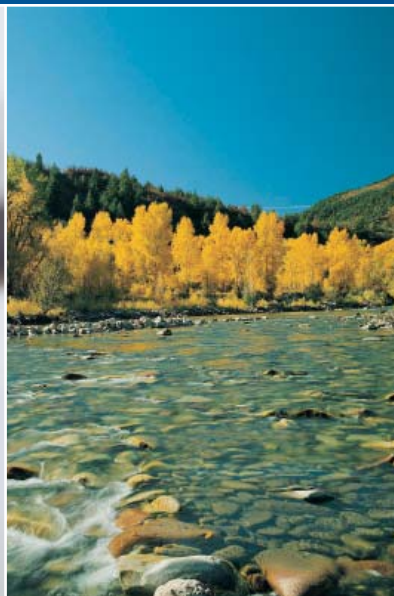


Unused Pharmaceuticals in the Health Care Industry:

Interim Report



August 2008

FOREWORD

EPA is committed to taking action and working with our partners to ensure clean and safe water. The Agency is concerned about the detection of pharmaceuticals and personal care products in our water. EPA has been actively working with federal agencies and state and local partners to better understand the implications of emerging contaminants such as pharmaceuticals, endocrine disrupting chemicals, and personal care products detected in drinking water, wastewater, surface water and ground water. We continue to evaluate routes of exposure, levels of exposure, and potential effects on public health and aquatic life.

EPA is responding to emerging contaminants with a four-pronged approach aimed at improving science, improving public understanding, identifying partnership and stewardship opportunities, and taking regulatory action when appropriate. Over the last few years, EPA has increased its work in a number of areas to better understand pharmaceuticals and personal care products. This interim report on “Unused Pharmaceuticals in the Health Care Industry” is an important part of that effort.

Benjamin H. Grumbles
Assistant Administrator for Water
USEPA

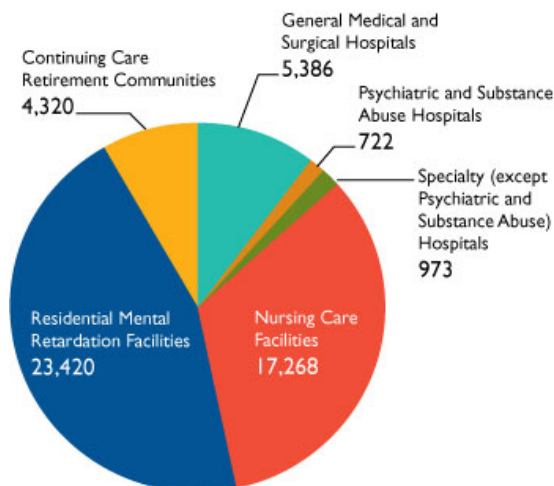
The Focus of EPA's Study

EPA initiated the study of unused pharmaceutical disposal practices at health care facilities with the goals of understanding one way in which pharmaceuticals enter our waterways and also understanding what factors contribute to pharmaceuticals entering through water. While EPA understands that there are many factors influencing the handling and disposal of pharmaceuticals by the health care industry, the focus of EPA's study is on disposal into water. EPA decided to study medical facilities because the Agency believes that these facilities dispose of a large quantity of unused pharmaceuticals. Thus far, EPA has only evaluated hospitals and long-term care facilities, so the information in this interim report pertains only to hospitals and long-term care facilities. Recently EPA decided to expand the scope of its study to include hospices and veterinary facilities and intends to issue a nationwide information collection request to gather better, representative data (see "Next Steps").

Hospitals include general and medical surgical hospitals, psychiatric and substance abuse hospitals, and specialty hospitals, such as those treating cancer. Long-term care facilities include nursing care facilities, residential mental retardation facilities, and continuing care retirement communities.

Figure 1 shows the distribution of the over 50,000 facilities in each of the six categories assessed for this report.

Figure 1: Number of Health Care Facilities, 2005



Source: U.S. Census, 2005

For many years, a common practice at many health care facilities has been to dispose of unused pharmaceuticals by flushing them down the toilet or pouring them down the drain. Through this study, EPA has sought answers to the following questions:

- What are the current health services industry practices for disposing of unused pharmaceuticals?
- Which pharmaceuticals are being disposed of and in what quantities?
- What are the options for disposing of unused pharmaceuticals other than down the drain or toilet?
- What factors influence disposal decisions?
- Do disposal practices differ across health services industry sectors?
- What Best Management Practices (BMPs) could facilities implement to reduce the generation of unused pharmaceuticals?
- What are the costs of current disposal practices compared to the costs of implementing BMPs or alternative disposal methods?

Upon completion of the health services study, EPA hopes to understand what factors contribute to unused pharmaceutical disposal methods at health service facilities and which disposal methods represent best practices to minimize environmental impacts.



Unused Drugs at Nebraska Veterans Home, Grand Island, NE © 2007

To date, EPA has found little readily available information in EPA databases to answer these questions. Consequently, EPA has researched industry trends and practices by examining federal and state laws; meeting with federal and state officials, health care stakeholder groups, and industry; holding a number of teleconferences; conducting site visits to understand industry practices; attending conferences; and gathering data from a number of secondary sources. Details of our data collection are contained in the more detailed technical report, “Health Services Industry Study, Management and Disposal of Unused Pharmaceuticals (Interim Technical Report),” which will be available at <http://www.epa.gov/guide/304m/> in Summer 2008.

Pollutants of Concern

Pharmaceutical waste is generated at health care facilities before, during, and after patient treatment, and includes expired pharmaceuticals. How much pharmaceutical waste is disposed of into our sewer systems is unknown. A 2007 publication by researchers at the Bren School of Environmental Science and Management in California indicated that drain disposal in Santa Barbara by hospitals, long-term care facilities, and pharmacies is infrequent. In contrast, a 2008 publication by Kansas State University researchers concluded that 59 local long-term care facilities disposed of pharmaceutical down the drain 46 percent of the time.

For the most part health care facilities discharge their wastewater to publicly owned treatment works (POTWs). This means that discharge information normally generated by permitted, direct dischargers is not available. Moreover, traditional wastewater treatment implemented in the 1970s and 1980s at POTWs is designed to remove conventional pollutants such as suspended solids and biodegradable organic compounds—not pharmaceuticals. While many POTWs have since added advanced treatment technologies at their facilities, those technologies were also not specifically designed to remove pharmaceuticals. Some studies suggest that both conventional and advanced treatment will remove some pharmaceuticals. EPA's Office of Water is conducting an extensive literature search to determine to what extent conventional, advanced, and other treatment technology is effective in removing certain pharmaceuticals from the waste stream. This report is expected to be completed in late 2008.

Factors Influencing Disposal of Unused Pharmaceuticals

Unused pharmaceuticals can be disposed of in a number of ways: 1) redistribution to the pharmaceutical manufacturer, 2) reuse/donation, 3) flushing down the drain, 4) disposal in landfills, and 5) incineration. A number of factors influence the disposal mechanisms a health care facility may use particular pharmaceuticals—classification as a controlled substance or medical hazardous waste; federal, state, or local laws; size of the facility; and ease of, access to, and cost of disposal.

Federal Regulations

Major federal regulations that influence disposal options for unused medications include:

- **The Controlled Substances Act (CSA):** The CSA provides for a closed distribution system for controlled substances (e.g., narcotics, opiates, and stimulants). CSA registrants, such as pharmacies and hospitals and their employees, have several options for disposing of an unused controlled substance. They may return it to the manufacturer; destroy it in accordance with state guidance and with appropriate documentation; or transfer it to reverse distributors, private companies that handle expired medications for manufacturers and pharmacies. Under the CSA, disposal down the drain sewer (or flushing) is an

acceptable destruction option. For the most part, long-term care facilities are not CSA registrants so they cannot generally return pharmaceuticals to the manufacturer or use reverse distributors.

- **The Resource Conservation and Recovery Act (RCRA):** Under RCRA, EPA regulates the generation, storage, transportation, treatment, and disposal of pharmaceutical wastes that are defined as hazardous. Common pharmaceuticals that are hazardous when disposed of include nitroglycerin, warfarin, and some chemotherapy agents. About 5 percent of pharmaceuticals on the market are listed as hazardous waste. RCRA regulations require that these and other hazardous wastes be transported in approved containers to permitted hazardous waste disposal facilities by a hazardous waste transporter. RCRA also prohibits health service facilities from disposing of hazardous pharmaceutical waste in municipal waste landfills, municipal incinerators, or medical waste plants. EPA is considering amending its hazardous waste regulations to add hazardous pharmaceutical wastes to the universal waste system to facilitate the disposal of pharmaceutical waste. In addition, the inclusion of hazardous pharmaceutical wastes in the universal waste rule may encourage health care facilities to manage all their pharmaceutical wastes as universal wastes, even wastes that are not regulated as hazardous but which nonetheless pose hazards.
- **The Health Insurance Portability and Accountability Act (HIPAA):** HIPAA requires long-term care facilities to destroy all pharmaceutical labels that contain private information (e.g., name, birth date, address) and re-label the medication prior to donation or redistribution. Most facilities that accept donations find that the labor cost of re-labeling, auditing, and assuming the risk of administering mislabeled redistributed pharmaceuticals exceeds the value of donated medication, thereby discouraging this method of “disposal.”

State and Local Regulations

State regulations vary widely and influence disposal practices. Many state regulations require both hospitals and long-term care facilities to destroy unused pharmaceuticals but often do not specify the process of destruction. Some states have hazardous waste regulations that are more stringent than EPA’s. For example, some wastes that are not regulated as hazardous under RCRA are identified as hazardous in the state of California.

State regulations for reuse of medications also vary widely. Many states allow reuse of uncontaminated pharmaceuticals (excluding controlled substances) that have been in a controlled environment such as an automatic dispensing system. At least five states strictly prohibit hospitals and long-term care facilities from reusing pharmaceuticals entirely: Arizona, Kentucky, Mississippi, New Mexico, and Texas. Some state Medicare and Medicaid requirements can also discourage long-term care facilities from donating or redistributing their unused medications. In contrast, California allows county health departments to collect unused pharmaceuticals from long-term care facilities, wholesalers, and manufacturers and redistribute them for dispensing to the uninsured poor.

Other Factors

Besides legal requirements, the other major factors that affect how a medical facility disposes of unused pharmaceuticals are organization size, ease and access of disposal, and cost. For example, some facilities use flushing to sewers as a primary means of disposal since it is easy, is accessible, and complies with CSA requirements for destruction. Facilities are most likely to flush pharmaceuticals if they do not have an onsite pharmacy and/or do not have a pre-existing contract with a hazardous waste hauler to dispose of the pharmaceuticals. In the past, public health agencies and health-related nongovernmental organizations guided the public to destroy unused medications by flushing them down the toilet. Many long-term care facilities have adopted this method for destruction of unused controlled substances and have extended this practice to include flushing all unused medications – controlled and non-controlled substances.

Moreover, the logistics for disposing of unused pharmaceuticals at hospitals are different from long-term care facilities. Hospitals typically have onsite pharmacies. It is common practice at hospitals to return some unused pharmaceuticals to the hospital pharmacy and then to the manufacturer for credit or disposal. However, this option extends only to those pharmaceuticals for which the hospital can receive credit and does not include unused pharmaceuticals that are considered waste (e.g., pharmaceuticals in an intravenous bag, drug samples brought into the hospital). Also, hospitals typically do not prescribe medication far in advance or in large quantities. As a result, the potential for pharmaceuticals to be wasted is less. In addition, hospitals typically have pre-existing arrangements for disposal of unused pharmaceuticals as hazardous waste.

Management Practices

There are ways in which disposal of unused pharmaceuticals can be managed to reduce their environmental impact. EPA examined guidance on managing pharmaceutical waste from three leading organizations: Hospitals for a Healthy Environment (<http://www.h2e-online.org>), Product Stewardship Institute (<http://www.productstewardship.us/>), and the Joint Commission on Accreditation of Healthcare Organizations (<http://www.jointcommission.org/>). The guidelines provided by these organizations all aim to reduce health and environmental impacts due to current disposal practices of pharmaceutical waste.

Some good management practices identified to date include the waste minimization and reverse distribution systems used by hospitals in California, Minnesota, and Washington. Waste minimization techniques include maintaining inventories of high-use pharmaceuticals and identifying those that are close to expiring. Short-dated pharmaceuticals are redistributed to other areas of the hospital where they are needed.

Dispensed pharmaceuticals can go unused at a hospital or long-term care facility if the patient has an allergic or adverse reaction to the medication, no longer requires treatment, refuses treatment, or the medication expires. Hospitals and long-term care facilities can reduce the amount of pharmaceutical waste generated by limiting the amount of

pharmaceuticals dispensed to patients and residents at one time. This can be accomplished by using unit-dose packaging, limited quantity dispensing, automatic dispensing systems, and standardized medication dosages. Hospitals have the option of hiring reverse distributors to manage their unused and/or expired medication that could be returned to the manufacturer or wholesaler for credit. The reverse distributor determines which medications may be returned to the manufacturer or wholesaler for credit and arranges for disposal of unused medications that are waste.

Some state hazardous waste control agencies also recommend that health care facilities develop a pharmaceutical waste management program. This management tool ensures proper communication among the various departments, including pharmacy, nursing, environmental services, safety, and building services. Program considerations include:

- Identifying unused pharmaceuticals and pharmaceutical wastes and the approved methods for returns or disposal.
- Communicating proper return or disposal practices to all staff involved with pharmaceutical dispensing or disposal.
- Determining a method of segregating unused pharmaceuticals and pharmaceutical waste with different return or disposal requirements.

Example pharmaceutical waste management programs that are currently used in the health care industry for pharmaceutical wastes include:

- Sorting unused pharmaceuticals and pharmaceutical waste at the point of health care delivery (“pre-sort” model) through use of different disposal bins, disposal information incorporated with dispensing software, and “Special Disposal Required” stickers applied to pharmaceutical packaging.
- Grouping together all unused pharmaceuticals and pharmaceutical waste at the point of health care delivery (“post-sort” model) for subsequent segregation by waste management contractor.
- Managing all drugs as hazardous.

Preliminary Observations

Based on our data collection thus far, a number of preliminary observations can be made:

1. Federal, state, and local laws and regulations often require special handling of pharmaceutical waste. These laws and regulations can influence the options hospitals and long-term care facilities have for disposing of unused pharmaceuticals.
2. Organization size, ease and access of disposal, and cost are also factors influencing the disposal of unused pharmaceuticals.
3. Fewer disposal opportunities exist for long-term care facilities because they are often not CSA registrants and cannot generally return pharmaceuticals to the manufacturer or use reverse distributors.

4. Best management practices, if widely implemented, have the potential to reduce the amount of unused pharmaceuticals entering our nation's waters from disposal.

Next Steps

EPA will continue to study the issue of how health care facilities are managing and disposing of unused pharmaceuticals. However, EPA does not have nationwide information on the amount of unused pharmaceuticals disposed of by health care facilities, the means of disposal, or cost. EPA would like to gather further information on current best management practices that might be adopted by others. Therefore, EPA plans to conduct a nationwide survey of hospitals, long-term care facilities, hospices, and veterinary facilities. EPA will use this information to estimate the amount of unused pharmaceuticals disposed of in our nation's waterways, evaluate current disposal practices and their cost, examine the barriers to alternate disposal methods, and evaluate best management practices and their costs. EPA has begun the process required under the Paperwork Reduction Act to receive Office of Management and Budget approval for this survey. EPA expects to work closely with health care services industry representatives and other affected stakeholders while designing the survey. EPA also plans to visit more facilities to obtain first-hand information on how health care facilities manage, track, and dispose of their unused pharmaceuticals.



United States
Environmental Protection Agency
Office of Science and Technology (MC 4303T)
1200 Pennsylvania Ave., NW
Washington, DC 20460

Official Business
Penalty for Private Use \$300

EPA-821-R-08-010
August 2008
<http://www.epa.gov/guide/304m>