15 minutes. One survey should be completed per facility. Surveys are anonymous.

If you have any questions about this survey, please contact Jessica Huybregts at 512-239-4709 or by email at <jhuybreg@tceq.state.tx.us>.

Definitions

Below are definitions for some of the terms used in this survey.

Pharmaceutical: Under the plain and ordinary meaning of the term, a pharmaceutical is considered a “drug”. Plainly stated, pharmaceuticals could be over-the-counter drugs or those that require a prescription to obtain, they can be in the solid, liquid or aerosol form, but they are not foods or nutritional supplements. For more information, see the definition of “drug” in Chapter 431 of the Texas Food, Drug and Cosmetic Act [§431.002(14)].

Facility: This is the type of practice or operation that you work in, such as a nursing home or assisted living operation. Answers to survey questions should relate to one facility you work in. If you work in multiple facilities and you are the most appropriate person to complete the survey for each facility, please complete a different survey for each facility.

Controlled substance: The term controlled substance has the meaning given in Chapter 481 (Texas Controlled Substances Act) of the Health and Safety Code, which is consistent with the definition in section 802(6) of Title 21, United States Code (U.S.C.).
Prescription drug: The term prescription drug has the meaning given in Chapter 431 (Texas Food, Drug and Cosmetic Act) of the Health and Safety Code, which lists the meaning assigned by section 203.3 of Title 21 Code of Federal Regulations. Under that definition, a prescription drug means any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by Federal law (including Federal regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the act.

Hazardous waste: A solid waste is considered a hazardous waste if it exhibits any of the four characteristics: ignitability, corrosivity, reactivity, or toxicity; or if it is specifically listed as a hazardous waste under Title 40 Code of Federal Regulations Part 61 Rule §261.30.

Unused: The term unused can include partially or completely unused, unwanted, wasted, or expired substances. These are items that are ultimately NOT used by patients and require disposal or transfer to another location.

Rural County: Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than 50,000. Rural County definition map: <www.tlc.state.tx.us/pubspol/Rural_Definition/Definition_19_and_20.pdf>.
Group 13: Long Term Care Facilities (Assisted Living and Nursing Homes) - Survey Questions

1. What type of facility do you operate?
   - Nursing Home - consultant pharmacist and facility staff are responsible for administering and disposing of resident’s unused pharmaceuticals
   - Assisted Living Facility - consultant pharmacist and facility staff are responsible for administering and disposing of resident’s unused pharmaceuticals
   - Assisted Living Facility - resident administers and disposes of their unused pharmaceuticals
   - Other (please specify)

2. Is your facility located in a rural county*?
   [*Under Section 88.621(6), Education Code, 1999, a “Rural county” means a county with a population of less than 50,000. Rural County definition map: http://www.tlc.state.tx.us/pubspol/Rural_Definition/Definition_19_and_20.pdf]
   - Yes
   - No

3. What kinds of unused pharmaceuticals are collected from patients by staff of the Long Term Care Facility (LTCF), or a consultant pharmacist, for disposal purposes?
   - No pharmaceuticals are collected from residents by facility staff or a consultant pharmacist (separate to the LTCF’s municipal trash) for the purposes of disposal. That is, if residents have unused pharmaceuticals they are solely responsible for their disposal. – IF YOU SELECT THIS PLEASE CONTINUE TO QUESTION 4.
   - Only non-controlled pharmaceuticals are collected from residents by facility staff or a consultant pharmacist (separate to the LTCF’s municipal trash) for disposal. – IF YOU SELECT THIS PLEASE GO TO QUESTION 6.
   - All unused pharmaceuticals that residents would like to dispose of are collected by facility staff or a consultant pharmacist (separate to the LTCF’s municipal trash) for the sole purpose of disposal. – IF YOU SELECT THIS PLEASE GO TO QUESTION 7.

4. For LTCFs that do not handle or dispose of resident’s unused pharmaceuticals, how do residents of the LTCF usually dispose of their unused pharmaceuticals? (Select answer then continue to question 5)
   - Residents usually dispose of their unused pharmaceuticals down the drain (sink/toilet).
   - Residents usually dispose of their unused pharmaceuticals in the regular trash.
   - residents usually transfer their unused pharmaceuticals to family members for disposal.
   - I do not know.
   - Other (please specify)
5. **For LTCFs that do not handle or dispose of resident's unused pharmaceuticals, what are the main factors that impact your decision to not collect any unused pharmaceuticals from residents? (Select up to 3 factors. Once question 5 has been completed, please proceed to question 10.)**

- [ ] There is no necessity - residents do not request LTCF staff to dispose of their unused pharmaceuticals.
- [ ] Drug Enforcement Administration (DEA) Policy (Controlled Substances Act)
- [ ] Compliance with Hazardous Waste Regulations (RCRA)
- [ ] Compliance with Texas Health and Safety Code
- [ ] Unsure about disposal regulations/requirements
- [ ] Unsure about current best disposal practices
- [ ] Drug-diversion concerns
- [ ] Accidental poisoning concerns
- [ ] Cost of disposal
- [ ] Additional staff time constraints
- [ ] Additional staff training constraints
- [ ] Staff safety concerns
- [ ] Other (please specify)

6. **For LTCFs that will dispose of resident’s unused non-controlled pharmaceuticals but not their controlled substances, what does your LTCF staff (or consultant pharmacist) advise residents do with their controlled substances? (Continue to questions 7-10)**

- [ ] Staff advises residents to dispose of controlled substances in the sink/toilet.
- [ ] Staff advises residents to dispose of controlled substances in the regular trash.
- [ ] Staff suggests residents transfer their controlled substances to family members for disposal.
- [ ] Staff advises residents to not dispose of their controlled substances.
- [ ] Staff is trained to avoid advising residents about how to dispose of their unused controlled substances.
- [ ] I do not know.
- [ ] Other (please specify)

7. **Approximately, how many pharmaceutical bottles/containers, containing some amount of unused pharmaceuticals, does your LTCF (staff or a consultant pharmacist) collect and dispose of per week (separate to what residents may dispose of on their own in the trash bin in their room)?**

- [ ] 1-10 containers
- [ ] 11-25 containers
- [ ] 26-50 containers
- [ ] >50 containers

8. **For LTCFs that employ a consultant pharmacist to manage and dispose of some or all unused pharmaceuticals that have already been dispensed to residents, what does the consultant pharmacist usually do with the unused pharmaceuticals?**
Separate unused pharmaceuticals controlled and non-controlled substances, and arrange for a waste disposal service to dispose of all the non-controlled substances, while the controlled substances are disposed of in the drain.

Separate unused pharmaceuticals into hazardous and non-hazardous wastes, and arrange for a waste disposal service to dispose of the waste separately.

Co-mingle all unused pharmaceuticals and arrange for waste management company to dispose of at a hazardous waste incinerator/hazardous waste landfill.

Co-mingle all unused pharmaceuticals and arrange for waste management company to dispose of as municipal waste.

Co-mingle all unused pharmaceuticals and arrange for waste management company to treat and dispose of as medical waste.

Co-mingle all unused pharmaceuticals and dispose of them in the LTCF’s regular trash (municipal solid waste).

Co-mingle all unused pharmaceuticals and dispose of them onsite in the sink/toilet.

I do not know

Other (please specify)

9. What are the most significant factors impacting your decision to choose the methods your facility employs for disposing of unused pharmaceuticals? (Select up to 3 factors)

- Ease of Disposal/Convenience
- Cost of Disposal
- Drug Enforcement Administration (DEA) Policy (Controlled Substances Act)
- Compliance with Hazardous Waste Regulations (RCRA)
- Complicated waste disposal regulations
- Facility Guidelines/Standard Operating Procedures
- Lack of proximity to disposal service options
- Drug-diversion concerns
- Accidental poisoning concerns
- Staff time constraints
- Staff training constraints
- Staff safety
- Waste minimization
- Perceived environmental outcomes
- Patient Health and Safety
- Other (please specify)

10. What are your preferred options for disposal or management of LTCF resident’s unused pharmaceuticals? (select your top 3 preferred options)

- The LTCF should not collect any unused pharmaceuticals from residents and prefers not to advise residents about how they could dispose of them.
- The LTCF should not collect unused pharmaceuticals from residents but prefers to provide guidance to residents about how to dispose of their unused pharmaceuticals according to State/Federal best management practices.
- State agencies should create educational materials (brochures, posters etc.) to provide guidance to the LTCF administrator about how they should advise residents to dispose of their unused pharmaceuticals.
☐ State agencies should create educational materials (brochures, posters etc.) to provide guidance to the LTCF administrator about what unused pharmaceuticals they could collect from residents and dispose of, by whom and how.

☐ The LTCF prefers to provide mail-back envelopes to residents to allow them to send their unused pharmaceuticals to a disposal facility.

☐ The LTCF prefers to provide for a locked drop-box inside the LTCF that would allow residents to deposit their unused non-controlled pharmaceuticals in the box and be disposed of.

☐ The LTCF prefers to separate unused pharmaceuticals into various waste groups and arrange for those waste groups to be disposed of according to State/Federal requirements.

☐ The LTCF prefers to dispose of collected unused pharmaceuticals in the regular trash (municipal solid waste).

☐ The LTCF prefers to dispose of collected unused pharmaceuticals onsite in the sink/toilet.

☐ Other (please specify)
### Appendix D: Acronyms

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<th>Definition</th>
<th>Acronym</th>
<th>Definition</th>
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<tbody>
<tr>
<td>ADI</td>
<td>Acceptable Daily Intake</td>
<td>H.B. 19</td>
<td>House Bill 19</td>
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<td>ADS</td>
<td>Automated Dispensing System</td>
<td>HCI</td>
<td>Health Care Industry</td>
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<td>AOP</td>
<td>Advanced Oxidation Process</td>
<td>HHS</td>
<td>(United States Department of) Health and Human Services</td>
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<td>API</td>
<td>Active Pharmaceutical Ingredient</td>
<td>HHSC</td>
<td>(Texas) Health and Human Services Commission</td>
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<td>AWWA</td>
<td>American Water Works Association</td>
<td>HIPAA</td>
<td>Health Insurance Portability and Accountability Act</td>
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<td>American Water Works Association Research Foundation</td>
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<td>Health and Safety Code</td>
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<td>BMP</td>
<td>Best Management Practice</td>
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<td>Household Hazardous Waste</td>
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<td>CCL3</td>
<td>Contaminant Candidate List 3</td>
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<td>Implementation Procedure</td>
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<td>Contaminant of Emerging Concern</td>
<td>LQG</td>
<td>Large Quantity Generator</td>
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<td>CESQG</td>
<td>Conditionally Exempt Small Quantity Generator</td>
<td>LTC</td>
<td>Long Term Care</td>
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<td>C.F.R.</td>
<td>Code of Federal Regulations</td>
<td>LTCF</td>
<td>Long Term Care Facility</td>
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<td>CSA</td>
<td>Controlled Substance Act</td>
<td>MCL</td>
<td>Maximum Contaminant Level</td>
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<td>CSL</td>
<td>Chemical-Specific Limit</td>
<td>MGD</td>
<td>Millions of Gallons per Day</td>
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<td>CWA</td>
<td>Clean Water Act</td>
<td>mg/L</td>
<td>Milligrams per liter</td>
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<td>(Texas) Department of Aging and Disability Services</td>
<td>MOU</td>
<td>Memorandum of Understanding</td>
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<td>DEA</td>
<td>Drug Enforcement Agency</td>
<td>MSDS</td>
<td>Materials Safety Data Sheet</td>
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<td>Department of Environmental Protection</td>
<td>MSW</td>
<td>Municipal Solid Waste</td>
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<td>DPS</td>
<td>(Texas) Department of Public Safety</td>
<td>MSWLF</td>
<td>Municipal Solid Waste Landfill Facilities</td>
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<td>DSHS</td>
<td>(Texas) Department of State Health Services</td>
<td>ng/L</td>
<td>Nanograms per liter</td>
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<td>DWEL</td>
<td>Drinking Water Equivalent Level</td>
<td>NPDES</td>
<td>National Pollutant Discharge Elimination System</td>
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<td>EDC</td>
<td>Endocrine Disrupting Compound</td>
<td>NSPS</td>
<td>New Stationary Sources</td>
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<td>17α-ethyl estradiol</td>
<td>NSR</td>
<td>New Source Review</td>
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<td>(United States) Environmental Protection Agency</td>
<td>ONDCP</td>
<td>(White House) Office of National Drug Control Policy</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>GAC</td>
<td>Granulated Activated Carbon</td>
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<tr>
<td>OWC</td>
<td>Organic Wastewater Contaminants</td>
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<td>PBR</td>
<td>Permit By Rule</td>
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<td>PDAG</td>
<td>Pharmaceutical Disposal Advisory Group</td>
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<td>PEC</td>
<td>Predicted Environmental Concentration</td>
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<td>PhATE</td>
<td>Pharmaceutical Assessment and Transport Evaluation (model)</td>
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<td>PHI</td>
<td>Protected Health Information</td>
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<td>PhRMA</td>
<td>Pharmaceutical Research and Manufacturers of America</td>
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<td>PIE</td>
<td>Pharmaceuticals in the Environment</td>
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<td>PNEC</td>
<td>Predicted No-Effect Concentration</td>
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<td>POTW</td>
<td>Publicly Owned Treatment Works</td>
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<td>PPCPs</td>
<td>Pharmaceuticals and Personal Care Products</td>
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<tr>
<td>ppb</td>
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<td>ppm</td>
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<tr>
<td>ppt</td>
<td>Parts per trillion</td>
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<tr>
<td>RCRA</td>
<td>Resource Conservation and Recovery Act</td>
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<td>S.B. 1757</td>
<td>Senate Bill 1757</td>
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<td>SDDA</td>
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<td>SQG</td>
<td>Small Quantity Generator</td>
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<td>TAC</td>
<td>Texas Administrative Code</td>
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<td>Texas Commission on Environmental Quality</td>
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<td>Texas Pollutant Discharge Elimination System</td>
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<td>Texas Parks and Wildlife Department</td>
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<td>TRE</td>
<td>Toxicity Reduction Evaluation</td>
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<td>Unregulated Contaminant Monitoring Regulation</td>
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<td>United States Geological Survey</td>
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<tr>
<td>UV</td>
<td>Ultraviolet (light)</td>
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<td>VTG</td>
<td>Vitellogenin</td>
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<td>Whole Effluent Toxicity</td>
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<tr>
<td>µg/L</td>
<td>Micrograms per liter</td>
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Appendix E: Infrequent Single-Day Collection Events in the United States

Bay Area of California

In the Bay Area of California, a consortium of the 39 wastewater treatment plants piloted a first-of-its-kind regional collection event for residential pharmaceutical waste that was branded “Safe Medicine Disposal Week.” The week included 59 medication collection events in 39 locations that included Walgreens, City Hall and Senior Centers within five of the Bay Area Counties. The group organized this campaign to raise awareness about the potential public health and environmental risks posed by disposal of pharmaceutical products. Advertising expenditures totaled $86,360 and disposal fees added another $3,645 to the budget. Total staff time spent on the events was 1,980 hours, which included time planning and training for the events as well as operating and cleaning up after the collections and performing evaluations of the effectiveness of the events.

Local agencies collected 3,634 pounds of pharmaceutical waste from approximately 1,500 residents. Collected medicines were transported to a facility for disposal by incineration. The organizers concluded that event based collections are an inefficient way to have residents properly dispose of medications, since the events require an enormous amount of resources.396

City of Chicago

The City of Chicago began its program in 2003 with annual one-day collection events at 25 locations throughout the city and suburbs (population 9,661,840) for four years. The program was led by the Chicago Police Department and targeted older adults. During the four years time approximately 6,000 lbs of medicines were collected. At the same time, the City of Chicago also opened a permanent household hazardous waste collection facility (Goose Island). Collection of non-controlled pharmaceuticals at the facility began in 2007. In 2008, the City of Chicago received funding to establish permanent collection containers at five police stations. Between October 2008 and October 2009, nearly 1,000 lbs of unwanted medicines were collected at the police stations. This effort originally targeted older citizens because of the potential for identity theft and other privacy issues when seniors dispose of pills and pill bottles in the trash. Through the one-day collections over four years time, the ongoing collection program at five police stations and the Goose Island Recycling facility, over 7,000 lbs of pharmaceuticals have been collected and disposed of.397

396 Id.
397 Id.
City of Denton

The City of Denton, Texas held a one day collection event in April 2010. The event was held at an office building located on a hospital campus. The office building was used so that people would not think that they could use the hospital for disposal later. Reasons for holding the event included protecting the environment and public health. All medications were treated as controlled substances without separation. Everything stayed in law enforcement custody for witness destruction. Approximately 368 lbs of unwanted medications (including packaging) were collected at the event. Final disposal was at a hazardous waste incinerator because the available medical waste incinerator was not operational at the time. The cost of the event is estimated at $5,000 including supplies, personnel, advertising, transportation and disposal.398

Franklin County Solid Waste Management District

In December 2004, the Northeast Recycling Council (NERC) and the Franklin County Solid Waste Management District (FCSWMD) in Western Massachusetts partnered to carry out a pilot collection and disposal event for unwanted medications. Both entities had received grant funding to explore safe collection and disposal options for unwanted medications. The FCSWMD received funding from the United States Department of Agriculture, Rural Utilities Service, NERC and from the EPA. The material received at the collection event included a five gallon bucket of non-controlled substances, approximately 0.5 gallons of controlled substances and 140 medications (25 controlled, 115 non-controlled).399

Ithaca, New York

In Ithaca, NY, the Coalition for Safe Medication Disposal (CSMD) formed to organize the area’s first unwanted household pharmaceutical waste collection event. The CSMD includes representatives from the Tompkins County Health Department, Tompkins County Solid Waste Management Division, Cornell University, Lifelong (a seniors group), the Community Coalition for Healthy Youth, Tompkins County Area Transit (TCAT) and the Ithaca Area Wastewater Treatment Facility.

The collection event was held as a pollution prevention tool to prevent unused drugs from getting to the wastewater. Approximately one percent of the area population participated, and 509 vehicles passed through in the six hours of the event. This event was utilized by more than 1.35% of the area’s households. During the event, 22 barrels were filled with collected medications, plus 20 cases of medicated IVs. The gross weight of material incinerated was 1,970 lbs. Net weight collected was 1,741 lbs. Some medications collected, including a large bottle of oil of hemlock, were from 1915-1930. All collected materials were

399 Id.
treated as controlled substances, therefore medications were not separated by type.

Some inventory was accomplished during the event. Bar code scanners allowed some items to auto populate the data base fields and pill counts were then added. Three pharmacists and one sixth year pharmacy student assisted. Each pharmacist worked with two volunteers, one who scanned or read labels and the other who did the data entry. Participants answered several survey questions before dropping off their medications. Regarding what would have been done with the medications if they had not heard about the event, 10.35% would have flushed or washed them down the drain, 55.95% would continue to hold on to them and 26.21% would have thrown them in the trash. Regarding why they wanted to get rid of these medications, the reasons were that medication expired (50.00%), did not want anyone else to use it (4.06%), safety for self and household (4.55%), stopped using or did not need the medication (28.57%), to protect the environment (5.03%), no particular reason (0.81%) and deceased user (2.27%).

Milwaukee Metropolitan Sewerage District

In September 2006, the Milwaukee Wisconsin Metropolitan Sewerage District (MMSD) partnered with the Milwaukee Police Department and Aurora Pharmacy to hold a single-day medicine drop-off event for Milwaukee households. Participants could drop off their unused medicines for disposal. All medicines were sorted and separated at the collection site into controlled and non-controlled bins by volunteer pharmacists. Controlled substances were taken into the custody of the City of Milwaukee’s police department and incinerated with confiscated items, while non-controlled medicines were incinerated in an approved hazardous waste incinerator. A second drop-off event took place in June 2007 and boasted increased participation as well as increased quantities of drugs collected. In April 2008, the MMSD put together an event that included the collection of unwanted medicines and personal care products. During the event more than 2,300 residents participated. Residents were encouraged to drop off unwanted prescription medications, over-the-counter medicine, ointments, sprays, inhalers, creams and pet medications to one of the six different sites. Licensed pharmacists, law enforcement officials and waste disposal staff were positioned at each of the locations to properly identify, catalogue and dispose of the substances. All medicines were contained in fiber drums that were then incinerated at federally licensed facilities. Promotional efforts included posters, 200,000 printed postcards, thousands of electronic postcards, creation of the “pill fish” symbol by the MMSD and advertisements printed in newspapers.

Partners were involved in the event for different reasons. The MMSD was motivated by environmental concerns related to emerging research that shows trace amounts of pharmaceutical chemicals in waterways and the known and unknown adverse impacts on aquatic life and water quality. Police department participation was motivated by concerns relating to prescription drug abuse,

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400 Gottlieb, E., 2010. Information about the Ithaca, NY collection event was provided by Mr. Ed Gottlieb, Pretreatment Coordinator, Ithaca Area Wastewater Treatment Facility, email communication.
theft and accidental poisonings. There were increasing numbers of participants in the single-day events each year, with 128 people in 2006 and 508 in 2007. Eight hundred twenty-four pounds of non-controlled substances and 10,472 controlled substances (counting individual pills, patches and bottles) were collected in 2006, and the quantities increased to 2,387 lbs of non-controlled and 24,751 controlled substances in 2007. For 2008, goals of the program were to: 1) establish for the first time a coordinated annual, regional medicine collection program to keep drug related chemicals out of waste streams, 2) educate the public about what they can do to help protect area waterways and Lake Michigan, and 3) build public awareness and support for the need for additional scientific research on the impacts of drug related chemical contamination in the environment. A secondary goal of the organizers was to begin to raise awareness of the need for the medical and drug manufacturing industries to assume responsibility for the proper redistribution or disposal of drugs.401

Monroe County Solid Waste Management District

In 2001, the Monroe County Indiana Solid Waste Management District (SWMD) and the Monroe/Owen TRIAD (a partnership between police, sheriffs and senior citizens’ organizations) initiated a pilot take-back program for unwanted and expired pharmaceuticals. The items collected included liquid and solid over-the-counter and prescription medicines, pills, syrups, creams, ointments, eye drops, controlled substances, vitamins, health supplements and common medical equipment, including sharps, inhalers and mercury thermometers. The partnership is also implementing two medicine collection programs. In addition to annual week-long collection events specially designated for medicines, the county’s HHW drop-off site accepts medicines and is open six days per week, year-round. Since law enforcement officials can only be present at the HHW site for the annual week-long event, controlled substances are only accepted during that week, while non-controlled medications are accepted year-round. For the remainder of the year, controlled medications can be brought to the sheriff’s department for disposal.

At the week-long collection events, controlled substances are taken into the possession of a law enforcement official and transported to the Sheriff’s Department, where the drugs are incinerated with other confiscated drugs. All other collected items are transported to the Monroe County SWMD household hazardous waste (HHW) facility where they are sorted into categories such as aerosols, mercury-containing compounds, etc., and are disposed of by the SWMD’s hazardous waste contractor. Where appropriate, the unwanted medicines are incinerated. The collection program began with senior centers and has expanded to libraries, fire stations and police stations. Originally, Monroe County’s pharmaceutical disposal initiative was driven by TRIAD, an organization that connects law enforcement officials and seniors to help reduce crime and increase consumer education and safety. Concern for the accidental ingestion of expired pharmaceuticals by the elderly provided the motivation for the campaign.

Additionally, since 2001, potential harm to children and animals and concern for the environment has also been cited as motivators for the take-back program. Collection programs were publicized through an AARP mailer, a newspaper article, flyers, senior citizen publications, public service announcements, an advertisement on prescription drug packaging at the local pharmacies, and the Indiana State Police weekly radio show. Expenses were shared between the parties involved. There were an increasing numbers of participants in the single-day events each year, with 281 in 2006. Two hundred eighty pounds of solid pharmaceutical waste and 76 lbs of liquids were collected in 2006, in addition to 272 containers of controlled substances and 167 lbs of sharps.\textsuperscript{402}

\textbf{Northeast Recycling Council}

The Northeast Recycling Council (NERC) is a non-profit organization that encompasses 10 northeast states. Its mission is to promote sustainability in solid waste management. NERC received a grant from the EPA to pilot consumer pharmaceutical take-back programs. This project aimed to develop and implement a replicable pilot for collecting unwanted medications at HHW collections or in rural settings. The pilots were designed around three models: retail-based, senior center and HHW programs. The project focused on Massachusetts, Maine, New Hampshire and Vermont. NERC identified the following concerns as the primary drivers of the program: water contamination (drugs have been found in surface and drinking water), solid waste (access to drugs in trash; some drugs are hazardous waste), homeland security (need to limit access to chemicals) and inappropriate use/diversion (improper disposal can lead to poisoning of children and pets, drug theft and other related crimes). At all collections, the required team included a pharmacist, a data entry person, a law enforcement officer and at least two volunteers.\textsuperscript{403}

\textbf{San Antonio Water System}

In San Antonio, Texas, the MedDropSA program is an operation of the San Antonio Water System in conjunction with the City of San Antonio's single-day household hazardous waste (HHW) collection event and the San Antonio Police Department. This program is designed to collect unwanted or unused medications, both prescription and over-the-counter pharmaceuticals. The purposes of the events were to divert pharmaceuticals away from people who may abuse them, to remove drugs from the environment and to educate people about the disposal of drugs.

The events were held in December 2009, June 2010 and September 2010. Controlled substances were accepted because law enforcement was onsite. The San Antonio Narcotics Department received written approval from the Houston office of the DEA to conduct the program. The December 2009 event resulted in the collection of 171 lbs of drugs within five hours. The total incineration cost was $180. The June 2010 event resulted in collection of 1,007 lbs of pills and

\textsuperscript{402} Id.
\textsuperscript{403} Id.
329 lbs of liquids, powders, and creams. The total incineration cost was $1,402. The September 2010 event collected 1,270 lbs of returned medication, which included 21 boxes of pills and 28 boxes of syrups, powders and creams.

Drugs were not sorted at either of the events. Boxes incinerated by law enforcement at a permitted RCRA Hazardous Waste incinerator totaled 36. Law enforcement handled the transport and incineration of the drugs (type of incinerator was unknown), which were accepted on site by the police department and kept in their vault. The cost of incineration was paid by the San Antonio Water System. The San Antonio Water System ran the event as a HHW event in accordance with the TCEQ notification process for HHW collection events.\(^{404}\)

### South Hadley Department of Public Works

In June 2005, NERC worked with the South Hadley, Massachusetts Department of Public Works to hold a successful unwanted medication collection in conjunction with the town’s annual HHW event. Two thousand five hundred estrogen patches were collected at the event. In total, 30 gallons of hazardous waste were shipped for incineration and 0.5 gallons of controlled substances went to the South Hadley Police Department. One Conditionally Exempt Small Quantity Generator (a pharmacy) brought in two boxes of compounding chemicals for which the pharmacy paid a $190 disposal fee to the hazardous waste hauler. There were 22 participants and 2,197 items collected at the event with an average of 100 items per participant. Thirty gallons of hazardous waste and ½ gallon of controlled substances were collected. Seventy percent of the contributions were prescription medications and 358 different types of medications were collected.

### Texas Panhandle Poison Center

A community take-back program called Medication Cleanout™ began in Amarillo and consists of recurring drive-through collection events at the Texas Tech University Health Science Center (TTUHSC). These events are limited to households with the listed primary goals of preventing poisonings, abuse, misuse and environmental contamination. Secondary goals are to collect data from events as an initial step of discovery into why medications are not used. Law enforcement is present to accept controlled substances, and final disposal is to an out-of-state medical waste incinerator, chosen because it was cost effective.

This drive-through recurring collection event model was chosen due to lack of funding for a permanent collection site, the ability to spark community interest, a desire to obtain important data, and the involvement of law enforcement. In addition, the Poison Center is hosted by the TTUHSC School of Pharmacy, there was easy access to many volunteers, pharmacy students are required to obtain “volunteer” hours for their Introduction to Pharmacy Practice course, and there

\(^{404}\) Diehl, K., 2010b. Information on the San Antonio Water System MedDropSA events was provided by Mr. Ken Diehl, Environmental Protection Specialist, Resource Protection & Compliance Department, San Antonio Water System, email communication, 17 August and 13 September, 2010.
was a collaborative effort with the school district which also provided a volunteer base. The drive through feature was recommended by experienced programs, allowed for the ability to secure the collection area and allowed for participant surveys. This program provided the ability to study why people dispose of medications, what they would do otherwise, where they store medications at home and ages of persons in the home. Data collection did require additional resources.

The first event was held in September 2009 at two locations within Amarillo. There were 296 participants with 900 lbs of medications and 70 lbs of controlled substances collected. The most common OTCs medications were vitamins and vitamin/mineral combinations, analgesics (acetaminophen, aspirin, ibuprofen) and dermatologic agents (creams and ointments). The most common non-controlled substances collected were cardiovascular agents (ACE inhibitors, beta blockers, calcium channel blockers), analgesics and antidepressants. The most common controlled substances collected were analgesics (Vicodin, Lortab, Darvocet), upper respiratory agents (hydrocodone containing pills and liquids), anxiolytics, sedatives and hypnotics (benzodiazepines, Ambien). Some issues were identified throughout the process, including: the primary barrier to frequent events is funding; management of controlled substances is difficult; and the research model is valuable but not feasible on wide-scale basis.405

North Texas Poison Center

The North Texas Poison Center and Parkland Memorial Hospital held a “Medication Cleanout” event in June 2010. The primary reasons for running the program were as follows:

- To prevent medication drug poisonings, abuse, and misuse occurring among residents of Texas.
- To reduce improper disposal of hazardous waste to ensure that families, communities, and environment stay safe.
- To document collected items as a research effort to determine underlying causes of resulting unused medications.

Law enforcement was present onsite to take controlled substances. Medications were separated into boxes labeled controlled, non-controlled/OTCs, and unknown. Separate boxes were used for the controlled and non-controlled/OTC liquids. Final disposal was by law enforcement using Sharps Environmental Services, Inc. in Carthage, TX, which is a permitted medical waste incinerator. Challenges experienced at the event included volunteer recruitment and coordination, partnership/sponsorship and marketing. The plan is to conduct these events throughout a 42 county region at least biannually, but ultimately every quarter.

405 Jaramillo, J., 2010a. Information about the Medication Cleanout™ program in Amarillo was provided by Jeanie Jaramillo, PharmD, Managing Director, Texas Panhandle Poison Center, Assistant Professor, TTUHSC-School of Pharmacy. Email communication and presentation at the 27 May 2010 Advisory Group meeting.
Pharmaceutical collection information for the one-day event is as follows:

- 773 lbs from the public.
- 60 lbs from physicians’ offices/clinics.
- Approximately 350 participants.
- 10% of collection was controlled or scheduled prescriptions.
- 90% of collection was non-controlled prescriptions, OTCs, etc.
- Collected controlled substances containing hydrocodone worth $16,000-$20,000 in street value.\footnote{Manzo, P., 2010. Information about the North Texas Poison Center collection event was provided by Pamela Manzo, Public Health Educator, North Texas Poison Center, Parkland Health & Hospital System, email communication, 13 August, 2010.}
Appendix F: Permanent Collection Facilities - Drop Boxes/Kiosks at Pharmacies, Law Enforcement Offices and Other Locations

Alachua County, Florida

In the spring of 2004, the Alachua County, Florida (population 220,000) Environmental Protection Department (ACEPD) collected unwanted residential pharmaceuticals at 12 locations (pharmacies, clinics and county facilities). This five-month grant-funded collection program included prescription drugs, chemotherapy agents and over-the-counter medications that were expired, damaged, no longer needed or were otherwise unusable for their intended purpose. Only products in pill, capsule or liquid form were collected. This is an example of a program that utilized the pharmacy collection method, law enforcement involvement, HHW facilities and other permanent facilities.

At collection locations, residents were asked to empty their medications into a collection container and then take home the empty containers. The collection container held a dilute acid to render the drugs unusable. A comprehensive advertising campaign was implemented to inform residents of the pharmaceutical waste collection project. Included in the campaign was a press release to local media outlets, a public service announcement, advertising in newspapers, a weather channel crawl on the local cable system, printing of a point of purchase flyer, posting on the Alachua County web page and on the Earth 911 website. Twelve locations throughout Alachua County participated in the collection project.

Drop-off locations included the Alachua County Household Hazardous Waste Collection facility, the Alachua County Fire Rescue Department warehouse, pharmacies and health department clinics. The pilot project collected unwanted and expired pharmaceuticals in an effort to “prevent second-hand use of prescription drugs, reduce identity theft and prevent water supply contamination.” The intent of the project was to make residents more aware of the potential negative impacts of improper disposal practices and to determine the effectiveness of a local program to collect and properly dispose of unwanted medicines.

The pilot project was funded by a matching grant from the Florida Department of Environmental Protection. The final budget for the pilot project was $15,944, including personnel expenses of $9,384, professional services (drum disposal costs) of $550, promotional activities and advertising costs of $4,643 and operating expenses (drums, pails, funnels, labels) of $1,367.

During the pilot project a total of 305 lbs of pharmaceutical waste was collected and shipped to a hazardous waste disposal facility for incineration. An estimated 500 residents participated in the project. The Household Hazardous Waste
collection facility continued to collect the medications after the five-month pilot as part of their existing program. 407

Clark County, Washington

In late 2003, Clark County, Washington, (population 380,000) established a program to safely dispose of unwanted medications. The county-funded program is called the Unwanted Medications Take-Back Program. Many of the county’s sixty to seventy pharmacies are participating in the program. Residents can drop off unwanted pharmaceuticals at participating pharmacies at no charge if the medication is not a controlled substance, is in the original container with the name of the medicine clearly marked, is in a sealed container that does not leak and is in a container that has all patient information either removed or crossed out. Pharmacies put the collected pharmaceuticals into a shipping container. When the container is full, pharmacies notify the county and ship the materials to the county’s hazardous waste contractor for incineration. The county pays for the shipments by allowing pharmacies to charge the shipment to its account number.

Pharmacists can refuse any patient return as long as they tell the patient why the return was refused. For example, pharmacists will not accept leaking containers and controlled substances. When a product is refused, the pharmacist directs the resident to the county household hazardous waste program or to the sheriff. Clark County tells residents to check with a doctor or pharmacist to determine if their drug is a controlled substance. Residents are instructed to bring controlled medicines to any of four local police and sheriff’s offices, where each controlled substance is heat-sealed in a plastic bag and secured in a locked container until it is shipped off-site for disposal with drugs collected by the sheriff as evidence in criminal cases.

Collection of unwanted and expired medicines occurs at 47 pharmacies, two sheriff’s offices, and two police departments. Clark County has been primarily motivated by “the potential environmental threat posed by discharging pharmaceutical products to the environment”. The costs of this program were absorbed through public programs and the local pharmacies. The total weight and number of pills collected is not known. However, it has been documented that 23 lbs of controlled pharmaceuticals were collected in 2006. Additionally, Clark County has been taking back non-controlled consumer drugs for approximately 12 years at three household hazardous waste (HHW) facilities. 408

Iowa TakeAway Pharmacy Program

The Iowa TakeAway program uses community pharmacies across the state as consumer unused drug take-back locations. Some participating pharmacies also sell TakeAway envelopes, pre-addressed, pre-postage paid large envelopes that can be taken into the home, filled with unused and expired medicine, and mailed through the USPS to the disposal facility. In the pharmacy component of

408 Id.
the Iowa program, a box is usually set up on the pharmacy counter. The box has an opening at the top for consumers to place their unused non-controlled pharmaceuticals. Labels/signs note that controlled substances cannot be accepted. An advantage of this set-up is that a pharmacist is available onsite to answer any questions and help consumers identify a controlled substance. Funding for this program was provided through Iowa Department of Natural Resources grants to the Iowa Board of Pharmacy, who worked closely with the Iowa Pharmacy Association, to offer the TakeAway pilot program. The pharmaceutical waste is directed to a sharps disposal facility for incineration. The $165,000 grant paid for collection in 357 pharmacies and as of May 2010, 2,550 lbs were collected and destroyed (this does not count partially filled bins).  

**Prescription Pill and Drug Disposal Program (P2D2)**

The prescription pill and drug disposal program (P2D2) in Illinois developed out of a research project undertaken by Pontiac Township High School ecology students about the disposal of unwanted medicines. The project quickly expanded to Illinois Studies classes. The students undertook a multifaceted campaign to provide their community with safe medicine disposal options and partnered with local pharmacies in Livingston County, Illinois. The program adapted and evolved as they looked for sustainable approaches for their community. The program has since grown to include pharmacies in 25 Illinois counties. The students developed collection bins, billboards and press releases, and contacted many federal, state and local officials to help “encourage local communities to reduce the amount of unwanted medicines being thrown away inappropriately and ending up in Illinois waterways”.

Illinois-Indiana Sea Grant works with communities that want to join the P2D2 network by providing information needed to undertake safe and legal medicine collection programs and by providing funding for program advertisements and for communities to purchase safe medicine collection bins for police stations. The P2D2 network also works with the state of Illinois to identify and coordinate collection programs state-wide. The State provides funding for disposal and transportation of unwanted medicines through state contracts with hazardous waste haulers. Illinois-Indiana Sea Grant has provided funding for collection bins for police stations and some advertising (billboards and flyers).

Pharmaceuticals that are collected by the P2D2 program are sent for incineration in a hazardous waste incinerator. Items accepted through the P2D2 program at local pharmacies include prescription medications (except controlled), all over-the-counter medications, medication samples, pet medications, vitamins, supplements, medicated ointments, lotions, creams and oils, liquid medication in leak proof containers and homeopathic remedies. Items not accepted include needles/sharps (including syringes), thermometers, controlled prescriptions, IV bags, infectious waste, personal care products, empty containers and hydrogen peroxide. Items accepted at police departments include controlled substances.

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The purpose of the P2D2 program is to provide students with the opportunity to act as a catalyst for change in their community. Through this program, students educate themselves on environmental protection and the dangers of drug abuse, while at the same time partnering with government agencies and grassroots campaigns to eliminate drug abuse, diversion of substances and environmental degradation. Program costs vary by community.

Currently either the pharmacy or Illinois EPA is paying for the disposal of non-controlled substances. In some cases, Illinois-Indiana Sea Grant has purchased the secure collection bins for police stations and provided funding for program advertisement through billboards, flyers and radio advertisements. As of November 2009 the state of Illinois, including counties that have initiated P2D2 collection and education programs, has collected and disposed of over 87,500 lbs of pharmaceuticals. P2D2 program coordinators will continue operating in counties and states that have already adopted the program, and hope to eventually educate and engage communities on a national level.410

Pharmaceuticals from Households: A Return Mechanism (PH:ARM), Washington State

To address the need for a safe way to dispose of unwanted medicines, a coalition of government, nonprofit and business partners in Washington State began a pilot in 2006 called Pharmaceuticals from Households: A Return Mechanism (PH:ARM) at a regional healthcare organization in Washington, a retail pharmacy chain and two boarding homes. The goal of the pilot was to demonstrate the viability, security and convenience of a pharmacy-based collection model for unwanted household medicines, similar to programs operated by pharmaceutical manufacturers in other countries. The pilot also aimed to lay the groundwork for an ongoing statewide medicine return program provided by drug manufacturers.

Thirty-seven Washington State pharmacies and two boarding homes participated in the safe collection of unwanted medicines from household consumers, including prescription drugs, over-the-counter medicines and nutritional supplements. The pilot was unable to accept controlled substances. Comprehensive security protocols ensured that no diversion of medicines occurred from collection through final disposal; drug were placed in a tray, a pharmacist inspected the items in the tray and had residents take back any identified controlled substances before they left the pharmacy.

Medicines were collected at 25 clinical pharmacies and 12 retail pharmacies. The PH:ARM program boasted high participation with little advertising, as well as high cost-effectiveness. With little advertising, a total of 15,798 lbs of unwanted medicine was collected from residents during the two year PH:ARM pilot. While it seems that the PH:ARM results included the weight of the drug container, the program collected a prodigious amount of waste for the money allotted, compared to some other take back programs. With a similar budget as the St. Louis program mentioned, PH:ARM program operated nearly twice as many collection sites over a study period twice as long. Prescription medicines

410 Id.
accounted for more than half of all returned medicines, and over-the-counter drugs comprised 19 to 25 percent.

Surveys indicated that 74 to 96 percent of pharmacy customers were willing to participate in the program. Pharmacy staff reported spending relatively little time on the program (between 15 minutes to two hours per week) and that it had little impact on staff workloads.

The program was intended to last for a two-year period during 2006-2008, but two pharmacy chains, Group Health and Bartell Drug have elected to continue on an interim basis.411

Key findings reported for the program were as follows:

- Community demand for safe disposal of medicines is high.
- Pharmacy-based medicine return is convenient and effective.
- Returning medicines to a pharmacy with proper oversight and strict protocols can be safe and secure for any type of medicine, including controlled substances.
- Medicine return programs are cost-effective to operate (operational costs for two years at 37 pharmacies, including start-up expenses, were about $134,000; outreach costs were $35,600).
- Sustainable funding is needed for a statewide medicine return programs.412

**Live Oak Pharmacy, Austin**

In Austin, Texas, on Earth Day (April 22, 2010), Live Oak Pharmacy began a medication take back program as a community service and as a marketing opportunity. Customers drop off their drugs and fill out a form, and the pharmacist screens every item brought in so that the controlled substances can be rejected. Assistance with the form is provided if needed. The collected materials are immediately documented and placed in a tamper proof Sharps TakeAway box, and the box is stored within the pharmacy department at all times. No other security measures are used. Unused drugs from the pharmacy are not mixed with customer’s returned drugs. The medications are sent to Sharps Inc. as part of their Take-Away Environmental Disposal System, which ultimately is incinerated in a medical waste incinerator. Costs of the program are estimated to be approximately $11 per pound, including the cost of the drop box, printing of the forms and time involved. One hundred forty pounds of materials have been collected since inception, including the vials and other packing of the medications. The program will be continued indefinitely if finances allow.

411 See Grasso et al., 2010.
412 Id.
San Mateo County, California

The San Mateo County, California Pharmaceutical Disposal Program was launched in September 2006 to operate year-round within law enforcement offices and legally accept all pharmaceuticals, including controlled substances.

During the first four months of operations, the program collected more than 585 lbs of medicines discarded by the public at four locations in the county. As of summer 2009, 15 law enforcement agencies were managing 16 drop off sites in the county. By June 2009, the program had collected more than 25,200 gross pounds of discarded pharmaceuticals. During the same period, disposal costs to the county were less than $1.50 per pound, including pick up fees.

The three main goals of the program are to help seniors avoid dangerous medication dosage errors, help reduce or prevent recreational pharmaceutical use and to help stop the contamination of the environment by medicines flushed down drains. Disposal receptacles were placed with law enforcement agencies because that was the only way to create a program able to legally accept all pharmaceuticals, including those defined as controlled substances.

Each participating department is responsible for securing its own receptacle, monitoring its contents and transporting the medicines to locked containers at three consolidation points. The containers are then picked up by a licensed and bonded hazardous waste disposal company which disposes of the medicines in a commercial incinerator. Media coverage, physical and electronic flyers and word of mouth all helped publicize the program. The cost to purchase and paint courier boxes was in the $700 to $800 range. Disposal costs include $60 per pickup plus $0.75 per pound. Syringes or other sharps incur additional costs. The public’s response has been complimentary and positive. The sole criticism has been the unavailability of disposal receptacles at neighborhood pharmacies or senior centers.413

Area Resources for Community and Human Services (ARCHS), Missouri and Illinois

During 2008, Area Resources for Community and Human Services (ARCHS) implemented the U.S. EPA project known as Regional eXcess Medication Disposal (RxMEDS). The RxMEDS project model was conceived following discussions with a family-owned regional supermarket chain having multiple locations and full-time pharmacies. Within a very short time, a diverse regional partnership of pharmacies, disposal services, senior service agencies, and the St. Louis College of Pharmacy (COP) was created.

ARCHS’ project staff and partners conducted this bi-state medication collection program through the grocery store chain in Missouri and Illinois counties in or around St. Louis. A total of 220 collection days were conducted near the store’s pharmacy counters.

The goal of the project was to create an efficient regional model that removes and disposes of unwanted medications and informs citizens of related health and environmental issues. Locations were selected that were convenient to the patrons, closely represented the counties’ demographics, and offered full-time pharmacies at each of the sites. The pharmacies operated daily from 9:00 a.m. to 9:00 p.m. The hours of collection were set from 10:00 a.m. to 1:00 p.m. on the second and fourth Thursdays of each month. All medications collected were picked up within 24 hours of the collection period. In addition to the medications, the project sorted the various plastics, paper, and cardboard for recycling. Over a ton of materials was collected and recycled. All medications were incinerated.\textsuperscript{414}

A major hurdle in the approval process for the RxMEDS project was the collection method for controlled substances. The original plan was to collect them and a tentative agreement was reached with the DEA, but this was not possible under state law. As a compromise, the decision was made to record data about any medication that was presented for disposal but without taking possession of any medication identified as a controlled substance. The procedure established that the collection site staff first reviewed all medications presented for disposal. Those identified as a non-controlled medication were collected, medications removed from their package or container, counted, and data entered. Controlled substances were not opened or unwrapped. Information about the drug was recorded and the unopened container was returned to the patron with a brochure (available upon request) and a demonstration (video available upon request) on how to properly dispose of the drug so it would have little or no impact on the environment. This process was acceptable to local, state, and federal agencies that had jurisdiction over medications.

A summary of the RxMEDS project’s overall results is as follows:

- Program cost $137,849 (EPA grant award $150,050); $289,000 in leveraged funds were reported by the partnership.
- Over 2,000 volunteer hours were needed to operate the year-long program.
- 20 collection sites were operated each month, January through October 2008. Only 10 collection sites were operated in November and December due to holidays.
- 39 other local, state, and federal organizations or agencies assisted, provided information, or requested assistance during the project.
- 387 elementary students and 15 teachers were presented an educational program on poison prevention via safe medication handling and disposal.
- A secondary survey was conducted with 448 non-participants and 220 participants (7 non responses) for a total of 675.
- Over 300 St. Louis College of Pharmacy students participated in the program as collection agents.

• 3,331 older adults were educated by senior partnership programs and community outreach efforts about safe handling and disposal of medications.

• Media/publications reached an estimated 704,300 in the bi-state area.

• 892 participants returned one or more medications.

• 296,650 medications were returned.

• 244,708 over-the-counter (OTC) and non-controlled prescription individual capsules, tablets, and suppositories were collected and incinerated.

• 51,942 controlled substances were recorded but not collected from the participants. RxMEDS project guidelines required collection sites to identify all controlled substances, keep the container closed, visually estimate the amount of medication presented for return, and then give the container back to the participant.

• 10,095 “bottles” were recorded; a bottle may include multiple tablets.

• Most frequent medication returned by category: Controlled – Hydrocodone (prescription painkiller, e.g., Oxycontin); non-controlled – Furosemide (prescription diuretic, e.g., Lasix); OTC – Aspirin, Acetaminophen, Ibuprofen (painkiller, anti-inflammatory).

• Most commonly, the returned medications were expired. Many participants returned medications due to the patient having moved away or being deceased.

• The findings show 36.8% previously flushed them down a toilet. Approximately 20% of participants were keeping their medications in the home.

The overall conclusions and recommendations from the program are as follows:

• In determining the number of locations for a collection the first thing to consider is the amount of human resources available to staff the sites. The lack of someone whose full time job was the recruitment and assignment of community volunteers greatly hampered the quality and quantity of volunteers actually involved in the year-long project.

• The distance between locations and the time involved to collect the medications efficiently should be considered. The waste hauler business responsible for the collection must re-route its trucks to collect on special days at the various locations, as well as arrive after a collection event has been completed.

• Collection sites located in low income areas of the region had the least participation from the community. Low income residents believed that the collections were a good idea, but were reluctant to dispose of unused medication just in case it might be needed in the future and be costly to purchase.
• Many participants turned in quantities reflecting the unused balance of a 30 day supply. It was almost universal that participants took doses until they felt better and then attempted to save the remainder of the prescription for future needs.

• Many of the participants turned in the balance of medications remaining from a 90-day supply. These medications generally fell into two categories: 1) medications that were discontinued due to side effects or 2) medications that were unused by patients after their death.
Appendix G: Mail-Back Programs

State of Maine

In 2007, the State of Maine implemented a statewide model for the disposal of unused household medications using a mail-back return envelope system with the USPS. The program “Safe Medicine Disposal for ME” was established through state legislation and included funding from the EPA’s Aging Initiative. The program was authorized to handle both controlled and non-controlled medications. Disposal of returned medications was through high heat incineration, using procedures already established for Maine’s law enforcement drug seizures.

The program included counting returned pills and a statewide education campaign. Participating pharmacies served as envelope distribution sites and the Maine Drug Enforcement Agency maintained continuous, unbroken custody of the returned medicines. Cataloging of returned drugs was done with law enforcement supervision and drugs were sorted into non-controlled, controlled hazardous and controlled non-hazardous categories. During the first two phases (years) of operation, the program disposed of more than 2,300 lbs of drugs from 3,926 returned envelopes. Approximately 42% of the envelopes distributed were returned, and the average returned envelope weight was 7 ounces. Most returns were in pill form. Surveys indicated that most would have flushed drugs down the toilet (46%) or placed drugs in the trash (37%).

Aggregated Phase I and II actual and in-kind contributions calculated to a cost of $18.79 per unit mailer. Subsequent Phase III costs are anticipated to be $7.50 per unit mailer. Maine’s mail back program has claimed that this program is both feasible and effective. The state intends to continue the program for an additional two years.

State of Wisconsin

In 2008, the State of Wisconsin began a six month “Old Medicines Mail-Back Pilot” to establish an efficient collection system for pharmaceutical waste from consumers. The program targeted two counties and included publicity through newspapers and radio, distribution of posters and handouts, newsletter articles, inserts and a call center. Only non-controlled medicines were accepted in this mail-back program due to lack of DEA approval in accepting dispensed controlled substances.

A total of 1,730 households returned medicines through the project period with a total of 15,164 items returned. Most of the materials were generated from one county. A wide variety of materials were sent in, with maintenance prescription medicines being the primary item. Major costs were estimated to include materials packaging, shipping to and from the consumer, and processing and incineration (70%), operation of the call center and 800 service (20%) and...
administrative components of the program (10%) with a total estimated cost of $30,900.

“TakeAway” Mail-Back

In 2009, Sharps Compliance, Inc. launched a program to provide a prepaid mailer for individuals to return unwanted non-controlled pharmaceuticals on a national basis. The envelopes were sold individually or in large volumes on the company website. The cost of the envelope included shipping and disposal. All containers were mailed by USPS to a facility in Carthage, Texas, where law enforcement witnessed the destruction of returned items in a MSW Type V processing facility (it is not a hazardous waste incinerator).

The program could not accept controlled substances due to the DEA restrictions. The company provided customized promotional items for pharmacies or other entities providing the envelopes. When packages arrived at the Carthage facility, an on site a full-time police officer is the only one who accepted the envelopes and boxes when delivered, document acceptance, locked them up, and witnessed their destruction.
Appendix H: Render Undesirable and Dispose of In Municipal/Household Trash

SMARxT Disposal Approach

The SMARxT Disposal Partnership is a partnership between the United States Fish and Wildlife Service, the American Pharmacists Association and PhRMA. The SMARxT Disposal Guidance is generally consistent with the FDA/ONDCP recommendations and includes instructions to remove labels, mix the drugs with undesirable materials such as sawdust, used coffee grounds or cat litter, seal then mixture in a container and place it in the trash for collection. Flushing down the toilet or the sink is discouraged in the SMARxT guidance and participation in collection events is encouraged, where available.

City of Los Angeles

The City of Los Angeles, Los Angeles County Sanitation Districts and the Orange County Sanitation District launched a public education campaign to address disposal of household medications in Southern California. The education campaign mainly focused on providing information for residents about how to safely dispose of unused pharmaceuticals in the household trash, and it also promoted collection of drugs at HHW events. The campaign's tagline, No Drugs Down the Drain, is meant to encourage Southern California residents to dispose of their unneeded medicine in ways more appropriate than flushing them down the toilet.

The primary element of the program is a two-sided postcard that alerts Southern California residents to the problems associated with flushing unwanted and expired medications down the toilet or drain. As alternatives, the program recommends taking them to a household hazardous waste collection center/event (no controlled substances are allowed) or disposing of them in the trash in a sturdy and secure container, taking precautions to avoid accidental ingestion by children and animals and to prevent diversion for illicit uses. The card was developed with input from a broader group interested in residential pharmaceutical disposal including city, county, state, federal and private participants.

The program kicked off in March 2006 to coincide with National Poison Prevention Week. Cards in lots of 1,500-2,000 were sent to approximately 1,900 pharmacies in Los Angeles and Orange Counties with a request to distribute the cards to customers as prescriptions were filled. Cards were also handed out at Household Hazardous Waste Centers/Events and at agency outreach functions, and were made available to Los Angeles County Public Works for their public counters and to Los Angeles County Health Services for their clinics. Additionally, more than 25% of the cities in Los Angeles County (apart from the City of Los Angeles who is a primary sponsor of the program) have requested cards to distribute to their residents either at public counters, city events or through direct mailings. As of August 2006, the City of Los Angeles, Los Angeles
County Sanitation Districts, and the Orange County Sanitation District had distributed approximately 3.7 million cards. There is an associated website (www.nodrugsdownthedrain.org) to provide more detailed information on the program such as why flushing is a problem, household hazardous waste collection event links, discussion of controlled substances (which will not be accepted at the household hazardous waste events because of DEA requirements) and tips on how to more safely dispose of medications in the trash. The disposal options outlined in the No Drugs Down the Drain program have been determined by the wastewater agency sponsors from Los Angeles and Orange counties to be appropriate in the geographical areas for which these sponsors have oversight.

The three agencies involved (Los Angeles County Sanitation Districts, the City of Los Angeles, and Orange County Sanitation Districts) spent approximately $80,000 to print and mail informational cards and develop the website. In-kind services, mainly in the form of staff time, were also provided by each agency, but no attempt to quantify the cost of these services has been made. It is not known how effective the educational campaign has been since there was no success measure determined.