Health Care Industry
Unused Pharmaceuticals Detailed Study
2007-2009 Data Collection and Outreach

Pills collected for disposal at a Veterans Home in Nebraska. Reprinted with permission from The Omaha World-Herald.

I.   Overview

To date, scientists have identified numerous pharmaceutical compounds at discernable concentrations in our nation's rivers, lakes, and streams (EPA-HQ-OW-2006-0771-1694). To address this issue at the source, EPA is studying how the drugs are entering waterways and what factors contribute to the current situation. Towards this end, EPA initiated a study on pharmaceutical disposal practices at health care facilities including hospitals, hospices, long-term care facilities, health care clinics, doctor's offices, and veterinary facilities. Unused pharmaceuticals include dispensed prescriptions that patients do not use as well as materials that are beyond their expiration dates. Another potential source of unused pharmaceuticals is the residuals remaining in used and partially used dispensers, containers, and devices. In particular, the medications contained in the dispensers, containers and devices may be sewered (e.g., intravenous (IV) bags emptied into sink).[1] For many years, a standard practice at many health care facilities was to dispose of unused pharmaceuticals by flushing them down the toilet or drain.

For the Final 2008 Plan EPA completed an interim technical report for the Health Care Industry (EPA-HQ-OW-2006-0771-1694). The interim technical report focused on hospitals and long-term care facilities (LTCFs) because these facilities are likely responsible for the largest amounts of unused pharmaceuticals being disposed into sewage collection systems within this industry sector. In 2005, there were about 7,000 hospitals and 35,000 LTCFs in the United States (EPA-HQ-OW-2006-0771-1694). EPA is continuing its detailed study to investigate the following questions:

- What are the current industry practices for disposing of unused pharmaceuticals?
- Which pharmaceuticals are being disposed of and at 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 within industry sectors?
- What best management practices (BMPs) could facilities implement to reduce the generation of unused pharmaceuticals?
- What reductions in the quantities of pharmaceuticals discharged to POTWs would be achieved by implementing BMPs or alternative disposal methods?
- What are the costs of current disposal practices compared to the costs of implementing BMPs or alternative disposal methods?

II.   Description of Information Collection Request and Approval Process

The Paperwork Reduction Act stipulates that every federal agency must obtain approval from the Office of Management and Budget before collecting the same or

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[1] As a point of clarification, the term "unused pharmaceuticals" does not include excreted pharmaceuticals.

similar information from 10 or more members of the public. An Information Collection Request (ICR): (1) describes the information to be collected; (2) gives the reason the information is needed, and (3) estimates the time and cost for the public to answer the request. After reviewing the request, the Office of Management and Budget may approve or disapprove the ICR, or place conditions that must be met for approval. This process was designed to prevent unnecessary collections and reduce costs.

EPA's survey approval process requires the publication of two Federal Register notices on the survey design and instruments. These two notices provide the public with two opportunities to review and comment on the survey before OMB review.

EPA published the first Federal Register notice for the health care industry ICR on August 12, 2008 (73 FRN 46903). The public had 60 days to review and comment on the survey design and instrument. The ICR was originally developed to collect technical and economic information on unused pharmaceutical management and to identify technologies and BMPs that reduce or eliminate the discharge of unused pharmaceuticals to POTWs. EPA received 31 comments and conducted outreach meetings with industry to obtain further comments on the survey design and instrument.

Commenters included hospitals and clinics, health care trade associations, pharmacists associations, reverse distributors, pharmaceutical manufacturers, individuals, and municipal wastewater treatment plants and their associations. Following publication of the first Federal Register notice for the ICR, EPA conducted three hour-long teleconferences in September 2008 with 259 stakeholders to provide an overview of the project, scope of the survey instrument, potential recipients, and schedule. These meetings solicited early feedback from participants to facilitate the development of a subsequent draft of the survey instrument and population and sample frames. These teleconferences also identified interested stakeholders for the site visits/additional outreach meetings. Overall, the comments received were supportive of the survey. Most commenters had a number of suggestions on how to improve the survey. Improvements suggested were to expand the scope of sectors receiving the survey, to shorten the survey, and to tailor the survey to each health care sector. There were a few health care organizations who felt a survey was not necessary for a variety of reasons including burden to the facilities, that they are already practicing BMPs, or that they would favor the more immediate issuance of EPA guidance.

EPA's outreach (see following sections) identified that there is near universal interest from stakeholders to better manage unused pharmaceuticals at health care facilities. There is also general interest in more quickly advancing the use of best practices for managing unused pharmaceuticals at health care facilities. This considerable outreach and data collection has led EPA to re-consider the use of an industry survey for this sector. The survey would be an effective but potentially time-consuming tool for gathering facility-specific data on the management of unused pharmaceuticals. EPA estimates that it has gathered sufficient data from its site visits and outreach to begin the development of best practices for unused pharmaceutical management at health care facilities.

III.   Outreach Activities in 2007-2009

The outreach goals for the Health Care Industry (HCI) Detailed Study and ICR include: (1) establish points of contact between the EPA HCI Team and industry associations, facilities, contractors, and vendors; (2) further EPA's understanding of the HCI, including challenges with pharmaceutical management and disposal; (3) discuss comments on the draft survey and scope of the survey; (4) identify outreach opportunities to association members and other interested stakeholders; (5) provide transparency on EPA's actions and decision-making; and (6) identify and resolve issues as early as possible.

In 2007 to 2009, EPA worked with a wide range of stakeholders (e.g., industry representatives; Federal, State, and Tribal representatives; waste management and disposal companies; and other interested parties) to obtain the best available information on the industry and its unused pharmaceutical management practices. In total, EPA met or spoke with over 700 different people during the outreach and data collection activities from 2007 through 2009. EPA developed its outreach by contacting interested stakeholders, holding open outreach meetings for anyone interested in EPA's survey following the first Federal Register notice, and following up with teleconferences and meetings with contacts from the industry.

EPA began contacting HCI stakeholders in 2007 to gather information on the industry and to understand unused pharmaceutical management practices. EPA completed a preliminary study and developed a draft industry survey. Following the September 2008 open outreach teleconferences, EPA contacted various stakeholders including industry associations, researchers, facilities, and contractors to set up additional meetings. See Appendix A for a listing of the meetings and their document numbers in the on-line docket (EPA-HQ-OW-2008-0517).

IV.   Site Visits in 2008 - 2009

EPA visited five hospitals in four states/districts, four LTCFs in three states/districts, a veterinary hospital in Virginia, a hospice facility in Virginia, a hematology/oncology clinic in Virginia, a long-term care pharmacy in Maryland, a reverse distributor in Wisconsin, and a waste management vendor facility in Maryland to gather data for the HCI Detailed Study. In total EPA conducted 15 sites visits to different locations and met with 70 different stakeholders during these visits. EPA visited a range of HCI facilities and operations that demonstrate unused pharmaceutical management options for that type of facility.

During each site visit, EPA collected general site information and specific unused pharmaceutical management and disposal information. The objectives of these site visits included:

- Collect information on the amount of unused pharmaceuticals disposed;
- Observe pharmaceutical waste management practices;
- Identify common industry disposal practices, guidance, and regulatory requirements;
- Identify challenges with the generation and disposal of unused, unwanted, and expired pharmaceuticals;
- Identify BMPs and their costs;
- Understand potential impacts of pharmaceuticals in water; and
- Gather information about how hospitals, LTCFs, or other facilities operate.

Information collected during each site visit is documented in a report. Confidential Business Information (CBI) in these site visit reports is redacted from the public versions of the reports in the on-line docket. See Appendix A for a listing of the site visit reports and their document numbers in the on-line docket (EPA-HQ-OW-2008-0507).

V.   Other Data Collection Activities in 2007 - 2009

EPA also identified and collected a series of information during 2007-2009 to support the HCI Detailed Study. These documents are listed in the on-line docket for the preliminary study (EPA-HQ-OW-2006-0771) and on-line docket for the current study (EPA-HQ-OW-2008-0517).

Appendix A: Summary of Outreach Activities and Data Collection Supporting the EPA HCI Detailed Study

Table A-1. HCI Detailed Study Outreach Meetings and Activities

No.	Title	Location	Date	DCN[a]
1	Meeting with the Pharmaceutical Research and Manufacturers of America (PhRMA)	Teleconference	05/01/07	5964
2	Meeting with the Center of Excellence in Assisted Living (CEAL) Advisory Council	Arlington, VA	10/18/07	5961
3	Health Services Outreach Teleconference with Hospitals for a Healthy Environment (H2E) Members	Teleconference	10/19/07	5962
4	Health Services Outreach Meeting with Stakeholders	Teleconference	10/26/07	5963
5	Fifth Annual Maine Benzodiazepine Study Group Conference & Fourth Annual Unused Drug Return Conference	Bangor, ME	10/31/07	(b)
6	Health Services Meeting with SolmeteX	Teleconference	12/19/07	5958
7	Region 3 Pharmaceutical Workgroup Meeting Notes	Teleconference	01/09/08	5467
8	Meeting Minutes from EPA/PhRMA Meeting	Teleconference	01/16/08	5473
9	Health Services Meeting with the Food and Drug Administration (FDA)	Bethesda, MD	03/04/08	5959
10	Health Services Meeting with the Members of the Department of Health and Human Services (HHS)	Teleconference	04/01/08	5960
11	Summary of the Meeting with the Drug Enforcement Administration (DEA)	Washington, DC	07/01/08	5998
12	Stakeholder Outreach Meeting	Teleconference	09/11/08	6252
13	Stakeholder Outreach Meeting	Teleconference	09/16/08	6253
14	Stakeholder Outreach Meeting	Teleconference	09/18/08	6254

Table A-1. HCI Detailed Study Outreach Meetings and Activities

No.	Title	Location	Date	DCN[a]
15	Summary of Voicemail Message from Maureen Gallagher	Teleconference	10/01/08	6452
16	Meeting with Vestara Regarding the Health Care Industry Information Collection Request (ICR)	Teleconference	10/08/08	6245
17	Outreach Meeting with AHA and ASHES	Teleconference	10/21/08	6255
18	Summary of Phone Conversation with Charlotte Smith from PharmEcology	Teleconference	11/18/08	6454
19	Outreach Meeting with the American Society of Consultant Pharmacists (ASCP)	Teleconference	11/03/08	6256
20	Outreach Meeting with the American Veterinary Medical Association (AVMA)	Teleconference	11/04/08	6257
21	Outreach Meeting with the American Health Care Association (AHCA)	Teleconference	11/05/08	6258
22	Summary of Phone Conversation with Bruce Cuhna	Teleconference	11/19/08	6453
23	Outreach Meeting with the Hematology Oncology Pharmacy Association (HOPA)	Washington, DC	12/01/08	6259
24	PSI Pharmaceutical Dialogue Meeting	Washington, DC	12/2/08 and 12/3/08	6260
25	Meeting with the American Society of Health-System Pharmacists (ASHP)	Teleconference	12/04/08	6261
26	Meeting with the American Hospital Association (AHA) Statisticians	Washington, DC	12/04/08	6262
27	National Association of Boards of Pharmacy: Report of the Task Force on Medication Collection Programs	Tucson, AZ	12/06/08	6848
28	Meeting with the Assisted Living Federation of America (ALFA)	Teleconference	12/09/08	6263

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No.	Title	Location	Date	DCN[a]
29	Meeting with the American Society for Healthcare Environmental Services (ASHES)	Teleconference	12/10/08	6264
30	Summary of Phone Conversation with Quest Diagnostics Laboratories	Teleconference	12/10/08	6912
31	Meeting with Dr. Bryan Boulanger, Texas A&M University	Teleconference	12/11/08	6265
32	Email Correspondence with Danette Cox: Nursing Home Survey Results Conducted by the Metropolitan Water Reclamation District of Greater Chicago	Email	12/22/08	6458
33	Summary of Phone Conversation with Nancy Larson	Teleconference	01/06/09	6457
34	Summary of Phone Conversation with Diane Darvey	Teleconference	01/15/09	6455
35	Meeting with the Long Term Care Pharmacy Alliance (LTCPA)	Teleconference	02/03/09	6295
36	Meeting with ExcelleRx	Teleconference	02/09/09	6296
37	Summary of Phone Conversation with Jon Keyserling of the National Hospice and Palliative Care Organization	Teleconference	02/12/09	6456
38	Meeting with Talyst	Teleconference	02/24/09	6501
39	Meeting with the American Medical Association (AMA)	Teleconference	02/24/09	6500
40	Email correspondence with Jennifer Crittenden: Mailback Program data from the UMaine Center on Aging	Email	02/24/09	6459
41	Meeting with the American Nurses Association (ANA)	Teleconference	03/03/09	6502
42	Meeting with the National Association of Home Care and Hospice	Teleconference	03/12/09	6503
43	Meeting with Clear River Enviro, LLC	Teleconference	04/03/09	6575
44	Teleconference with Alexian Brothers Medical Center	Teleconference	4/6/2009	6438
45	Meeting with Stericycle	Washington, DC	04/16/09	6439
46	Teleconference with Bruce Cunha, Marshfield Clinic	Teleconference	05/20/09	6573

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No.	Title	Location	Date	DCN[a]
47	Teleconference with Brock Slabach, National Rural Health Association	Teleconference	05/27/09	6412
48	Teleconference with National Hospice and Palliative Care Organization (NHPCO)	Teleconference	06/05/09	6574
49	Teleconference with Centers for Medicare & Medicaid Services (CMS)	Teleconference	06/23/09	6498
50	Teleconference with Geisinger Hospital	Teleconference	07/14/09	6850
51	Meeting with Stericycle	Washington, DC	07/23/09	6497

a – EPA Docket Numbers: EPA-HQ-OW-2006-0771 and EPA-HQ-OW-2008-0517

b – See web site: http://www.mainebenzo.org/2007conference.htm

Table A-2. HCI Detailed Study Site Visits

No.	Title	Location	Date	DCN[a]
1	Site Visit Report for Capital Returns, Milwaukee, WI	Milwaukee, WI	6/3/08	6086
2	Site Visit Report for North Memorial Hospital, Robbinsdale, MN	Robbinsdale, MN	6/4/08	6087
3	Site Visit Report for Abbott Northwestern Hospital, Minneapolis, MN	Minneapolis, MN	6/4/08	6088
4	Site Visit Report for Hope Center For Advanced Veterinary Medicine	Vienna, VA	1/7/09	6241
5	Site Visit Report for Sunrise on Connecticut Ave Washington DC	Washington, DC	1/26/09	6432
6	Site Visit Report for Baltimore VA Medical Center	Baltimore, MD	1/13/09	6433
7	Site Visit Report for The Methodist Home Washington, DC	Washington, DC	1/30/09	6578
8	Site Visit Report for Genesis HealthCare Churchman Village Newark, DE	Newark, DE	2/3/09	6428
9	Site Visit Report for Omnicare Long Term Pharmacy	Annapolis Junction, MD	2/20/09	6434
10	Site Visit Report for Thomas Jefferson University Hospital	Philadelphia, PA	3/17/09	6435
11	Site Visit Report for Francis E. Parker Home for the Aging	Piscataway, NJ	3/16/09	6436
12	Site Visit Report for Walter Reed Army Medical Center	Washington, DC	3/30/09	6437
13	Site Visit Report for Capital Hospice	Arlington, VA	7/22/2009	6576
14	Site Visit Report for Fairfax -Northern Virginia Hematology Oncology	Arlington, VA	8/24/2009	6577
15	Site Visit Report for Stericycle	Baltimore, MD	9/9/2009	6789

a – EPA Docket Numbers: EPA-HQ-OW-2006-0771 and EPA-HQ-OW-2008-0517

Table A-3. HCI Detailed Study Voluntary Data Request Submissions

No.	Title	Location	Date	DCN[a]
1	Voluntary Data Request for the Health Services Industry - Lakeview Hospital	Bountiful, UT	4/16/2008	5752
2	Voluntary Data Request for the Health Services Industry - Heritage Place	Bountiful, UT	4/18/2008	5749
3	Voluntary Data Request for the Health Services Industry - Great River Medical Center	Blytneville, AR	4/21/2008	5445
4	Voluntary Data Request for the Health Services Industry - Southwest Regional Hospital Center	Little Rock, AR	4/28/2008	5751
5	Voluntary Data Request for the Health Services Industry - White County Medical Center – North	Searcy, AR	4/30/2008	5747
6	Voluntary Data Request for the Health Services Industry - Arkansas Heart Hospital	Little Rock, AR	5/16/2008	6014
7	Voluntary Data Request for the Health Services Industry - Rapid City Regional Hospital	Rapid City, SD	5/16/2008	6015
8	Voluntary Data Request for the Health Services Industry - White County Medical Center – South	Searcy, AR	5/19/2008	5748
9	Voluntary Data Request for the Health Services Industry - Golden Living Center Black Hills	Rapid City, SD	5/20/2008	5750
10	Voluntary Data Request for the Health Services Industry - Boulder Park Terrace	Charlevoix, MI	7/23/2008	5798
11	Voluntary Data Request for the Health Services Industry - Northern Michigan Regional Hospital	Petoskey, MI	7/23/2008	5800
12	Voluntary Data Request for the Health Services Industry - Northern Michigan Regional Hospital Mental Health Unit	Petoskey, MI	7/23/2008	5799
13	Voluntary Data Request for the Health Services Industry - Facility #1	VA	7/30/2008	5804
14	Voluntary Data Request for the Health Services Industry - Facility #2	VA	7/30/2008	5805

Table A-3. HCI Detailed Study Voluntary Data Request Submissions

No.	Title	Location	Date	DCN[a]
15	Voluntary Data Request for the Health Services Industry - Facility #3	FL	7/30/2008	5806
16	Voluntary Data Request for the Health Services Industry - Facility #4	Unknown	7/30/2008	5807
17	Voluntary Data Request for the Health Services Industry - Facility #5	Unknown	7/30/2008	5808
18	Voluntary Data Request for the Health Services Industry - Facility #6	Unknown	7/30/2008	5809
19	Voluntary Data Request for the Health Services Industry - Saint Anne Home	Fort Wayne, IN	10/24/2008	6192
20	Voluntary Data Request for the Health Services Industry – Franklin County Nursing Home	Malone, NY	12/17/2008	6430

a – EPA Docket Numbers: EPA-HQ-OW-2006-0771 and EPA-HQ-OW-2008-0517