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United States
Environmental Protection
Agency

Health Services Industry Study

Management and Disposal of Unused Pharmaceuticals (Interim Technical Report)

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1. INTRODUCTION

Under the Clean Water Act (CWA), EPA establishes national regulations (called effluent limitations guidelines and standards) to reduce discharges of pollutants from industries to surface waters and publicly owned treatment works (POTWs). Section 304(m) of the CWA requires EPA to publish a final Effluent Guidelines Program Plan every other year and to give the public an opportunity to comment on such plan before it is final. EPA selected the health services industry for further analysis in the 2006 Plan (EPA, 2006a) based in part on public concern about disposal of unused pharmaceuticals from health services facilities and information from other studies that investigated the presence and potential effects of pharmaceuticals in U.S. waters. EPA received 17 comments on the 2006 Plan that raised concerns about discharges from health services facilities. EPA divided the study of discharges from the health services industry into two study areas: 1) disposal of unused pharmaceuticals to surface water and 2) discharge of mercury from dental amalgam to surface water (see EPA-HQ-OW-2006-0771, DCN 05518). This interim report discusses the disposal of unused pharmaceuticals and addresses the following questions:

- How many health services entities exist in the U.S., and how are they structured?
- What unused pharmaceuticals are discharged to surface water (i.e., what are the pollutants of concern?) What are the current industry practices for disposing of unused pharmaceuticals and why? Do publicly owned treatment works (POTWs) report pass-through or interference problems related to unused pharmaceutical discharges?
- What are the federal, state, or local requirements or guidance for disposal of unused pharmaceuticals? How are control authorities currently limiting unused pharmaceutical discharges?
- What management practices and technologies are used as alternatives to wastewater disposal and/or to control discharges? How effective are these practices and technologies?
- What are the pathways for the release of unused pharmaceuticals into the environment?
- What is the amount of unused pharmaceuticals currently being disposed? What are the costs of the identified technologies and/or management practices?
- What are EPA's next steps in studying the disposal of unused pharmaceuticals to surface water?

To date, EPA's analysis has focused on hospitals and Long-Term Care Facilities (LTCFs). EPA plans to expand the scope of its study to include discharges from hospices and veterinary facilities. This report describes EPA's analysis of unused pharmaceutical discharges from hospitals and LTCFs and is organized into the following sections:

- Section 2 provides a preliminary profile of the health services industry that includes the number of hospitals and LTCFs, the number of small businesses, discharge information, and financial characteristics;
- Section 3 discusses the sources of pharmaceuticals in the environment, the potential fate of pharmaceuticals at POTWs, and detected concentrations of pharmaceuticals in wastewater, surface water, and groundwater;
- Section 4 describes the federal and state requirements and other factors that affect unused pharmaceutical disposal practices currently used by hospitals and LTCFs;

- Section 5 describes management practices and technologies currently used by hospitals and LTCFs as alternatives to reduce the amount of unused pharmaceuticals disposed of in wastewater;
- Section 6 describes the pathways through which pharmaceuticals are released to water, land, and air;
- Section 7 describes case studies of hospitals and LTCFs: the quantities and types of pharmaceuticals disposed of in wastewater, management practices, alternate disposal methods, and costs associated with disposal;
- Section 8 summarizes EPA's 2008 annual review of hospitals and LTCFs and describes the next steps planned for the 2009 annual review, which is planned to also include veterinary facilities and hospices.

2. INDUSTRY PROFILE

This section provides a preliminary profile of hospitals and LTCFs. The economic data include the number of establishments in each sector, the number of small businesses, discharge information, and financial characteristics. For economic information on other health services industry sectors, including offices, clinics, and veterinary care services, see EPA's 2007 industry profile (ERG, 2007). EPA presents industry profile information using the North American Industry Classification System (NAICS) codes and the Standard Industrial Classification (SIC) codes. The U.S. Census Bureau classifies information by NAICS codes and EPA classifies discharge information (Toxic Release Inventory (TRI) and Permit Compliance System (PCS) database information) by SIC code.

Three NAICS codes apply to hospitals and three NAICS codes apply to LTCFs. These NAICS codes are listed below along with the Census Bureau's definition of each industry:

The following NAICS codes apply to hospitals:

- *622110 — General and Medical Surgical Hospitals.* This industry comprises establishments known and licensed as general medical and surgical hospitals primarily engaged in providing diagnostic and medical treatment (both surgical and nonsurgical) to inpatients with any of a wide variety of medical conditions. These establishments maintain inpatient beds and provide patients with food services that meet their nutritional requirements. These hospitals have organized staffs of physicians and other medical personnel to provide patient care. These establishments usually provide other services, such as outpatient services, anatomical pathology services, diagnostic X-ray services, clinical laboratory services, operating room services for a variety of procedures, and pharmacy services.
- *622210 — Psychiatric and Substance Abuse Hospitals.* This industry comprises establishments known and licensed as psychiatric and substance abuse hospitals primarily engaged in providing diagnostic, medical treatment, and monitoring services for inpatients who suffer from mental illness or substance abuse disorders. The treatment often requires an extended stay in the hospital. These establishments maintain inpatient beds and provide patients with food services that meet their nutritional requirements. They have organized staffs of physicians and other medical personnel to provide patient care. Psychiatric, psychological, and social work services are available at the facility. These hospitals usually provide other services, such as outpatient services, clinical laboratory services, diagnostic X-ray services, and electroencephalograph services.
- *622310 — Specialty (Except Psychiatric and Substance Abuse) Hospitals.* This industry consists of establishments known and licensed as specialty hospitals, primarily engaged in diagnosing and treating inpatients with a specific type of disease or medical condition (except psychiatric or substance abuse). Hospitals providing long-term care for the chronically ill and hospitals providing rehabilitation, restorative, and adjustive services to physically challenged or disabled people are included in this industry. These establishments maintain inpatient beds and provide patients with food services that meet their nutritional requirements. They have organized staffs of physicians and other medical

personnel to provide patient care. These hospitals may provide other services, such as outpatient services, diagnostic X-ray services, clinical laboratory services, operating room services, physical therapy services, educational and vocational services, and psychological and social work services.

The following NAICS codes apply to LTCFs:

- *623110 — Nursing Care Facilities.* This industry comprises establishments primarily engaged in providing inpatient nursing and rehabilitative services. The care is generally provided for an extended period of time. These establishments have a permanent core staff of registered or licensed practical nurses who, along with other staff, provide nursing and continuous personal care services.
- *623210 — Residential Mental Retardation Facilities.* This industry comprises establishments (e.g., group homes, hospitals, intermediate care facilities) primarily engaged in providing residential care services for persons diagnosed with mental retardation. These facilities may provide some health care, though the focus is room, board, protective supervision, and counseling.
- *623310 — Continuing Care Retirement Communities.* This industry comprises establishments primarily engaged in providing a range of residential and personal care services with onsite nursing care facilities for (1) the elderly and other persons who are unable to fully care for themselves and/or (2) the elderly and other persons who do not desire to live independently. Individuals live in a variety of residential settings with meals, housekeeping, social, leisure, and other services available to assist residents in daily living. Assisted-living facilities with onsite nursing care facilities are included in this industry.

EPA also used the U.S. Census Bureau's bridge between NAICS and SIC to associate the EPA discharge information with the appropriate NAICS code (Census, 1997a and 1997b). Table 2-1 lists the bridge between the in-scope NAICS and SIC codes. Table 2-2 provides a bridge from SIC code to NAICS code. For some industries there is not a 100 percent direct comparison between NAICS and SIC. For example, SIC 8361 (residential care) does not fully flow into in-scope NAICS codes. NAICS 623210 (residential mental retardation facilities) includes approximately 18 percent of SIC 8361, with the remainder of the establishments out of the NAICS 623210 scope (Census, 1997b).

Table 2-1. Bridge Between NAICS and SIC for In-Scope NAICS

NAICS Code	SIC Code
622110: General Medical and Surgical Hospitals	8062: General Medical and Surgical Hospitals
622210: Psychiatric and Substance Abuse Hospitals	8069: Substance Abuse Hospitals
	8063: Psychiatric Hospitals
622310: Specialty (Except Psychiatric and Substance Abuse) Hospitals	8069: Specialty Hospitals, Except Psychiatric
623110: Nursing Care Facilities	8051: Skilled Nursing Care Facilities
	8052: Intermediate Care Facilities
	8059: Nursing and Personal Care Facilities, Not Elsewhere Classified
623210: Residential Mental Retardation Facilities	8051: Skilled Nursing Care Facilities
	8052: Intermediate Care Facilities
	8059: Nursing and Personal Care Facilities, Not Elsewhere Classified
	8361: Residential Care
623311: Continuing Care Retirement Communities	Not applicable

Source: Census, 1997a and 1997b.

Table 2-2. Bridge Between SIC and NAICS

SIC Descriptions	SIC	Percent of SIC is split into NAICS	NAICS	NAICS Description
Nursing Homes and Assisted Living Facilities	8051	Not available	623110	Nursing Care Facilities
	8051		623210	Residential Mental Retardation Facilities
Intermediate Care Facilities	8052		623110	Nursing Care Facilities
	8052		623210	Residential Mental Retardation Facilities
Nursing and Personal Care Facilities, Not Elsewhere Classified	8059		623110	Nursing Care Facilities
	8059		623210	Residential Mental Retardation Facilities
Hospitals, General Medical and Surgical	8062	100%	622110	General Medical and Surgical Hospitals
Hospitals, Mental (Except Mental Retardation)	8063	100%	622210	Psychiatric and Substance Abuse Hospitals
Hospitals, Specialty (Except Psychiatric)	8069	3%	622110	General Medical and Surgical Hospitals
	8069	9%	622210	Psychiatric and Substance Abuse Hospitals
	8069	88%	622310	Specialty (Except Psychiatric and Substance Abuse) Hospitals
Not applicable			623311	Continuing Care Retirement Communities

Source: Census, 1997a and 1997b.

2.1 Number of Facilities

Table 2-3 provides state totals for hospitals (NAICS 622) and Table 2-4 lists the number of LTCFs (NAICS 623). Table 2-5 presents the changes in the number of establishments between 1998 and 2005 and compares data from three Census collection periods. In general, the health services industry has grown. Specialty hospitals (NAICS 622310), such as those treating patients with cancer, grew by more than 100 percent in the last seven years. More moderate increases (40 to 60 percent) were seen in residential mental retardation facilities (NAICS 623210) and continuing care retirement communities (NAICS 623311). The number of psychiatric and substance abuse hospitals (NAICS 622210) decreased 15 percent.

Table 2-3. Number of Hospitals by State (2005)

State	NAICS 622110, General Medical and Surgical	NAICS 622210, Psychiatric and Substance Abuse	NAICS 622310, Specialty (Except Psychiatric and Substance Abuse)
Alabama	108	10	14
Alaska	24	1	1
Arizona	77	9	26
Arkansas	81	10	14
California	439	71	59
Colorado	76	7	13
Connecticut	35	11	6
Delaware	11	3	1
District of Columbia	12	3	3
Florida	234	48	116
Georgia	159	21	22
Hawaii	21	2	4
Idaho	46	6	4
Illinois	213	22	13
Indiana	120	27	27
Iowa	121	5	6
Kansas	139	4	13
Kentucky	106	17	17
Louisiana	149	27	64
Maine	39	6	2
Maryland	55	23	16
Massachusetts	84	24	24
Michigan	154	19	24
Minnesota	138	4	7
Mississippi	99	7	10
Missouri	130	18	10
Montana	58	4	0
Nebraska	91	4	5
Nevada	32	10	8

Table 2-3. Number of Hospitals by State (2005)

State	NAICS 622110, General Medical and Surgical	NAICS 622210, Psychiatric and Substance Abuse	NAICS 622310, Specialty (Except Psychiatric and Substance Abuse)
New Hampshire	27	2	4
New Jersey	98	19	38
New Mexico	44	6	13
New York	231	47	20
North Carolina	125	16	14
North Dakota	44	3	4
Ohio	174	20	34
Oklahoma	120	20	30
Oregon	61	2	4
Pennsylvania	217	39	59
Rhode Island	15	2	3
South Carolina	72	6	5
South Dakota	57	0	3
Tennessee	143	14	21
Texas	441	45	149
Utah	46	6	6
Vermont	15	2	0
Virginia	92	19	18
Washington	103	7	4
West Virginia	59	7	5
Wisconsin	127	12	10
Wyoming	24	5	0
Total U.S.	**5,386**	**722**	**973**

Source: Census, 2005a.

Table 2-4. Number of In-Scope Nursing and Residential Care Facilities by State (2005)

State	NAICS 623110, Nursing Care Facilities	NAICS 623210, Residential Mental Retardation Facilities	NAICS 623311, Continuing Care Retirement Communities
Alabama	250	193	86
Alaska	6	73	12
Arizona	180	336	103
Arkansas	323	83	26
California	1,501	1,778	388
Colorado	211	163	57
Connecticut	276	366	41
Delaware	52	64	15
District of Columbia	16	64	7

Table 2-4. Number of In-Scope Nursing and Residential Care Facilities by State (2005)

State	NAICS 623110, Nursing Care Facilities	NAICS 623210, Residential Mental Retardation Facilities	NAICS 623311, Continuing Care Retirement Communities
Florida	815	545	297
Georgia	490	207	89
Hawaii	38	14	9
Idaho	88	59	28
Illinois	775	802	162
Indiana	421	905	71
Iowa	396	393	94
Kansas	297	341	89
Kentucky	306	408	30
Louisiana	323	338	33
Maine	111	277	28
Maryland	338	444	101
Massachusetts	569	841	83
Michigan	493	1,460	92
Minnesota	366	1,589	106
Mississippi	213	15	37
Missouri	554	314	134
Montana	69	83	29
Nebraska	177	81	38
Nevada	52	91	15
New Hampshire	95	35	29
New Jersey	406	611	86
New Mexico	90	244	25
New York	700	2,262	76
North Carolina	519	838	184
North Dakota	72	73	13
Ohio	949	1,128	231
Oklahoma	380	435	56
Oregon	183	449	105
Pennsylvania	942	1,558	291
Rhode Island	103	173	28
South Carolina	185	240	80
South Dakota	96	40	32
Tennessee	329	309	64
Texas	1,217	898	250
Utah	104	138	23
Vermont	53	21	22
Virginia	307	225	112
Washington	287	200	162

Table 2-4. Number of In-Scope Nursing and Residential Care Facilities by State (2005)

State	NAICS 623110, Nursing Care Facilities	NAICS 623210, Residential Mental Retardation Facilities	NAICS 623311, Continuing Care Retirement Communities
West Virginia	145	319	31
Wisconsin	377	881	118
Wyoming	23	16	2
Total U.S.	**17,268**	**23,420**	**4,320**

Source: Census, 2005a.

Table 2-5. Number of Establishments in 1998, 2002, and 2005 by NAICS Based on County Business Patterns

NAICS	Number of Establishments			
	1998	2002	2005	% Change from 1998 to 2005
622110: General Medical and Surgical Hospitals	5,646	5,971	5,386	-5%
622210: Psychiatric and Substance Abuse Hospitals	848	797	722	-15%
622310: Specialty (Except Psychiatric and Substance Abuse) Hospitals	466	801	973	109%
623110: Nursing Care Facilities	16,060	16,779	17,268	8%
623210: Residential Mental Retardation Facilities	14,771	19,369	23,420	59%
623311: Continuing Care Retirement Communities	3,055	4,163	4,320	41%
Total	**40,846**	**47,880**	**52,089**	

Source: Census, 1998, 2002, and 2005a.

2.2 Revenues and Employees

Table 2-6 lists, for hospitals and LTCFs, the number of establishments, total revenues, total number of paid employees, average revenue and average number of employees per establishment based on the 2002 Economic Census data.[1] Average revenue and average number of paid employees were determined by dividing total revenue and total paid employees by the total number of establishments, respectively. General and surgical hospitals (NAICS 622110) showed much higher revenue per establishment than the other two hospital categories. For LTCFs, nursing and continuing care facilities (NAICS 623110 and 623311) had higher revenue per establishment than residential mental retardation facilities (NAICS 623210).

[1] Note: Minor discrepancies in number of establishments arise when comparing County Business Patterns and Economic Census data due to the different data collection methods. See U.S. Census Bureau, "Overview of Economic Statistical Programs," http://www.census.gov/econ/overview/index.html, May 5, 2007.

Table 2-6. Nationwide Summary by NAICS (2002) Based on Census 2002

NAICS	Number of Establishments	Revenues ($1,000)	Paid Employees	Average Revenue per Establishment ($1,000)	Employees per Establishment
622110: General Medical and Surgical Hospitals	5,193	469,726,928	4,772,422	90,454	919
622210: Psychiatric and Substance Abuse Hospitals	603	13,626,730	216,005	22,598	358
622310: Specialty (Except Psychiatric and Substance Abuse) Hospitals	615	16,759,183	185,835	27,251	302
623110: Nursing Care Facilities	16,568	74,116,741	1,606,003	4,473	97
623210: Residential Mental Retardation Facilities	22,319	13,279,613	371,429	595	17
623311: Continuing Care Retirement Communities	3,916	14,861,905	312,583	3,795	80
Total	**49,214**	**$602,371,100**	**7,464,277**		

Source: Census, 2005b.

2.3 Number of Companies

Table 2-7 shows the number of establishments, total firms, and single- and multi-unit firms. The majority of hospitals (NAICS 622) are multi-unit firms and the majority of LTCFs (NAICS 623) are single-unit firms.

Table 2-7. Number of Single-Unit and Multi-Unit Firms (2002)

NAICS	Number of Firms	Number of Establishments	Single Unit Firms	Multi-Unit Firms
622110: General Medical and Surgical Hospitals	3,242	5,193	1,543	1,699
622210: Psychiatric and Substance Abuse Hospitals	476	603	87	389
622310: Specialty (Except Psychiatric and Substance Abuse) Hospitals	332	615	130	202
623110: Nursing Care Facilities	8,903	16,568	7,301	1,602
623210: Residential Mental Retardation Facilities	5,262	22,319	3,602	1,660
623311: Continuing Care Retirement Communities	2,881	3,916	2,298	583
Total:	**21,096**	**49,214**	**14,961**	**6,135**

Source: Census, 2005b.

2.4 Number of Small Businesses

Tables 2-8 and 2-9 list the Small Business Administration (SBA) size standard for each NAICS industry and the number of establishments that meet these criteria. Table 2-8 presents the NAICS industries with size standards below $10 million and uses data from the 2002 Census

reporting of receipts/revenue size of establishments. Table 2-9 presents the NAICS industries with size standards above $10 million and uses U.S. Census Company Statistics Data. Nursing and continuing care facilities (NAICS 623110 and 623311) have a size standard of $12.5 million, hospitals (NAICS 622) have a size standard of $31.5 million in annual receipts, and residential mental retardation facilities (NAICS 623210) have a size standard of $9 million.

Table 2-8. Establishment Small Businesses (2002)

NAICS	Revenue Size Standard (Million)	Number of Establishments	Definitely Small	Possibly Small	Best Estimate Small	% Small
623210: Residential Mental Retardation Facilities	$9.0	22,319	20,726	1,428	22,154	99.3%

Source: Census, 2005b.

Table 2-9. Firm Small Businesses (2002)

NAICS	Revenue Size Standard (Million)	Number of Firms	Definitely Small	Possibly Small	Best Estimate Small	% Small
622110: General Medical and Surgical Hospitals	$31.5	3,581	981	600	1,581	44.1%
622210: Psychiatric and Substance Abuse Hospitals	$31.5	609	193	134	327	53.8%
622310: Specialty (Except Psychiatric and Substance Abuse) Hospitals	$31.5	548	319	49	368	67.2%
623110: Nursing Care Facilities	$12.5	8,672	7,043	72	7,115	82.0%
623311: Continuing Care Retirement Communities	$12.5	2,792	2,179	26	2,205	79.0%

Source: Census, 2007.

For Table 2-8, EPA classified establishments into two categories: "Definitely Small" and "Possibly Small." EPA counted an establishment in the "definitely small" category if it operated for the entire year and had revenue ranging from less than $10,000 to $4.99 million. EPA counted establishments in the $5 million to $9.9 million revenue group in the "possibly small" category. The SBA size standard of $9 million occurred within the range of this revenue group for this industry. As a result, some, but not all, of the establishments in that revenue group were small. EPA assumed that the establishments were evenly distributed within the revenue group and prorated the company count accordingly. Specifically, NAICS 623210 has a size standard of $9 million and there are 250 establishments in the $5,000,000 to $9,999,999 revenue category. EPA estimated the number of "possibly small" establishments by multiplying 250 establishments by the ratio of the number of units from $9 million to the lower end of the range to the total number of units in the range — i.e., (9-5) ÷ (9.99-5) = 0.80 — for a total of 200 establishments (Census, 2005b). EPA counted the 1,237 establishments that did not operate for the entire year in the "possibly small" category. EPA assumed that the proportion of establishments that did not operate for an entire year and also qualified as small was equal to the proportion of

establishments that qualified as small in the overall population, 99.3 percent, or 1,228 establishments. Thus, Table 2-8 lists a total of 1,428 possibly small establishments.

For Table 2-9, similar calculations were made for NAICS industries with size standards larger than 10 million using U.S. Census Company Statistics Data. These data combine 2002 County Business Pattern and 2002 Economic Census Data at a firm level (i.e., multi-unit establishments are one firm) (Census, 2007). Nursing and residential care facilities (NAICS 623110 and 623311) have an estimated 80 percent of firms that are potentially small businesses. The best estimated percent of hospitals that are small is 44 percent of general and surgical hospitals, 54 percent of psychiatric and substance abuse hospitals, and 67 percent of specialty hospitals.

In general, only hospitals have a substantial portion of large entities (33 to 56 percent). However, Section 2.5 indicates that many of these entities are not commercial, for-profit businesses. The Regulatory Flexibility Act sets different size standards for government and nonprofit entities. For government entities, the size standard is serving a population of 50,000 residents or fewer. For nonprofit entities, a small organization is one that it independently owned and not dominant in its field (5 U.S.C. 601(3-5)). Thus, a more detailed investigation would involve identifying individual facilities, their ownership, and whether they serve a population of more than 50,000 residents.

2.5 Ownership

Table 2-10 splits each industry sector into those that are subject to federal income taxes (e.g., commercial or for-profit organizations) and those that are not (Census, 2005b). The non-commercial establishments include federal, state, religious, and other groups organized on a not-for-profit basis to provide health services. Nearly 90 percent of the general medical and surgical hospitals (NAICS 622110) are nonprofit organizations. Between half and two-thirds of psychiatric and substance abuse hospitals (NAICS 622210) and residential mental retardation facilities (NAICS 623210) are nonprofit. About 40 percent of the continuing care retirement communities (NAICS 623311) and 20 percent of the nursing care facilities (NAICS 623110) are nonprofit organizations.

Table 2-10. For-Profit and Not-for-Profit Establishments (2002)

NAICS	Total Number of Establishments	Number of Establishments Subject to Federal Income Taxes	Non-Tax, Not-for-Profit Establishments	% Not-for-Profit
622110: General Medical and Surgical Hospitals	5,193	697	4,496	87%
622210: Psychiatric and Substance Abuse Hospitals	603	211	392	65%
622310: Specialty (Except Psychiatric and Substance Abuse) Hospitals	615	349	266	43%
623110: Nursing Care Facilities	16,568	13,101	3,467	21%

Table 2-10. For-Profit and Not-for-Profit Establishments (2002)

NAICS	Total Number of Establishments	Number of Establishments Subject to Federal Income Taxes	Non-Tax, Not-for-Profit Establishments	% Not-for-Profit
623210: Residential Mental Retardation Facilities	22,319	8,173	14,146	63%
623311: Continuing Care Retirement Communities	3,916	2,374	1,542	39%

Source: Census, 2005b.

Table 2-11 presents the legal organization of the commercial entities. Individual proprietorships are rare for hospitals but more common for LTCFs.

Table 2-11. Legal Form of Organization for Establishments (2002)

NAICS	Number of Establishments That File Federal Income Taxes	Corporations	Individual Proprietorships	Partnerships	Other Legal Forms of Organization
622110: General Medical and Surgical Hospitals	697	555	5	136	1
622210: Psychiatric and Substance Abuse Hospitals	211	157	1	53	0
622310: Specialty (Except Psychiatric and Substance Abuse) Hospitals	349	267	3	79	0
623110: Nursing Care Facilities	13,101	9,934	532	2,632	3
623210: Residential Mental Retardation Facilities	8,173	6,876	914	376	7
623311: Continuing Care Retirement Communities	2,374	1,401	213	760	0

Source: Census, 2005b.

2.6 Discharge Information

Table 2-12 presents the number of facilities included in the 2004 databases *TRIReleases2004_v03* and *PCSLoads2004_v03* (see EPA-HQ-OW-2006-0771, DCN 04419 and DCN 04417). Under the Emergency Planning and Community Right-to-Know Act (EPCRA), certain facilities are required to report toxic chemical releases to EPA's Toxic Release Inventory (TRI). Facilities are required to report chemical releases to air, disposal to land, and wastewater releases to streams and POTWs. For SIC 80 (Health Services), only federal facilities are required

to report to TRI. Further, only facilities that manufacture or use certain toxic chemicals in quantities greater than the reporting threshold (e.g., more than 1 pound per year of chlorine) are required to report. No SIC 80 facilities reported wastewater discharges of toxic chemicals to TRI for 2004.

Table 2-12. 2004 TRI and PCS Facility Counts

SIC Code	TRI 2004				PCS 2004	
	Direct	Indirect	Both	No Discharge Reported	Direct Major	Direct Minor
8051: Skilled Nursing Care Facilities	0	0	0	0	0	52
8052: Intermediate Care Facilities	0	0	0	0	0	25
8059: Nursing and Personal Care Facilities, Not Elsewhere Classified	0	0	0	0	0	20
8062: General Medical and Surgical Hospitals	0	0	0	1	1	21
8063: Psychiatric Hospitals	0	0	0	2	1	10
8069: Specialty Hospitals, Except Psychiatric	0	0	0	0	0	6
Total	0	0	0	3	2	134

Source: *TRIReleases2004_v03* (DCN 04419)*; PCSLoads2004_v03* (DCN 04417).

PCS is a database that tracks permit, compliance, and enforcement status of facilities regulated by the National Pollutant Discharge Elimination System (NPDES) Program under the CWA. EPA developed a major/minor classification system for industrial and municipal wastewater dischargers. Major dischargers almost always have a greater capability to impact receiving waters if not controlled and, therefore, have received more regulatory attention than minor dischargers. The major dischargers must report compliance with permit limits monthly to their permitting authority, and that authority then enters the reported data into PCS, including pollutant concentration and quantity. EPA does not require permit limit compliance data to be entered into PCS for minor dischargers; however, facility information is maintained in PCS for them.

PCS contains facility information for 136 hospitals and LTCFs. Only two of these facilities (one general medical and surgical hospital and one psychiatric hospital) are classified as majors and have pollutant concentration and quantity data in PCS. The two hospitals reported wastewater flows of 8,000 and 40,000 gallons per day. *PCSLoads2004_v03* calculates annual discharge pounds using the pollutant concentration and quantity data from PCS, then weights the annual pounds of different pollutants on the basis of their toxic potential by calculating toxic-weighted pound equivalents (TWPE) using EPA's toxic weighting factors (TWFs). The total calculated TWPE for the two hospitals in *PCSLoads2004_v04* is 13.56 TWPE compared to over 20 billion TWPE for all discharges in *PCSLoads2004_v04*.

Of the 52,089 hospitals and LTCFs potentially discharging spent pharmaceuticals that were estimated in the 2005 U.S. Census Bureau's County Business Patterns data, PCS has discharge data for two major dischargers and facility identification information for 134 minor dischargers. Because PCS does not have data for most of the facilities in this profile, most of the facilities that discharge wastewater must discharge it indirectly to municipal sewer systems.

2.7 Financial Characteristics

The federal government is by far the largest contributor to hospital revenues through Medicare and Medicaid payments. Table 2-13 summarizes the difference in typical payor mix between nonprofit and for-profit markets (S&P, 2006).

Table 2-13. Typical Payor Mix for Hospitals

Payor	For-Profit Hospitals	Not-for-Profit Hospitals
Medicaid	13%	35%
Medicare	44%	19%
Private	36%	16%
Self-pay	6%	22%
Other	4%	8%

Source: S&P, 2006.

The remainder of Section 2.7 describes the financial condition of commercial, for-profit enterprises.

2.7.1 Operating Statistics

Table 2-14 presents several operating statistics for seven for-profit hospital systems. Notice that bad debt makes up anywhere between 7.4 to 11.1 percent of revenues. Hospitals typically collect only 8 to 10 percent of self-pay bills and 50 to 60 percent of copays and deductibles (S&P, 2006). The bad debt does not necessarily include charity care. Hospitals have the option of not recording revenue from patients who they determine are unable or unlikely to pay their bills. By not recording revenue from such patients, a hospital does not record associated bad debts. A detailed investigation of hospital finances would therefore include examining the level of both bad debt and charity care (S&P, 2006).

Table 2-15 summarizes the financial statistics for commercial health care companies. There is a mix of revenue size, profitability, liquidity, and leverage (as measured by the debt/capital and debt-as-a-percentage-of-net-working-capital).

Table 2-14. Key Operating Statistics of For-Profit Hospital Systems (Quarter Ended September 30, 2006, Except as Noted)

	HCA Inc [a]	Health Management Associates	Community Health Systems	Lifepoint Hospitals	Tenet Healthcare	Triad Hospitals	Universal Health Services	Average
Number of hospitals	172	57	76	51	57	50	21	69
Licensed beds	40,382	8,331	8,929	5,705	14,941	9,316	5,139	13,249
Average length of stay (days)	4.9	4.2	4.0	4.2	4.9	4.7	4.4	4.5
Total admissions (% change from previous year)	(2.6)	5.4	16.9	10.1	(3.3)	3.1	(3.0)	3.8
Same-store comparison (% chg. from previous year)								
Admissions	0.1	0.6	2.6	(0.1)	(3.3)	3.7	1.9	0.8
Revenues per admission	6.4	4.6	7.8	7.3	2.8	6.0	6.0	5.8
As % of revenues								
Salaries and benefits	41.8	40.7	40.1	39.4	45.0	40.4	44.0	41.6
Supplies	16.8	13.4	11.6	13.9	18.2	17.3	14.1	15.0
Bad debt	10.9	9.5	10.7	10.9	7.4	11.1	9.4	10.0
Outpatient services	16.7	17.2	20.9	17.4	24.2	19.7	20.3	19.5
Consolidated EBITDA margin (%)	14.4	16.7	14.8	18.4	5.1	10.6	10.7	13.0

Source: S&P, 2006.
a — Excludes ambulatory surgical centers and seven point-venture facilities.
EBITDA — Earnings before interest, taxes, depreciation, and amortization.
HCA — Hospital Corporation of America

Table 2-15. Comparative Company Analysis — 2005 Data

Company	Operating Revenues ($ Million)	Net Income ($ Million)	Return on Revenues (%)	Return on Assets (%)	Current Ratio	Debt/ Capital (%)	Long-Term Debt/Net Working Capital [d]
Health Services Facilities							
Amsurg Corp.	391.8 [a,b]	36.4	9.3	7.6	3.3	22.0	1.74
Community Health Systems Inc.	3,738.3 [a,b]	190.1	5.1	5.0	2.1	48.9	3.46
Genesis Healthcare Corp.	1,683.3 c	42.4	2.5	3.3	2.1	38.2	1.89
Hospital Corporation of America (HCA) Inc.	24,455.0	1,424.0	5.8	6.5	1.3	60.3	7.49
Health Management Assoc.	3,543.8 [a,b]	353.7	10.0	9.4	0.9	13.0	NM
LCA Vision Inc.	192.4	31.7	16.5	21.4	9.1	1.0	0.01
Lifepoint Hospitals Inc.	1,855.1 [a]	79.8	4.3	3.9	1.8	51.7	7.92
Manor Care Inc.	3,417.3	161.0	4.7	6.9	1.2	45.5	9.25
Odyssey Healthcare Inc.	381.6 [a]	18.6	4.9	8.3	1.9	0.0	0.0
Sunrise Senior Living Inc.	1,738.0 [b]	79.7	4.6	6.6	1.2	15.9	2.02
Tenet Healthcare Corp.	9,614.0 [b,c]	(621.0)	NM	NM	1.5	79.5	3.94
Triad Hospitals Inc.	4,747.3 [c]	229.4	4.8	4.3	2.9	33.6	1.77
United Surgical Partner Intl.	474.7	47.1	9.9	4.8	1.7	30.0	2.98
Universal Health Services — CL B	3,935.5 [a,b]	109.8	2.8	3.7	1.2	31.2	7.58
VCA Antech Inc.	839.7 [a]	67.8	8.1	8.3	1.8	56.1	6.91
Other Companies with Significant Health Services Facilities Operations							
Kindred Healthcare Inc.	3,924.0 [a,b]	128.6	3.3	7.7	1.5	2.9	0.08
Rehabcare Group Inc.	454.3 [a]	(17.0)	NM	NM	1.9	2.0	0.07

Source: S&P, 2006.
a — Data reflect merger or acquisition.
b — Data reflect an accounting change.
c — Data exclude discontinued operations.
d — Analogous to comparing an outstanding mortgage to what remains in the homeowner's checkbook after the monthly bills are paid.
NM — Not meaningful.

2.7.2 Major Players

Table 2-16 lists the top 10 healthcare systems based on 2005 patient revenues. Table 2-17 lists the top 15 nursing care chains based on the number of facilities in 2005. Table 2-18 lists the top 15 assisted living chains based on the number of beds in 2005 (S&P, 2006).

Table 2-16. Top 10 Largest Healthcare Systems (Ranked by 2005 Net Patient Revenues)

Chain	Net Patient Revenues ($ Million)	Total Hospitals
Hospital Corporation of America	24,445	175
U.S. Department of Veterans Affairs	23,547	156
Ascension Health	10,280	64
Tenet Healthcare	9,441	73
New York Presbyterian Healthcare	8,627	34
Catholic Healthcare Initiatives	6,502	69
Catholic Healthcare West	5,463	40
Sutter Health	5,333	24
Catholic Health East	4,929	27
Mayo Clinic	4,902	NA

Source: S&P, 2006.

Table 2-17. Top 15 Nursing Homes Chains — 2005 (Ranked by Number of Facilities)

Chain	Total Facilities	Number of Beds	Average Beds per Nursing Home	Number of States of Operation
Beverly Enterprises	335	34,292	102.4	23
ManorCare	284	37,882	133.4	30
Sava Senior Care	256	30,617	119.6	23
Kindred Healthcare	247	33,050	133.8	29
Life Care Centers of America	224	29,092	129.9	28
Evangelical Lutheran Good Samaritan Society [a]	192	14,886	77.5	24
Genesis Health Ventures	171	22,549	131.9	12
Extendicare Health Services	147	15,018	102.2	11
Trans Healthcare	98	10,895	111.2	16
Sun Healthcare Group	92	9,916	107.8	14
Daybreak Healthcare	78	8,520	109.2	1
Five Star Quality Care	76	6,332	83.3	20
National Healthcare Corporation	73	9,163	125.5	10
Life Care Services	70	5,393	77.0	26
Senior Health Management	68	8,365	123.0	4

Source: S&P, 2006.
a — Not-for-profit hospital; all others are for-profit.

Table 2-18. Top 15 Assisted Living Chains — 2005
(Ranked by Number of Beds)

Company	Number of Beds	Total Facilities	Occupancy Rate (%)	Number of States of Operation
Sunrise Senior Living	32,244	397	90.0	38
Emeritus Assisted Living	14,483	181	83.2	35
Atria Senior Living Group	14,362	128	87.0	27
Sunwest Management	12,921	169	NA	26
Brookdale Senior Living	12,529	295	88.0	32
Extendicare Health Services	8,828	216	87.0	17
Merrill Gardens	8,741	67	96.0	11
Summerville Senior Living	6,097	62	90.3	12
American Retirement	5,557	70	93.0	19
HCR Manor Care	5,080	65	89.0	13
Leisure Care	4,867	36	93.0	8
Five Star Quality Care	4,041	80	92.0	17
Hearthstone Assisted Living	4,000	32	90.0	10
Benchmark Assisted Living	3,992	43	93.0	6
KISCO Senior Living	3,409	20	95.0	5

Source: S&P, 2006.
NA — Not available.

2.7.3 Current Ratio

Liquidity measures an industry's ability to meet current obligations without having to convert assets to cash with a loss in value. A current ratio is calculated as total current assets divided by total current liabilities. Table 2-19 lists the current ratio by industry sector and revenues (RMA, 2007). As shown in Table 2-19, some LTCFs and hospitals in the lower revenue brackets have current obligations that exceed their available revenue at the time the balance sheet was calculated; i.e., the current ratio is less than one. This can be due to a number of factors including obligations that come due before the insurance payments appear (a timing problem for their liquidity) or obligations that have a substantial portion of uncollectible revenue (i.e., bad debt and charity care). S&P (2006) reports that bad debt formed an average of 10 percent of revenues in its analysis of for-profit hospitals. RMA (2007), however, does not report this level of detail, so the specific causes are not known.

Table 2-19. 2006 Current Ratio of Assets to Liabilities (Liquidity)

	Revenues ($Millions)						
NAICS	All	$0–$1	$1–$3	$3–$5	$5–$10	$10–$25	>$25
622110: General Medical and Surgical Hospitals	1.9	0.7	1.9	1.7	2.2	2.2	1.9
622210: Psychiatric and Substance Abuse Hospitals	1.8	[a]	[a]	[a]	1.3	2.1	1.9

Table 2-19. 2006 Current Ratio of Assets to Liabilities (Liquidity)

	Revenues ($Millions)						
NAICS	**All**	**$0–$1**	**$1–$3**	**$3–$5**	**$5–$10**	**$10–$25**	**>$25**
622310: Specialty (Except Psychiatric and Substance Abuse) Hospitals	1.4	[a]	1.7	1.0	2.1	2.0	1.3
623110: Nursing Care Facilities	1.1	0.5	0.8	1.2	1.3	1.2	1.1
623210: Residential Mental Retardation Facilities	1.5	[a]	[a]	[a]	1.4	1.4	1.5
623311: Continuing Care Retirement Communities	1.1	0.7	0.7	1.3	1.0	1.2	1.3

Source: RMA, 2007.
a — Ten or fewer observations, data not shown.

2.7.4 Profit Before Taxes

Profit before taxes is calculated from an income statement, which is a one-year summary of costs and revenues. Table 2-20 lists the current ratio by industry sector and revenues (RMA, 2007).

Table 2-20. 2006 Profit Before Taxes (%)

	Revenues ($Millions)						
NAICS	**All**	**$0–$1**	**$1–$3**	**$3–$5**	**$5–$10**	**$10–$25**	**>$25**
622110: General Medical and Surgical Hospitals	4.5	2.6	6.6	11.8	8.7	4.8	3.4
622210: Psychiatric and Substance Abuse Hospitals	3.5	[a]	[a]	[a]	0.0	3.1	5.5
622310: Specialty (Except Psychiatric and Substance Abuse) Hospitals	6.9	[a]	8.7	9.4	10.1	7.0	6.1
623110: Nursing Care Facilities	5.2	14.4	5.2	3.9	3.3	4.2	3.3
623210: Residential Mental Retardation Facilities	3.5	[a]	[a]	[a]	3.7	2.4	2.9
623311: Continuing Care Retirement Communities	2.9	4.3	1.6	2.9	1.2	2.1	6.2

Source: RMA, 2007.
a — Ten or fewer observations, data not shown.

3. POLLUTANTS OF CONCERN

Due to developments in analytical methods, researchers are able to detect lower concentrations of chemicals in the aquatic environment (AWWARF, 2007). A number of studies conducted over the past 10 years suggest detection of pharmaceutical compounds in treated wastewater effluent, streams, lakes, seawater, and groundwater, as well as in sediments and fish tissue (Bren School, 2007). For example, the United States Geological Survey (USGS) conducted a study of 139 streams in the United States in 1999 and 2000. USGS detected pharmaceutical compounds in 80 percent of the streams sampled (Kolpin et al., 2002).

Two major pathways in which pharmaceutical compounds enter wastewater are excretion of partially metabolized pharmaceutical active ingredients and disposal of unused or expired medications down the drain (Daughton CG, 2007). Pharmaceutical-containing wastewater is discharged from households and medical facilities such as hospitals, LTCFs, hospices, and veterinary facilities. Medications are stored in and disposed from a very broad and diverse array of locations (H2E, 2006). In terms of both excretion and disposal, hospitals, LTCFs, hospices, veterinary hospitals, and domestic dischargers are expected to be the largest sources of pharmaceutical discharges (EC Workgroup[2], 2005). This Health Services Industry Detailed Study focuses on the disposal of unused or expired medications down the drain rather than excretion because disposal is a practice that can be controlled through implementation of best management practices (BMPs) including waste minimization.

The following subsections describe sources of pharmaceuticals in wastewater, the potential fate of pharmaceutical active ingredients in POTWs, and concentrations of pharmaceutical active ingredients detected in wastewater effluent, surface water, and groundwater.

3.1 Sources of Pharmaceutical Waste at Health Services Facilities

Pharmaceutical waste is generated at health services facilities before, during, and after treatment, as well as during stocking materials used for regular care (ERG, 2008a):

- Waste from stocking materials for regular care (expired pharmaceuticals):
  - Approximately 3 percent of all purchased medications reach their expiration date before they are used; and
  - Some pharmacies work with manufacturers to send back their expired pharmaceuticals through a reverse distributor.
- Waste generated before treatment (during preparation):
  - Partially used vials from IV preparation;

[2] The Emerging Contaminants Workgroup (EC Workgroup) was chartered at the request of the Santa Clara Basin Watershed Management Initiative (WMI) in 2001 to provide a forum to discuss issues related to endocrine disrupting compounds and recycled water. The workgroup has since broadened its scope to include all emerging contaminants of concern, not just those having endocrine disrupting effects. The current purpose of the group is to collect and review information based on the best available science on emerging contaminants of concern in and around the San Francisco Bay.

- — Partially used vials from filling syringes; and
- — General compounding[3].

- Waste generated during patient treatment:
  - — Excess medication eliminated from overfilled syringes to adjust dose prior to administering to patient; and
  - — Used syringes and IVs, which are biohazardous waste.
- Waste generated after patient treatment, or leftover medications:
  - — Discontinued, unused preparations;
  - — Unused unit doses; and
  - — Patients' unused medications after treatment completion.

Pharmaceutical wastes can be generated in the facility pharmacy, satellite pharmacies, patient care units, emergency rooms, intensive care units, oncology/hematology, radiology, ambulances, outpatient clinics, satellite medical clinics, and LTCFs (ERG, 2008a).

3.2 Potential Fate and Effects of Pharmaceuticals at POTWs

The major environmental concerns resulting from the disposal of pharmaceuticals in wastewater include the potential that POTWs may not effectively remove them through treatment and the possible effects on aquatic life and human health.

Traditional wastewater treatment operations implemented in the 1970s and 1980s at POTWs are designed to remove conventional pollutants such as suspended solids and biodegradable organic compounds; they are not designed to remove pharmaceuticals that are present in discharges from medical and veterinary facilities. POTWs may have implemented advanced treatment technologies at their facilities. However, these technologies are also not designed to remove pharmaceuticals. In addition, synthetic compounds, such as pharmaceuticals, are often manufactured to be resistant to metabolic transformation. As a result, some pharmaceutical compounds that are present in the influent to POTWs may pass through treatment systems at conventional POTWs and discharge to receiving waters. Section 6 of this report describes POTW removal efficiencies for pharmaceutical active ingredients.

There is much information about the health effects of pharmaceutical products at the therapeutic doses provided in medication (Collier, 2007). There is uncertainty about their potential effects on public health and aquatic life at the extremely low levels observed in drinking water and surface water, and ongoing studies continue to research the effects. Potential concerns include hormone disruption, antibiotic resistance, and synergistic effects from the mixtures of various pharmaceutical compounds present in water (Bren School, 2007). While observed levels of pharmaceutical compounds in streams may not be acutely toxic, the effects of discharges of pharmaceuticals on aquatic life can include subtle and gradual effects, such as those listed below:

- *Selective serotonin reuptake inhibitors (SSRIs)*. Exposure to SSRIs found in antidepressants can alter the behavior and reproductive functions of fish and mollusks (Daughton and Ternes, 1999).

[3] "Compounding" is the process of mixing drugs by a pharmacist or physician to fit the unique needs of a patient. This may be done to change the form of the medication from a solid pill to a liquid, to avoid a non-essential ingredient that the patient is allergic to, or to obtain the exact dose needed.

- *Antibiotics*. Gradual long-term exposure to antibiotics can result in the selection of bacterial pathogens that display resistance to antibiotics (Daughton and Ternes, 1999).
- *Hormones*. There are several documented cases of hormone disruption in fish and other wildlife (EC Workgroup, 2005). Typically in toxicology, the toxic effects increase as dose increases. However, endocrinologists have determined that hormones do not follow this trend and have different effects at different doses (Myers and Hessler, 2007). At low doses, hormones can affect an organism's growth, reproduction, and development (Environment Canada, 2007).

Many other types of potential effects have been reported for a wide array of therapeutic classes (U.S. EPA, 2008). Deciphering the potential for effects can be greatly complicated by the occurrence of mixture effects (Pomati, 2007). The potential health implication for humans exposed to drugs recycled from the environment via drinking water or foods is a topic of recent and ongoing studies (Collins, 2007).

3.3 Presence of Pharmaceuticals in Water

Many studies have been conducted in Europe, Canada, and the United States to determine the presence of pharmaceutical compounds in wastewater effluent, surface water, and groundwater. Although these studies demonstrate the presence of pharmaceuticals, they do not investigate the potential sources of pharmaceuticals in water. Table 3-1 presents concentrations of pharmaceuticals documented in selected studies: in surface water, groundwater, POTW influent, and POTW effluent. The concentrations from the studies were compiled in three references: a 2007 paper by researchers at the Donald Bren School of Environmental Science (Bren School, 2007), a Water Environment Research Foundation (WERF) report (Stephenson, 2007), and a report sponsored by the American Water Works Association Research Foundation (AWWRF). Table 3-1 is an example of representative data and does not represent the many published studies on this topic.

Table 3-1. Concentrations of Selected Pharmaceuticals in Wastewater, Surface Water, and Groundwater

Compound	Therapeutic Family	Concentration (ug/L)				Reference [b,c]
		POTW Influent [a]	POTW Wastewater Effluent [a]	Surface Water	Ground-water	
Acetaminophen	Painkiller/anti-inflammatory	No data	No data	ND – 10,000	No data	AWWARF, 2007 [b]
Benzafibrate	Lipid regulator	0.6	0.2	0.015	0.027	Bren School, 2007 [b]
Caffeine	Stimulant	ND – 31	No data	No data	No data	Stephenson, 2007 [c]
		No data	No data	0.040 – 0.250		AWWARF, 2007 [b]
Carbamazepine	Anti-epileptic	ND– 0.7	ND – 0.7	0.0716		Bren School, 2007 [b]
Clofibric acid	Lipid regulator	ND – 0.34	ND	ND	0.27	Bren School, 2007 [b]
Diazepam	Central nervous system agent	No data	No data	ND – 0.00213	No data	AWWARF, 2007 [b]

Table 3-1. Concentrations of Selected Pharmaceuticals in Wastewater, Surface Water, and Groundwater

Compound	Therapeutic Family	Concentration (ug/L)				Reference [b,c]
		POTW Influent [a]	POTW Wastewater Effluent [a]	Surface Water	Ground-water	
Diclofenac	Painkiller/anti-inflammatory	ND– 1.3	ND – 0.29	0.015	0.006	Bren School, 2007 [b]
		No data	No data	ND – 0.568		AWWARF, 2007 [b]
Erythromycin	Antibiotic	No data	No data	ND – 1.0		AWWARF, 2007 [b]
Estradiol	Steroid	No data	No data	0.0015 – 0.0036	No data	AWWARF, 2007 [b]
Estriol	Steroid	No data	No data	0.0006 – >0.040	No data	AWWARF, 2007 [b]
Estrone	Steroid	No data	No data	0.001 – 0.0041	No data	AWWARF, 2007 [b]
Ethinyl estradiol	Steroid	No data	No data	ND – 0.0051	No data	AWWARF, 2007 [b]
Fluoxetine	Antidepressant	<10	13 –18	0.012	No data	Bren School, 2007 [b]
		No data	No data	ND – 0.012	No data	AWWARF, 2007 [b]
Gemfibrozil	Lipid regulator	0.7 – 3.02	0.733 – 1.3	0.015 – 0.048	No data	Bren School, 2007 [b]
	Heart medication	No data	No data	ND – 1.55	No data	AWWARF, 2007 [b]
Ibuprofen	Painkiller/anti-inflammatory	2.75 – 38.7	0.043 – 4.1	0.084 – 0.20	0.003	Bren School, 2007 [b]
		ND – 32	No data	No data	No data	Stephenson, 2007 [c]
		No data	No data	ND – 5.04	No data	AWWARF, 2007 [b]
Iopromide	X-Ray contrast media	No data	No data	ND – 3.6	No data	AWWARF, 2007 [b]
Ketoprofen	Painkiller/anti-inflammatory	5.7 – 28.0	ND – 3.0	0.015	No data	Bren School, 2007 [b]
Naproxen	Painkiller/anti-inflammatory	1.8 – 41.0	0.035 – 9.5	0.044	No data	Bren School, 2007 [b]
		No data	No data	ND – 0.40	No data	AWWARF, 2007 [b]
Progesterone	Steroid	No data	No data	ND – 0.199	No data	AWWARF, 2007 [b]
Propranolol	Beta-blocker	70	304	No data	No data	Bren School, 2007 [b]
Salicylic acid	Painkiller/anti-inflammatory	325	2.8	0.015 – 0.036	0.29	Bren School, 2007 [b]
Salicylic acid, benzyl ester	Painkiller/anti-inflammatory	ND – 3.2	No data	No data	No data	Stephenson, 2007 [c]
Sulfa-methoxazole	Antibiotic	0.320 – 0.882	0.25–0.919	0.15	No data	Bren School, 2007 [b]
				ND – 1.02		AWWARF, 2007 [b]
Tamoxifen	Hormone	0.15	0.20	No data	No data	Bren School, 2007 [b]

Table 3-1. Concentrations of Selected Pharmaceuticals in Wastewater, Surface Water, and Groundwater

Compound	Therapeutic Family	Concentration (ug/L)				Reference [b,c]
		POTW Influent [a]	POTW Wastewater Effluent [a]	Surface Water	Ground-water	
Testosterone	Steroid	No data	No data	0.4 – 5.550	No data	AWWARF, 2007 [b]
Triclosan	Antibiotic	No data	No data	ND – 2.300	No data	AWWARF, 2007 [b]
Trimethoprim	Antibiotic	No data	No data	ND – 0.249		AWWARF, 2007 [b]

Sources: AWWARF, 2007; Bren School, 2007; Stephenson, 2007.
ND — Nondetect. Nondetect and the less than sign (<) denotes that the value was below sample-specific method detection limits (MDL). The MDL can change with instrument, analyst, and matrix, and therefore may vary for each sample. The MDL is different from the Practical Quantitation Level (PQL). EPA sets the PQL as the lowest concentration of an analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory operating conditions. The PQL is always greater than the MDL.
a — Higher concentrations in effluent than in influent due to design of the sampling program, retention times at the POTW, unrepresentative effluent samples, polar conjugates reforming into the parent pharmaceutical during the treatment, and interferences from high levels of organic matter (Thomas et al, 2007).
b — The AWWARF, 2007 and Bren School, 2007 studies compiled their data from existing literature and did not perform water sampling and analysis.
c — The Stephenson, 2007 study performed water sampling and analysis to obtain primary data on pharmaceuticals in the environment.

In addition to the studies compiled in the reports listed above, EPA also reviewed other studies for further information on the presence of pharmaceuticals in wastewater. For example, USGS samplers in Virginia's Shenandoah and James River Basins monitored for 30 pharmaceuticals. Only eight of the thirty pharmaceuticals were detected, at the following concentrations:

- 1,7-dimethylxanthine (a major metabolite of caffeine): ND (<0.005) to 0.012 µg/L;
- Caffeine: ND (<0.005) to 0.048 µg/L;
- Carbamazepine (an anticonvulsant drug): ND (<0.005) to 0.017 µg/L;
- Codeine (a narcotic analgesic): ND (<0.005) to 0.007 µg/L;
- Cotinine (the metabolite of nicotine): ND (<0.005) to 0.0025 µg/L;
- Sulfamethoxazole: ND (<0.005) to 0.0037 µg/L;
- Trimethoprim (an antibiotic commonly prescribed in tandem with sulfamethoxazole): ND (<0.005) to 0.1 µg/L;
- Venlafaxine (antidepressant): ND (<0.0009) to 0.046 µg/L.

All eight pharmaceuticals, except sulfamethoxazole, were detected at multiple sample sites. The most commonly detected pharmaceutical (at eight of ten sites) was trimethoprim (Alvarez, et. al. 2007).

A Norwegian study conducted in 2006 measured concentrations of pharmaceutical compounds in wastewater from two large hospitals located in central Oslo. The study tested for 20 compounds. Of the targeted compounds, parcetamol, metroprolol, diclofenac, ibuprofen, and

estriol were detected in all of the effluent samples collected at both hospitals. Paracetamol was detected at the highest concentrations ranging from 5.42 to 1,370 µg/L. Table 3-2 presents the concentrations of pharmaceutical compounds detected in hospital wastewater (Thomas et al, 2007).

Table 3-2. Concentrations of Pharmaceutical Compounds in Effluent from Two Norwegian Hospitals

Pharmaceutical (Application)	Ullevål Hospital		Rikshospitalet	
	Median Concentration (µg/L)	Frequency %	Median Concentration (µg/L)	Frequency %
Acetaminophen, or paracetamol (pain reliever)	47	100	197	100
Metoprolol (beta-blocker)	0.951	100	3.41	100
Diclofenac (anti-inflammatory)	0.784	100	1.55	100
Ibuprofen (pain reliever/ anti-inflammatory)	0.417	100	1.22	100
17β-estradiol (steroid)	0.028	100	0.041	100
17α-ethinylestradiol (steroid)	[a]	0	[a]	0
Estriol (steroid)	0.319	100	0.452	100
Estrone (steroid)	0.035	100	0.014	92
Oxytetracycline (antibiotic)	[a]	25	[a]	33
Tetracycline (antibiotic)	[a]	50	1.25	83
Demeclocycline (antibiotic)	[a]	0	[a]	8
Chlorotetracycline (antibiotic)	[a]	0	[a]	8
Doxycycline (antibiotic)	[a]	42	[a]	25
Meclocycline (antibiotic)	[a]	0	[a]	0
Trimethoprim (antibiotic)	1.81	100	3.07	92
Ciprofloxacin (antibiotic)	36	75	16.8	83
Sulfamethoxazole (antibiotic)	0.326	83	1.33	92
Cefuroxime (antibiotic)	[a]	0	[a]	0
Cyclophosphamide (antitumor agent)	[a]	8	[a]	0
Ifosfamide (antitumor agent)	0.012	100	[a]	50

Source: Thomas et al., 2007.
a — No mean and median concentrations were calculated for analytes with a frequency less than 50%.

Although pharmaceutical compounds have been detected in treated wastewater, surface water, and groundwater, neither the EPA nor any other organization has quantified how much results from the disposal of unused pharmaceuticals versus human excretion (Ruhoy, 2007).

4. FACTORS AFFECTING DISPOSAL PRACTICES

This section discusses the regulations related to pharmaceutical waste management and other factors that limit disposal alternatives at medical facilities. The discussion of disposal limitations focuses on factors that apply specifically to hospitals and LTCFs, and includes:

- Federal regulations;
- State regulations; and
- Non-regulatory factors such as ease of disposal and costs.

LTCFs may have more restrictions and limitations regarding disposal practices than hospitals. These restrictions include Drug Enforcement Administration (DEA) regulations for non-DEA-registrants (see Section 4.1.1) and state Medicaid and Medicare and Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements (see Section 4.1.4). In particular, controlled substances may be more frequently flushed down the drain because they cannot be returned to pharmacies or manufacturers by LTCFs.

4.1 Federal Regulations

This subsection summarizes available information regarding federal regulations for disposal of unused pharmaceuticals. The major federal regulations that restrict disposal alternatives for unused medications include:

- The Controlled Substances Act (CSA);
- The Resource Conservation and Recovery Act (RCRA); and
- The Health Insurance Portability and Accountability Act (HIPAA).

4.1.1 Controlled Substances Act

The Drug Enforcement Agency (DEA) enforces the Controlled Substances Act (CSA). The goal of the CSA is to provide a closed distribution system for controlled substances.[4] As part of this closed distribution system, DEA prohibits the return of controlled substances from end-users to any DEA registrant, or transfer to anyone except, in certain cases, a law-enforcement agent. Disposal of controlled substances by DEA registrants is carefully regulated to ensure that the substance is destroyed or rendered unrecoverable. One acceptable method of destruction is flushing controlled substances into the wastewater.

Requirements for Hospitals

DEA registrants include individuals that fall into, or are employed by, one of the following categories: pharmacy, hospital, clinic, practitioner, teaching institution, mid-level practitioner, manufacturer, distributor, reverse distributor,[5] researcher, analytical laboratory,

[4] Controlled substances are drugs or other substances, or immediate precursors, included in schedule I, II, III, IV, or V listed in Section 1308 of Title 21 Code of Federal Regulations. Examples include narcotics, opiates, and stimulants.

[5] DEA defined "reverse distributor" and established it as a new category of registration for handling controlled substances on May 2, 2005 (see 83 FR 22591; May 2, 2005).

importer, exporter, or narcotic treatment program. DEA registrants have the following options for disposing of controlled substances:

- They can return the controlled substance to the pharmaceutical manufacturer.
- They can transfer the controlled substances to a reverse distributor to return them to the manufacturer or dispose of them.
- They can dispose of the controlled substances under the procedures outlined in 21 CFR 1307.21, which provides that a DEA Special Agent in Charge can authorize for the disposal of the controlled substance in one of the following manners:
    1. By transfer to person registered under the Act and authorized to possess the substance;
    2. By delivery to an agent of the Administration or to the nearest office of the Administration;
    3. By destruction in the presence of an agent of the Administration or other authorized person; or
    4. By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.

Requirements for Long-Term Care Facilities (LTCFs)

Employees of LTCFs typically are not DEA registrants and therefore may not return controlled substances to the LTC pharmacy or transfer them to reverse distributors, or any other DEA registrant, for disposal. This is because controlled substances that are in the possession of a LTCF are no longer part of the closed distribution system and, as a result, are no longer subject to DEA's system of accountability. This means that LTCFs must directly dispose of controlled substances. Only with special approval from the regional DEA offices may LTCF employees return controlled substances to their contracted pharmacies. DEA states that "In cases where LTCFs must dispose of controlled substances, they should follow the guidelines within their state for disposing of the drugs and maintain appropriate documentation of the disposal" (DEA, 2005b). LTCFs and their contracted/associated pharmacies must submit extensive records to DEA agents documenting the disposal of controlled substances (Lewin Group, 2004).

In 2005, DEA finalized a rule to address the issue of controlled substances accumulating at LTCFs by allowing registered pharmacies to operate automated dispensing systems (ADS) at LTCFs (see 70 FR 25462; May 13, 2005). The advantage of ADSs is the dispensing of single doses to patients. This could potentially reduce the amount of medications that become waste.

4.1.2 Resource Conservation and Recovery Act (RCRA)

RCRA's definition of hazardous waste includes both "listed" and "characteristic" wastes. Thus, a pharmaceutical waste may be considered hazardous because: 1) the pharmaceutical or its sole active ingredient is specifically listed in 40 CFR Part 261.33(e) or (f) (commonly referred to as the P or U lists, respectively); and/or 2) the waste exhibits one or more characteristic of hazardous waste (ignitability, corrosivity, reactivity, or toxicity as defined in 40 CFR Parts 261.21-24, respectively). Common pharmaceuticals that are RCRA hazardous wastes when

disposed of include epinephrine[6], nitroglycerin, warfarin, nicotine, and some chemotherapy agents (U.S. EPA Region 2, 2007; H2E, 2006).

EPA regulates the generation, storage, transportation, treatment, and disposal of any pharmaceutical waste defined as hazardous waste. Federal regulations implementing RCRA can be found at 40 CFR Chapter I Parts 260 through 265. These regulations include hazardous waste identification, training, manifesting, and notification/recordkeeping requirements. In addition, RCRA regulations require the transport of hazardous pharmaceutical waste in Department of Transportation–approved containers to permitted hazardous waste disposal facilities by a hazardous waste transporter. Thus, RCRA[7] prohibits the disposal of hazardous pharmaceutical waste as regulated medical waste (red sharps, red bag) or chemotherapy waste (yellow or white sharps, bags) (Chemical Disposal Services, 2008; PharmEcology, 2005). Table 4-1 presents an example of pharmaceutical waste management practices at health services facilities.

Table 4-1. Example of Pharmaceutical Waste Management Practices

Type of Waste Container	Color Code	Contents	Treatment Method
Red bag	Red	Biohazardous, no pharmaceutical waste	Autoclave/landfill
Red sharps/needlebox	Red	Biohazardous needles, no pharmaceutical waste	Autoclave/landfill
Trace chemotherapy waste	Yellow or white	Biohazardous and trace chemotherapy waste	Medical waste incinerator
Hazardous pharmaceutical waste	Black	RCRA and PharmE Hazardous® waste [a]	RCRA incinerator
Non-hazardous pharmaceutical waste	White or blue	Non-hazardous pharmaceutical waste	Medical waste incinerator

Source: ERG, 2008.
a — PharmE Hazardous® is a list of waste identified by PharmEcology that is recommended to be handled as hazardous waste, even if it is not a P- or U-listed waste.

[6] The Agency clarified its regulation at 40 CFR Part 261.33, explaining that epinephrine salts are not included in the epinephrine P042 listing (since the listing only specifies epinephrine and not epinephrine salts); the salts, therefore, would be hazardous only if the waste epinephrine salt exhibited one or more of the hazardous waste characteristics (See "Scope of Hazardous Waste Listing P042 (Epinephrine)," October 15, 2007, RCRA Online# 14778).

[7] RCRA has an exclusion, the Domestic Sewage Exclusion (DSE), for hazardous materials that are sent to POTWs. The DSE exclusion at 40 CFR Part 261.4 (a)(1)(i) and (ii) has two parts: (a)(1)(i) excludes "[d]omestic sewage" and (a)(1)(ii) excludes "[a]ny mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works (POTW) for treatment. 'Domestic sewage' means untreated sanitary wastes that pass through a sewer system. Under Part 261.4(a)(1)(ii), mixtures of sanitary wastes and other wastes (including hazardous industrial wastes) that pass through a sewer system to a POTW are excluded from Subtitle C regulation. The exclusion applies to a waste when it first enters a sewer system provided that it will mix with sanitary wastes prior to storage or treatment by a POTW. The Agency interprets this exclusion to begin at the point of entry into the sewage system, not at the point the hazardous waste actually mixes with the sewage (45 FR 33097, May 19, 1980). A mixed stream of chemical process waste (considered a characteristic or listed hazardous waste under RCRA) and sanitary waste which subsequently leaks from the sewer line before it reaches the POTW would not qualify for the DSE (OSW, 1997). The rationale behind this exclusion from RCRA included that, "the Agency's pretreatment program provides a basis for EPA and local communities to insure that users of sewer and treatment systems do not dump wastes into the system that will present environmental problems" (45 FR 33097, May 19, 1980). Please note that states may issue regulations that are more stringent or broader in scope than the federal hazardous waste regulations.

4.1.3 Medicare and Medicaid

The Centers for Medicare & Medicaid Services (CMS), a federal Agency within the Department of Health and Human Services, administers the Medicare and Medicaid programs. Medicare provides health insurance to elderly and disabled Americans, while Medicaid provides health insurance for low income Americans, including long-term care coverage (CMS, 2007). LTCFs that are certified by CMS may be recipients of Medicare/Medicaid payments, and must meet and maintain compliance with the federal requirements for certification of their provider type. While there are no accrediting organizations for skilled nursing facilities or nursing facilities, hospitals may be audited for their compliance with federal Medicare and Medicaid requirements by The Joint Commission (previously known as the Joint Commission on Accreditation of Healthcare Organizations) or the American Osteopathic Association. A hospital that fails an audit (done about once every three years) is at risk for losing their federal certification, and thus their federal funding. Section 5.1.3 discusses the Joint Commission's standards.

While Medicare is a federal program, Medicaid is a state-run program that is partly funded by federal dollars. Therefore, many Medicaid requirements are set at the state level, including regulations for disposal of unused pharmaceuticals. The focus of many federal and state Medicare and Medicaid requirements for disposal of unused pharmaceuticals are in place to prevent fraud. The following discusses the Medicare and some of the Medicaid requirements specific to LTCFs and LTC pharmacies that must be followed for the return and reuse of unused pharmaceuticals:

Return of Unused Pharmaceuticals. In a March 22, 2006, letter, CMS provided guidance to state Medicaid programs encouraging them to require LTCFs to return unused medications to pharmacies and to ensure that Medicaid is repaid for unused treatments when nursing home patients die, are discharged, or have their prescriptions changed. In addition, some state Medicaid programs require LTC pharmacies to accept returned unused pharmaceuticals (excluding controlled substances) from LTCFs. The LTC pharmacy then credits Medicaid for the unused doses. However, LTC pharmacies typically receive little payment for these return services and have not found them to be cost effective. For example, when a pharmacy takes back a previously dispensed medication for disposal, it must pay to have the medication destroyed, but is not compensated for this service (APhA, 2006).

In addition, the CMS letter recommends that state Medicaid programs limit the amount of medications provided to LTCFs from their LTC pharmacies at one time to reduce the amount of prescription drugs wasted (APhA, 2006). Some state Medicaid requirements may determine whether LTC pharmacies can receive credit for the returned pharmaceuticals:

- Some states allow crediting to LTC pharmacies;
- Some states (at least 10 according to APhA) prohibit crediting; and
- Other states do not have a clear requirement on crediting.

Reuse[8] of Pharmaceuticals. State boards of pharmacy determine if unused medications can be returned and redistributed (reuse) and the policies vary by state. Most states allow reuse

[8] "Reuse" refers to the redistribution of unused pharmaceuticals.

of uncontaminated pharmaceuticals (excluding controlled substances) that have been in a controlled environment, such as an automatic dispensing system (APhA, 2006). At least five states (Arizona, Kentucky, Mississippi, New Mexico, and Texas) strictly prohibit the reuse of any pharmaceutical. The following states allow reuse of medications:

- California allows counties to collect unused pharmaceuticals from LTCFs, wholesalers, and manufacturers and redistribute them to the uninsured.
- Oklahoma, Louisiana, and Ohio have passed legislation allowing unused pharmaceuticals to be redistributed:
  - Ohio has not yet implemented a redistribution program due to a lack of interest by LTCFs.
  - Louisiana has 12 pharmacies that redistribute unused pharmaceuticals collected from LTCFs. Expired drugs, controlled substances, and those that are potentially dangerous are not accepted. The LTCFs must have controlled storage and distribution systems and use blister packaging.
- Nebraska permits consumers to return unused drugs if they are in tamper-resistant packaging (e.g., blister packages) (APhA, 2006).

Physician samples can be donated to charitable institutions by licensed practitioners if the samples meet certain criteria set for the in 21 CFR Part 203.39.

In January 2006, Medicare Part D was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003[9]. Part D is a federal program to subsidize the costs of prescription drugs for Medicare beneficiaries in the United States. Under this program, it is illegal to reuse medications (ERG, 2008a).

Groups such as the American Society of Health-Systems Pharmacists (ASHP), American Society of Consultant Pharmacists (ASCP), the American Medical Association (AMA), and the American Nurses Association (ANA) encourage the redistribution of pharmaceuticals under certain conditions. The redistribution conditions include: 1) the returned pharmaceuticals are not controlled substances, 2) the pharmaceuticals are dispensed in tamper-evident packaging and the packages are returned intact, and 3) policies and procedures are followed for the appropriate storage and handling of pharmaceuticals at the LTCF (APhA, 2006). If all of these conditions are met, the current redistribution practice recommended by the APhA is for donation to uninsured patients (APhA, 2006).

During a November 18, 2007, meeting with EPA, several members of the Center of Excellence in Assisted Living (CEAL) stated that the CMS Part D requirements often deter LTCFs from donating or redistributing their unused medications. Once CMS identifies a LTCF as a donor or as using a reverse distributor, CMS requires the LTCF to maintain record to prove that Medicare is not double-billed and that the pharmaceuticals are not being illegally redistributed. Industry groups are finding that the cost of labor to maintain these records discourages LTCFs from redistributing their unused pharmaceuticals (Hessenauer, 2007).

[9] For more information on the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, see http://www.cms.hhs.gov/mmaupdate/.

4.1.4 Health Insurance Portability and Accountability Act (HIPAA)

HIPAA requires LTCFs to meet certain privacy requirements. To conform to HIPPA requirements, LTCFs often destroy all labels that contain private information (e.g., name, birth date, address, medication) and relabel the medication prior to donation/redistribution of unused pharmaceuticals. The facility must document the relabeling of medications to ensure that the medication name and dose are being transferred properly. Some facilities that accept donations find that the labor cost of relabeling, auditing, and assuming the risk of administering mislabeled redistributed pharmaceuticals exceeds the value of donated medication (Hessenauer, 2007).

4.2 State Regulations

State regulations for the disposal of unused pharmaceuticals and controlled substances at health services facilities vary widely (APhA, 2006; Lewin Group, 2004). Many states require unused pharmaceuticals to be destroyed but often do not specify the process of destruction; however, many states (33 according to the Lewin Group) have requirements for the types of personnel required to conduct and oversee the destruction (Lewin Group, 2004).

Some states have hazardous waste regulations more stringent than EPA's (Premier, 2007). For example, some wastes that are not regulated as hazardous under RCRA are identified as hazardous in California. These wastes include substances that are listed under Title 22 of the California Code of Regulations and exceed specified concentration limits. California also classifies pharmaceutical waste as hazardous if it is toxic when inhaled or is fatal to certain types of fish in laboratory tests. Pharmaceutical wastes that meet California's definition of hazardous waste (known as "California-only" pharmaceuticals) are subject to the Medical Waste Management Act (Division 104, Part 14 California Health and Safety Code) and fall under the regulatory authority of the Department of Toxic Substances Control and the California Department of Health Services (Bren School, 2007). The California Medical Waste Management Act requires that all "California-only" pharmaceutical hazardous waste be incinerated (California, 2002). In addition, the state of California requires medical facilities to obtain permission from their POTW before disposing of any pharmaceutical waste to their sewerage system (McGurk, 2003).

To compare existing regulations governing pharmaceutical disposal, EPA collected information on state and federal regulations pertaining to LTCFs. NHRegsPlus is an online compilation of federal and state regulations applicable to LTCFs.[10] Table 4-2 summarizes EPA's review of the state regulations regarding pharmacy services in nursing homes.

[10] NHRegsPlus was created by the University of Minnesota School of Public Health and is available at http://www.hpm.umn.edu/nhregsplus/.

Table 4-2. State Regulations for Pharmacy Services at Nursing Homes

State	How to Dispose of Controlled Substances?	How to Dispose of Non-controlled Substances?	Who Destroys Unused Meds?	Who Must Witness the Destruction?	How Soon Must Medications be Destroyed?	Under What Conditions are Medications Returned/ Donated?	Record Keeping and Labeling
Alabama	Destroyed on the premises (method not specified, but may include flushing or down the drain); or Collected by environmental agency providing disposal service	Destroyed on the premises (method not specified, but may include flushing or down the drain); or Collected by environmental agency providing disposal service	Pharmacist	Registered Nurse Controlled substances: a third witness (law enforcement official, management or supervisory personnel.)	30 days. Medications ordered to be used on an "as needed" basis: 90 days from purchase.	Unused legend drugs may be donated to a charitable clinic pursuant to state regulations.	Records must be completed and maintained by the facility that include facility information, date of destruction or collection, destruction method, prescription details (e.g., name and strength of drug, pharmacy, resident name), amount destroyed, and reason for destruction.
Alaska	Not addressed	Not addressed	Pharmacist	Not addressed	Not addressed	Not addressed	Not addressed
Arizona	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed
Arkansas	Delivered in person or by registered mail to the Arkansas Department of Health	All discontinued medications (except controlled drugs) shall be destroyed on the premises of the facility. All unused medications shall be destroyed (location not specified). See end of table for recommended destruction methods.	Consultant pharmacist	Nurse	Not addressed	Facilities may donate designated medications (in original packaging) to charitable clinics by following state regulations.	Not addressed

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State	How to Dispose of Controlled Substances?	How to Dispose of Non-controlled Substances?	Who Destroys Unused Meds?	Who Must Witness the Destruction?	How Soon Must Medications be Destroyed?	Under What Conditions are Medications Returned/ Donated?	Record Keeping and Labeling
California	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed
Colorado	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed
Connecticut	Follow state regulations.	Destroyed on the premises (method not specified, but may include flushing or down the drain).	Non-controlled substances may be destroyed by a licensed nurse or pharmacist .	Another staff person may witness destruction of non-controlled substances.	Not addressed	Not addressed	Destruction details: date, strength, form and quantity of drugs destroyed; and the signatures of the persons destroying the drugs and witnessing the destruction. Records for the destruction of drugs shall be kept on file for three (3) years.
Delaware	Return to the pharmacist for disposal.	See end of table for recommended destruction methods.	Not addressed	Not addressed	Not addressed	Not addressed	Labeling and disposal requirements [a]
District of Columbia	Return to the pharmacist; or Destroyed (location not specified; method not specified, but may include flushing or down the drain).	Return to the pharmacist; or Destroyed (location not specified; method not specified, but may include flushing or down the drain).	Not addressed	Two licensed nurses must witness destruction of controlled substances.	Not addressed	Each unopened, sealed medication may be returned to the issuing pharmacy.	Labeling and disposal requirements [a]

Table 4-2. State Regulations for Pharmacy Services at Nursing Homes

State	How to Dispose of Controlled Substances?	How to Dispose of Non-controlled Substances?	Who Destroys Unused Meds?	Who Must Witness the Destruction?	How Soon Must Medications be Destroyed?	Under What Conditions are Medications Returned/ Donated?	Record Keeping and Labeling
Florida	Follow state regulations.	Destroyed (facility-specific policy and procedure)	Not addressed	Not addressed	Not addressed	Non-controlled substances, in unit dose containers, may be returned to the dispensing pharmacy.	Records of the disposition of all substances shall be maintained in sufficient detail to enable an accurate reconciliation.
Georgia	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed
Hawaii	Discontinued and outdated drugs: return to the pharmacist for disposal.	Discontinued and outdated drugs: return to the pharmacist for disposal.	Not addressed	Not addressed	Not addressed	Not addressed	Labeling and disposal requirements [a]
Idaho	Follow state regulations.	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	It shall be noted in the patient's/resident's medical record when controlled drugs are returned.
Illinois	Expired and unused medication: follow facility-specific policy and procedure.	Expired and unused medication: follow facility-specific policy and procedure.	Not addressed	Not addressed	Not addressed	All discontinued medications, except controlled substances, shall be returned to the dispensing pharmacy.	Labeling and disposal requirements [a]

Table 4-2. State Regulations for Pharmacy Services at Nursing Homes

State	How to Dispose of Controlled Substances?	How to Dispose of Non-controlled Substances?	Who Destroys Unused Meds?	Who Must Witness the Destruction?	How Soon Must Medications be Destroyed?	Under What Conditions are Medications Returned/ Donated?	Record Keeping and Labeling
Indiana	Follow state regulations.	Follow state regulations.	Consultant pharmacist orlicensed nurse with a witness.	Not addressed	7 days.	Unopened and unexposed medication may be returned to the issuing pharmacy for credit.	Disposition of any released, returned, or destroyed medication shall be written in the resident's clinical record and shall include the following information: resident name, name and strength of the drug, prescription number, reason for disposal., amount disposed , disposal method of disposition, and date of disposal, and signatures of the persons conducting the disposal of the drug.
Iowa	Follow state regulations.	Return to the pharmacist for destruction (method not specified, but may include flushing or down the drain).	Qualified responsible nurse with a witness.	Not addressed	Within a reasonable time.	Unit dose system: unused drugs prescribed for deceased residents shall be returned to the pharmacist. Discontinued drugs may be returned to the pharmacist for resident credit.	Labeling and disposal requirements [a]

Table 4-2. State Regulations for Pharmacy Services at Nursing Homes

State	How to Dispose of Controlled Substances?	How to Dispose of Non-controlled Substances?	Who Destroys Unused Meds?	Who Must Witness the Destruction?	How Soon Must Medications be Destroyed?	Under What Conditions are Medications Returned/ Donated?	Record Keeping and Labeling
Kansas	Destroyed by pharmacist (method not specified, but may include flushing or down the drain).	Destroyed by pharmacist (method not specified, but may include flushing or down the drain).	Licensed pharmacist	Licensed nurse employed by the facility.	Not addressed	The nursing facility shall return to the dispensing pharmacy any drugs and biologicals which have been recalled.	The nursing facility shall maintain records of receipt and disposition of all controlled substances. A record shall be on file in the facility which contains the date, drug name, quantity of drugs and biologicals destroyed, and signatures of the pharmacist and licensed nurse.
Kentucky	Destroyed as outlined in federal and state regulations.	Follow federal and state regulations.	Not addressed	Not addressed	Not addressed	Not addressed	Labeling and disposal requirements [a]

Table 4-2. State Regulations for Pharmacy Services at Nursing Homes

State	How to Dispose of Controlled Substances?	How to Dispose of Non-controlled Substances?	Who Destroys Unused Meds?	Who Must Witness the Destruction?	How Soon Must Medications be Destroyed?	Under What Conditions are Medications Returned/ Donated?	Record Keeping and Labeling
Louisiana	Destroyed by pharmacist (after receipt of DEA authorization).	Destroyed or disposed as outlined in state regulations. Expired medications: destroyed on the premises (method not specified, but may include flushing or down the drain).	For noncontrolled drugs, either licensed nurses who are employees of the nursing home, or the consultant pharmacist.	Controlled substance: a licensed pharmacist after receiving DEA authorization, and witnessed by law enforcement officer or other licensed staff. Non-controlled substances: two witnesses (licensed nurses or the consultant pharmacist).	Discontinued medication, or the resident is discharged to the hospital, the nursing home will retain the medication(s) for up to 60 days. Expired medication: 90 days.	Not addressed	Records of non-controlled medication destruction shall be maintained in the resident's clinical record and shall include the following: prescription details, method and date of destruction, and signatures of those witnessing the destruction. All controlled substances to be destroyed shall be inventoried and listed on a DEA Form 41, a copy of which shall be maintained on the premises, and a copy mailed to the Louisiana State Board of Pharmacy.

Table 4-2. State Regulations for Pharmacy Services at Nursing Homes

State	How to Dispose of Controlled Substances?	How to Dispose of Non-controlled Substances?	Who Destroys Unused Meds?	Who Must Witness the Destruction?	How Soon Must Medications be Destroyed?	Under What Conditions are Medications Returned/ Donated?	Record Keeping and Labeling
Maine	Destroyed (location not specified). See end of table for recommended destruction methods.	Destroyed (location not specified). See end of table for recommended destruction methods.	Director of Nursing Service or a designee.	Non-controlled substances: a licensed member of the nursing staff. Controlled substances: Department representative, a Maine licensed pharmacist, or Federal DEA agent.	Following the death of the resident, medications shall be removed from circulation within seventy-two (72) hours.	Individual unit doses, other than controlled substances must be returned to the pharmacist and any credit or rebate made to person(s) who originally paid for the medication.	Prior to the destruction of these substances by the authorized person, the inventory shall be verified by that person. Notation shall be made of the destruction, date and signed by all authorized individuals. Labeling and disposal requirements [a]
Maryland	Destroyed (location not specified; method not specified, but may include flushing or down the drain).	Destroyed (location not specified; method not specified, but may include flushing or down the drain).	Two members of the nursing home staff (administrator or nurse) may destroy controlled on the premises of the facility.	Non-controlled medications shall be destroyed in the presence of an authorized representative of the Department or two witnesses, authorized by the facility.	Not addressed	Not addressed	A record of the disposal shall be maintained in the facility and a copy shall be forwarded to the Division of Drug Control.
Massachusetts	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Labeling and disposal requirements [a]
Michigan	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed

Table 4-2. State Regulations for Pharmacy Services at Nursing Homes

State	How to Dispose of Controlled Substances?	How to Dispose of Non-controlled Substances?	Who Destroys Unused Meds?	Who Must Witness the Destruction?	How Soon Must Medications be Destroyed?	Under What Conditions are Medications Returned/ Donated?	Record Keeping and Labeling
Minnesota	Destroyed as recommended by the Board of Pharmacy or consultant pharmacist.	Follow state regulations.	Not addressed	Not addressed	Not addressed	Drugs and prescribed medications used in nursing homes may be returned to the dispensing pharmacy according to state regulations.	For non-controlled substances, a notation of the destruction listing the date, quantity, name of medication, prescription number, signature of the person destroying the drugs, and signature of the witness must be recorded on the clinical record. For controlled substances, the board or the pharmacist must furnish the necessary instructions and forms, a copy of which must be kept on file in the nursing home for two years.
Mississippi	Follow state regulations.	Follow state regulations.	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed
Missouri	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed
Montana	Removed from the facility and destroyed.	Removed from the facility and destroyed.	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed

Table 4-2. State Regulations for Pharmacy Services at Nursing Homes

State	How to Dispose of Controlled Substances?	How to Dispose of Non-controlled Substances?	Who Destroys Unused Meds?	Who Must Witness the Destruction?	How Soon Must Medications be Destroyed?	Under What Conditions are Medications Returned/ Donated?	Record Keeping and Labeling
Nebraska	Disposal at the facility and follow state regulations.	Disposal at the facility and follow state regulations.	Pharmacist assisted by a licensed nurse employed by the facility.	Not addressed	Not addressed	The facility may return discontinued medication or expired resident medicines to the dispensing pharmacy for credit in accordance with state regulations.	Medication name, strength and quantity disposed of must be recorded in the resident's medical record, dated and signed by the pharmacist.
Nevada	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed
New Hampshire	Destroyed as outlined in state regulations.	Destroyed by incineration or disposal by flushing into sewage system.	Not addressed	Not addressed	Not addressed	Medication may be returned to pharmacies for credit only under provisions of state regulations.	Not addressed

Table 4-2. State Regulations for Pharmacy Services at Nursing Homes

State	How to Dispose of Controlled Substances?	How to Dispose of Non-controlled Substances?	Who Destroys Unused Meds?	Who Must Witness the Destruction?	How Soon Must Medications be Destroyed?	Under What Conditions are Medications Returned/ Donated?	Record Keeping and Labeling
New Jersey	Follow federal and state regulations.	Not addressed	Not addressed	All medication destruction in the facility shall be witnessed by at least two persons (pharmacist consultant, a registered professional nurse or a licensed practical nurse).	Not addressed	Where allowed by law, the facility shall generate a crediting mechanism for medications dispensed in a unit-of-use drug distribution system, or other system that allows for the re-use of medications.	A record of each instance of drug destruction shall be maintained. Labeling and disposal requirements [a]
New Mexico	Not addressed	Not addressed	Not addressed	Not addressed	Discontinued medications: 30 days.	A resident's medication may be returned to the pharmacy for credit.	Records shall be kept of all medication returned for credit and/or disposal.
New York	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Facilities using a vendor pharmacy can establish policies and procedures to return unused medications or drug products for credit or reimbursement, according to certain state provisions.	Not addressed

Table 4-2. State Regulations for Pharmacy Services at Nursing Homes

State	How to Dispose of Controlled Substances?	How to Dispose of Non-controlled Substances?	Who Destroys Unused Meds?	Who Must Witness the Destruction?	How Soon Must Medications be Destroyed?	Under What Conditions are Medications Returned/ Donated?	Record Keeping and Labeling
North Carolina	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed
North Dakota	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed
Ohio	Follow federal and state regulations.	Not addressed	Not addressed	Not addressed	Not addressed	Upon death, transfer, or discharge of a resident all drugs shall be returned to the pharmacy, or disposed.	Not addressed
Oklahoma	Not addressed	Destroyed (location not specified).	Director of nursing and the consultant pharmacist.	Not addressed	Within a reasonable time.	The facility may transfer unused prescription drugs to city-county health department pharmacies or county pharmacies in compliance with requirements.	The destruction and the method used shall be noted on the clinical record.
Oregon	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed

Table 4-2. State Regulations for Pharmacy Services at Nursing Homes

State	How to Dispose of Controlled Substances?	How to Dispose of Non-controlled Substances?	Who Destroys Unused Meds?	Who Must Witness the Destruction?	How Soon Must Medications be Destroyed?	Under What Conditions are Medications Returned/ Donated?	Record Keeping and Labeling
Pennsylvania	Follow facility-specific policy and procedure.	Follow facility-specific policy and procedure.	Determined by facility policy.	Determined by facility policy.	At least quarterly.	Outdated, deteriorated or recalled medications shall be returned to the dispensing pharmacy for disposal in accordance with acceptable professional practices.	The method of disposition and quantity of the drugs shall be documented on the respective resident's chart. The disposition procedures shall be done at least quarterly under Commonwealth and Federal statutes.
Rhode Island	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed
South Carolina	Follow facility-specific policy and procedure.	Follow facility-specific policy and procedure.	Not addressed	Not addressed	Discontinued medications must not be held beyond a 90-day period.	Not addressed	All medications destroyed must be documented. Labeling and disposal requirements [a]

Table 4-2. State Regulations for Pharmacy Services at Nursing Homes

State	How to Dispose of Controlled Substances?	How to Dispose of Non-controlled Substances?	Who Destroys Unused Meds?	Who Must Witness the Destruction?	How Soon Must Medications be Destroyed?	Under What Conditions are Medications Returned/ Donated?	Record Keeping and Labeling
South Dakota	Returned to the pharmacy for disposal; or disposed at the facility.	Returned to the pharmacy for disposal; or disposed at the facility.	Non-controlled substance: a professional nurse. Controlled substance: destroyed on the premises by a pharmacist and a registered nurse.	There must be another witness for destruction of legend drugs not controlled under state regulation SDCL 34-20B.	Not addressed	Medications, excluding controlled substances, in unit dose packaging may be returned to the pharmacy.	Labeling and disposal requirements [a]
Tennessee	Destroyed on the premises (method not specified, but may include flushing or down the drain).	Destroyed on the premises (method not specified, but may include flushing or down the drain).	Not addressed	Not addressed	Not addressed	Not addressed	Destruction to be recorded by a pharmacist. Such record shall be kept in the nursing home.
Texas	Follow federal and state regulations.	Follow federal and state regulations.	Not addressed	Not addressed	Quarterly basis.	Not addressed	Not addressed
Utah	Follow state's Pharmacy Practice Act.	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed
Vermont	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed
Virginia	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed
Washington	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed
West Virginia	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed

Table 4-2. State Regulations for Pharmacy Services at Nursing Homes

State	How to Dispose of Controlled Substances?	How to Dispose of Non-controlled Substances?	Who Destroys Unused Meds?	Who Must Witness the Destruction?	How Soon Must Medications be Destroyed?	Under What Conditions are Medications Returned/ Donated?	Record Keeping and Labeling
Wisconsin	Destroyed on the premises (method not specified, but may include flushing or down the drain).	Destroyed on the premises (method not specified, but may include flushing or down the drain).	Not addressed	Two or more personnel licensed or registered in the health field.	Within 72 hours of a physician's order discontinuing its use, the resident's discharge, the resident's death or passage of its expiration date.	May be returned for credit.	Not addressed
Wyoming	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed

Source: NHRegsPlus (http://www.hpm.umn.edu/nhregsPlus/index.htm).
Not addressed: States do not have requirements for pharmaceutical disposition beyond what is required by federal regulations.
a — These states require specific disposal based on labeling. See summary below.

Only four states listed approved or recommended methods of destruction. The methods approved include the following:

- Arkansas: Incineration, garbage disposal, or flushing down the commode;
- Delaware: Flushing down to sewage system (in the presence of a witness) or returning to pharmacy;
- Maine: Incineration or flushing down to sewage system; and
- New Hampshire: Incineration or flushing down to sewage system.

The states with labeling regulations included in the database have similar requirements. Improperly labeled medication containers (e.g., soiled, damaged, incomplete, illegible, makeshift labels) must be returned to the pharmacist for relabeling or disposal. This requirement is included in the regulations for Delaware, District of Columbia, Hawaii, Iowa, Kentucky, Maine, Massachusetts, and South Carolina. South Dakota requires that all improperly labeled medication should be destroyed. In addition to improper labeling, Delaware, Illinois, Kentucky, Massachusetts, and South Carolina require containers with missing labels to be disposed of or destroyed. New Jersey requires that the pharmacy and therapeutics committee establish and enforce procedures to remove medication containers with improper labeling.

4.3 Other Factors That Affect Disposal Practices

Besides legal requirements, the other major factors that affect disposal practices are organization size, ease of disposal, and cost. For example, a facility may use flushing as a primary means of disposal if it has no onsite pharmacy and/or has no pre-existing contract with a hazardous waste transporter to dispose of the pharmaceuticals. This section discusses the differences in pharmaceutical handling at LTCFs and hospitals.

4.3.1 LTCFs

In the past, public health agencies and health-related non-government organizations guided the public to destroy unused medications by flushing them down the toilet. Many LTCFs have adopted this method for destruction of unused controlled substances. Many LTCFs have also extended this practice to include flushing of all unused medications — controlled and non-controlled substances (Garvin, 2007).

For example, a survey conducted by the Bren School of Environmental Science in Santa Barbara, CA, during 2006 found that, if a LTCF flushed any unused pharmaceuticals down the drain or toilet, then flushing was the primary disposal method for all pharmaceuticals at that facility (Bren School, 2007). The 2006 Bren School survey was conducted to gain an estimate of local quantities of wasted drugs, current disposal practices, feasibility of a drug recycling program, and likelihood to support a disposal program for the public. Respondents were selected groups of institutions in Santa Barbara County boundaries, including pharmacies, nursing homes, hospitals, and hospices (Bren School, 2007).

Each institution was asked 15 questions, both open-ended and categorical over the phone, and multiple responses were accepted for some of the questions (Bren School, 2007). Topics covered in the survey included:

- Current disposal practices,
- Contact with the public,
- Likelihood to supply/support a recycling program,
- Likelihood to support a disposal program for the public, and
- Awareness of the issue.

At the completion of the survey, 116 facilities were contacted, 87 of which fit the intended category; 42 responses were obtained, for a total response rate of 48 percent (Bren School, 2007). The survey found that, of LTCFs who flushed any unused pharmaceuticals down the drain, flushing was the primary disposal method for all pharmaceuticals at that facility. In addition, the survey found that, in general, LTCFs do not use reverse distributors because the facilities do not generate enough pharmaceutical waste to justify hiring a reverse distributor. The company or organization size may also be a factor determining disposal practices at LTCFs. For example, small nursing homes that are not a part of a larger network may not be aware of the benefits of using a reverse distributor (Bren School, 2007).

4.3.2 Hospitals

Logistics for disposing of unused pharmaceuticals at hospitals are different than at LTCFs. Hospitals typically have onsite pharmacies; therefore, it is a common practice to return expired pharmaceuticals to the hospital pharmacy and then on to the manufacturer for credit or disposal. Hospitals typically do not prescribe medications far in advance or in large quantities; this reduces the potential for pharmaceuticals to be wasted. Finally, hospitals typically have pre-existing arrangements with hazardous waste disposal firms and therefore do not need to make special arrangements for disposal of unused pharmaceuticals as hazardous waste (Garvin, 2007).

5. ALTERNATIVES TO WASTEWATER DISPOSAL INCLUDING MANAGEMENT PRACTICES AND TREATMENT OPTIONS FOR UNUSED PHARMACEUTICALS

This section describes the management practices and treatment options that hospitals and LTCFs may use as alternatives to unused pharmaceutical disposal to wastewater. EPA notes that some of the information presented in this section only applies to managing pharmaceutical wastes at hospitals. EPA will continue to collect information on management practices for hospitals, LTCFs, hospices, and veterinary facilities during the 2009 Effluent Guidelines annual review. The remainder of this section describes current guidance on pharmaceutical waste management, summarizes the management practices outlined in the guidance, and discusses treatment options for pharmaceutical waste.

5.1 Current Guidance on Pharmaceutical Waste Management

Three organizations that provide guidance to medical facilities on managing pharmaceutical waste include Hospitals for a Healthy Environment (H2E), the Product Stewardship Institute (PSI), and the Joint Commission. The guidelines provided by these organizations all aim to reduce health and environmental impacts from disposal of pharmaceutical waste. In addition to these three organizations, EPA collected data on state guidance for pharmaceutical waste management. Section 5.2 discusses the management practices recommended by these organizations and three states. This section describes the three nongovernmental organizations.

5.1.1 Hospitals for a Healthy Environment (H2E)

H2E is an organization founded by the American Hospital Association, EPA, Health Care Without Harm, and the American Nurses Association. H2E educates health service professionals on pollution prevention opportunities and provides tools and resources to facilitate the industry's movement toward environmental sustainability. H2E developed a Pharmaceutical Waste Blueprint that describes a 10-step approach hospitals can use to develop and manage a pharmaceutical waste management program. The 10 steps include:

- *Step One*. Form a committee to meet regularly and implement the program. The committee should include experts in the areas of pharmacy, environmental science, safety, nursing, education, and infection control.
- *Step Two*. Understand how RCRA regulations apply to hazardous waste management.
- *Step Three*. Consider best management practices (BMPs) for non-regulated pharmaceutical waste.
- *Step Four*. Perform a drug inventory for all drugs administered at the facility and identify the proper disposal method.
- *Step Five*. Implement practices to minimize the pharmaceutical waste generated.
- *Step Six*. Conduct a review of current disposal practices to establish the baseline quantities of pharmaceuticals disposed and determine how frequently certain types of pharmaceutical waste are generated in different departments of the facility.
- *Step Seven*. Select a method for communicating proper disposal methods to staff.

- *Step Eight*. Evaluate pharmaceutical waste management options including segregating waste at the point of generation, segregating waste at a central location, and managing all pharmaceutical wastes as hazardous.
- *Step Nine*. Select areas for waste accumulation and storage, choose hazardous waste disposal and reverse distribution vendors, and implement a pilot program.
- *Step Ten*. Implement the pharmaceutical waste management program (H2E, 2006).

5.1.2 Product Stewardship Institute (PSI)

PSI is a national nonprofit organization aimed at reducing health and environmental impacts of consumer products, including pharmaceuticals. Members include 43 states and 50 local government agencies. Businesses and environmental organizations can join PSI as adjunct members. PSI is now developing a Product Stewardship Action Plan that will focus on unwanted or waste pharmaceutical products from households and LTCFs. PSI's goal is to develop a nationally coordinated system for management of unused pharmaceuticals and will focus on the unused pharmaceuticals that typically enter the municipal solid waste stream, municipal wastewater, or residential septic systems (PSI, 2008).

5.1.3 The Joint Commission

The Joint Commission[11] (formerly the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) is an independent not-for-profit organization aimed at improving healthcare by establishing standards and accrediting hospitals and other health services facilities. The Joint Commission has established a set of standards known as the Environment of Care (EC) Standards. These standards fall into four groups:

- Planning (EC.1);
- Implement/teach (EC.2);
- Other environmental considerations (EC.3); and
- Monitor and improve (EC.4).

The Joint Commission uses the EC standards to evaluate hospitals' performance in several areas including environmental protection. The EC requires the appointment of a qualified individual and designation of a committee responsible for managing implementation of the standards. In addition, the EC requires the development of the following seven management programs to improve and maintain the safety of the health services facility, and describes actions that health services facilities must take to comply with hazardous waste regulations (PharmEcology, 2005):

- Safety;
- Security;

[11] The mission of The Joint Commission is to continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health services organizations. In 1965 Congress passed the Social Security Amendments of 1965 with a provision that hospitals accredited by JCAHO are "deemed" to be in compliance with most of the Medicare Conditions of Participation for Hospitals and, thus, able to participate in the Medicare and Medicaid programs. (www.jointcommission.org/AboutUs/joint_commission_history.htm)

- Hazardous materials and waste;
- Emergency preparedness;
- Life safety;
- Medical equipment; and
- Utility systems.

The EC standards do not specifically address disposal of unused pharmaceuticals. However, pharmaceuticals that are classified as hazardous waste would be managed according to the standards.

5.2 Summary of Pharmaceutical Management Practices

Managing pharmaceutical waste properly includes minimizing pharmaceutical waste generated; complying with applicable Federal, state and local regulations; and using BMPs. Regulations for pharmaceutical waste disposal are described in Section 4 of this report. This subsection summarizes good management practices that EPA has identified thus far. These management practices are based on guidance provided by the aforementioned organizations, three states (California, Minnesota, and Washington), and the Albany Medical Center.

5.2.1 Waste Minimization Techniques

Waste minimization has the following components:

- Inventory of pharmaceuticals;
- Stock rotation;
- Minimizing receipt of sample products; and
- Limiting the amount of pharmaceuticals dispensed at one time.

Some of these practices may be more applicable to hospitals than LTCFs. Below is a more detailed discussion of each of these components:

Pharmaceutical Inventory

The facility maintains a detailed inventory of pharmaceuticals purchased, dispensed, and wasted in order to identify where waste comes from and how to minimize. Many hospitals use computerized inventory management systems that can track historical use and waste data, compile reorder lists, determine the amount of each pharmaceutical to be stocked, and can be used to develop labels for pharmaceuticals. When identifying waste minimization opportunities, a facility determines not just how much medication is wasted but the reasons for waste. Once a facility has evaluated its current practices, it can determine the most applicable or feasible method for minimizing its pharmaceutical waste.

Stock Rotation

Stock rotation is a practice that has effectively reduced expired pharmaceutical wastes in hospitals. Hospital staff maintain inventories of high-use pharmaceuticals and identify pharmaceuticals that are close to expiring. These short-dated pharmaceuticals are then redistributed to other areas of the hospital where they are needed. Two Minnesota hospitals,

Hennepin County Medical Center (HCMC) and Tri-County Hospital in Wadena, identified crash boxes, crash carts, and ambulances as locations with the greatest potential for pharmaceuticals to expire. Tri-County Hospital reduced its stock on ambulances by six vials of epinephrine and 15 vials of lidocaine as a result of stock rotation. Expired epinephrine and lidocaine are two hazardous pharmaceutical wastes commonly generated by this facility (MNTAP, 2007).

Minimizing Product Sample Waste

Pharmaceutical samples can be a large source of wasted medications at hospital pharmacies. Many samples that are left by pharmaceutical representatives are short-dated and often expire before they are used. The pharmaceutical representatives are not permitted to take back expired medications from hospitals. As a result, the hospital is left with the responsibility of identifying whether the sample is a RCRA hazardous waste and properly disposing of the sample (Cunha, 2007). Some hospitals no longer accept pharmaceutical samples from representatives (ERG, 2008b).

HCMC in Minnesota estimated that it accumulated 35 pounds of sample waste, costing $520 in disposal and sorting fees, over a two-month period (MNTAP, 2007). HCMC corrected this problem by moving its sample log from the pharmacy to the purchasing department. The purchasing department was then made responsible for logging in samples and making sure that no samples were accepted that had less than one year before expiration (MNTAP, 2007).

Dispensing Techniques

Dispensed pharmaceuticals can go unused if the patient has an allergic or adverse reaction to the medication, no longer requires treatment, or refuses treatment, or if the medication expires or is ineffective. Hospitals and LTCFs can reduce the amount of pharmaceutical waste generated by limiting the amount of pharmaceuticals dispensed to patients and residents at one time. In particular, new prescriptions can be dispensed in limited amounts until the doctor or nurse determines that the patient does not show any adverse or allergic reaction to the drug. Options for dispensing pharmaceuticals include:

- *Unit Dose Packaging*. Unit dose packages ("blister packs") consist of several sealed compartments, each containing one dose of the prescribed medication. As a result, unused doses are maintained in a tamper-free packaging and can be returned to the manufacturer for credit. As described in Section 4, LTCFs may not return unused controlled substances.
- *Limited-Quantity Dispensing*. The Albany Medical Center dispenses only a 24-hour supply of medications to patients. Medications are provided to patients in a "cassette." At the end of the 24-hour period, pharmacy personnel change out the patients' cassettes and fill the cassettes for the next 24-hour period. All unused pharmaceuticals are returned to the pharmacy (Albany Medical Center, 2007).
- *Automatic Dispensing Systems*. ADSs dispense single doses of medications to patients and residents. Medications that remain inside the ADS are considered within the DEA's closed distribution system for controlled substances and can therefore be returned to the manufacturer (see 68 FR 62255; November 3, 2003).

- *Standardized Medication Dosages*. Using the same doses for medications used in different departments of a hospital helps to facilitate stock rotation. For example, HCMC in Minnesota was using 15-gram Glutose gel tubes in its crash boxes and using 45-gram tubes in the Omnicells for diabetics. The facility switched all departments to 15-gram Glutose gel tubes and was able to rotate tubes from crash boxes to the Omnicells as they were needed (MNTAP, 2007).

5.2.2 Reverse Distribution

Hospitals and LTCFs have the option of hiring reverse distributors to manage unused and/or expired medications (not including controlled substances) the facility believes 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. The manufacturer or wholesaler credits the dispenser for the returned medications and determines whether the medications may be reused, reclaimed, sold overseas, or disposed. Unused pharmaceuticals may be returned to the wholesaler under the following circumstances (not an exhaustive list):

- There was an oversupply at the dispenser;
- The product has expired;
- A recall has been initiated by the manufacturer;
- The product was received as a result of a shipping error; or
- The product has been damaged (OSW, 1991).

Although reverse distributors will arrange for proper disposal of unused pharmaceuticals that cannot be returned for credit, reverse distributors are not waste management services. It is the facility's responsibility to segregate unused pharmaceutical that should be wasted, including pharmaceuticals that are RCRA hazardous waste, from pharmaceuticals that may be returned for credit (MNTAP, 2007). When using reverse distribution, guidance suggests that the facility only mail unused pharmaceuticals to the reverse distributor that the facility believes could potentially be returned for credit. Otherwise, unused pharmaceuticals would be identified as waste and the facility may use a waste hauling service for disposal. See Section 4 of this report for a discussion on limitations for reverse distribution of controlled substances.

5.2.3 Pharmaceutical Waste Disposal Practices

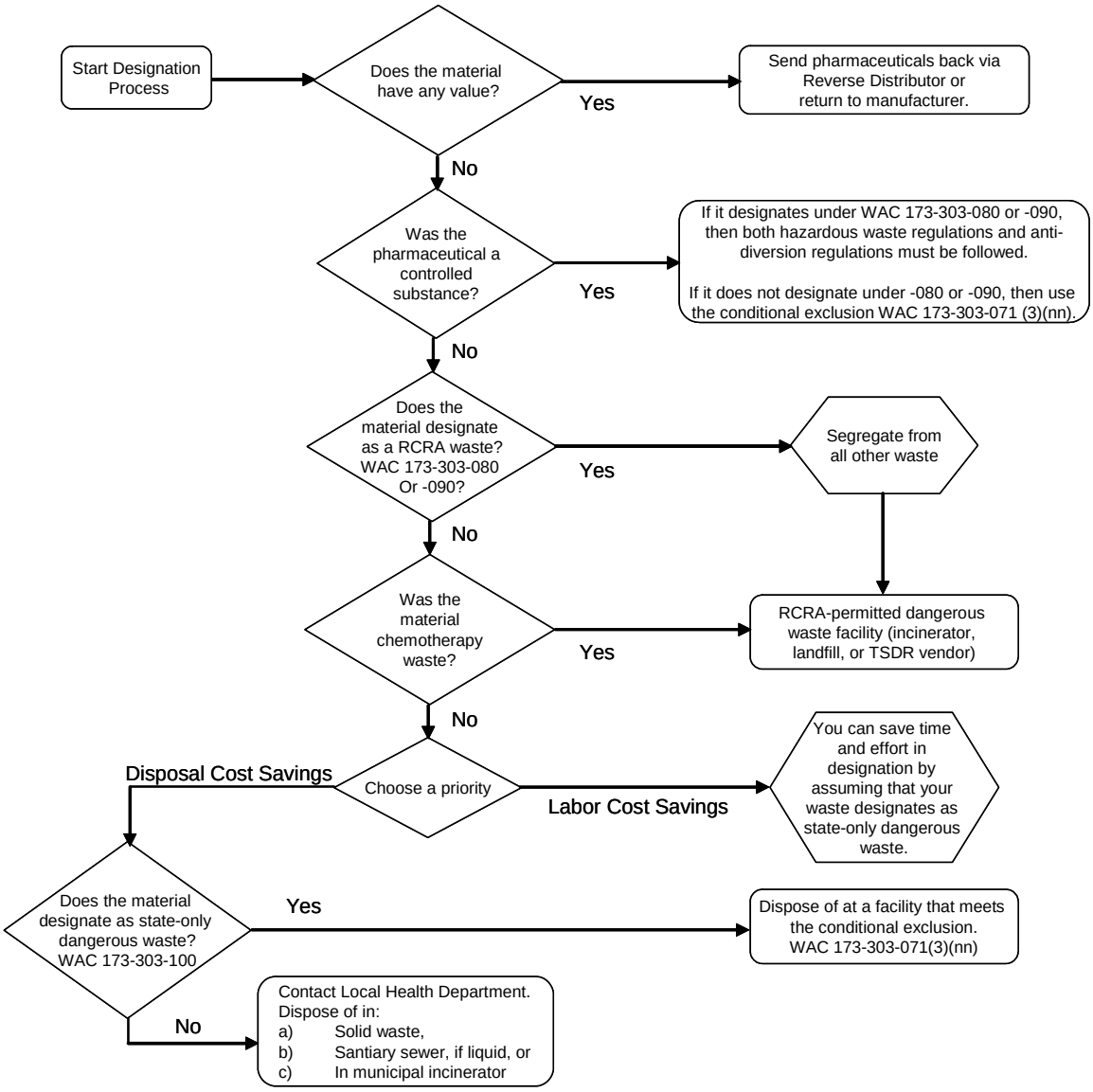
Pharmaceutical waste disposal consists of the following components:

- Perform an inventory of all wastes, including identification of proper disposal and incompatible wastes;
- Communicate proper disposal practices to staff;
- Limit disposal down the drain by handling all or some unlisted pharmaceutical wastes as RCRA-listed hazardous.

A more detailed discussion follows.

Perform an Inventory

Facilities perform an inventory of all pharmaceutical waste generated at the facility and determine the appropriate disposal method. As part of this process, facilities would identify pharmaceutical wastes that are incompatible with other pharmaceutical wastes and, as a safety consideration, should not be disposed of or stored in the same container. Tools exist to help facilities identify the correct disposal methods for each type of pharmaceutical waste. For example, one facility reported using a proprietary database to identify proper disposal methods for pharmaceutical products by name (Cunha, 2007). In addition, Figure 5-1 presents a flowchart from the Washington State Department of Ecology Web site to assist facilities to identify proper disposal methods.



Source: Washington State Department of Ecology.

Figure 5-1. Example Pharmaceutical Waste Management Flow Chart

Communicate Proper Disposal Practices

Once the facility identifies the proper disposal methods for the pharmaceuticals used onsite, the next step is to communicate the proper disposal method to staff and ensure that the unused pharmaceuticals are disposed in the proper receptacles. Tools exist to help facilities automate this process. Some hospitals currently use a bar code system to track drug utilization and avoid medication errors. This same system can be used to store information about the proper disposal. For example, one system uses a bar code scanner to categorize waste medications as infectious, chemotherapeutic, hazardous, mixed hazardous/infectious or lower risk. Once the type of waste is identified the appropriate tamper-proof container opens automatically. This system eliminates human error during pharmaceutical waste sorting and identification (Vestara, 2008).

Consider Disposing of Unlisted Pharmaceutical Wastes as RCRA-Listed Hazardous

Manufacturers continue to develop new drugs that are not currently listed as RCRA hazardous waste. As a result, many unlisted pharmaceutical products that are equally hazardous to listed pharmaceutical waste may be disposed of down the drain or disposed into municipal solid waste landfills. Suggested management practices for pharmaceutical waste generally encourage handling all pharmaceutical waste as hazardous when discarded. The H2E Blueprint recommends incinerating the following pharmaceuticals as hazardous waste (H2E, 2006):

- Formulations that use listed ingredients that are not the sole active ingredient. To meet the scope of a P or U listing under RCRA, the pharmaceutical formulation must contain only one active ingredient. For example, Fluori-methane is a formulation composed of 15 percent dichlorodifluoromethane (U075) and 85 percent trichloromonofluoromethane (U121). Although both ingredients are U-listed RCRA hazardous wastes, the combined formulation is not a listed waste because neither ingredient is the sole active ingredient.
- Chemotherapeutic agents. Only nine chemotherapy drugs are P or U listed. There are currently over 100 chemotherapy drugs used by the health services industry. Examples of common chemotherapy drugs that are not listed include methotrexate, vinblastine, vincristine, and 5-fluorouracil.
- Drugs meeting NIOSH hazardous drug criteria.[12] The NIOSH criteria include mutagenicity, carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low dose, genotoxicity, and structure and toxicity of new drugs that mimic existing drugs determined hazardous by previous criteria.
- Drugs listed in Appendix VI of the OSHA Technical Manual.[13]
- Drugs with a lethal dose (LD) less than or equal to 50 mg/kg (e.g., Colchicine).
- Carcinogenic drugs.
- Vitamin and mineral preparations that use heavy metals.
- Potential endocrine disrupting compounds.[14]

[12] Appendix A of ***NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Healthcare Settings*** provides a list of drugs that should be handled as hazardous. It is available online at http://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf. Note: these drugs may not be P-listed or U-listed RCRA hazardous waste, but may be classified as RCRA hazardous by characteristic, once they are a waste.

[13] The OSHA Technical Manual is available online at http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html.

As part of its guidance to health services facilities, the state of California lists the following pharmaceutical wastes as acceptable for sewering (in general): solutions in IV bags containing only saline solution, lactate, nutrients such as glucose, vitamins, and added salts such as potassium or other electrolytes. The state of California encourages health care facilities to minimize as much as possible the amount of pharmaceutical waste disposed to the sewer[15] (McGurk, 2003).

5.3 Treatment Options

As part of the Health Services Industry Study, EPA is obtaining information on pharmaceutical destruction devices that LTCFs and hospitals may use as an alternative to wastewater disposal. For example, a Canadian company has used a proprietary non-incineration technology to destroy pharmaceutical waste. This technology is a closed-loop, indirectly heated system that pyrolyzes all the organic components of the pharmaceutical waste and depolymerises all of the plastic from the pharmaceutical packaging. This depolymerized plastic is then recoverable as usable oil. According to a representative of this technology, it:

- Offers the destructive benefits of incineration;
- Does not produce any harmful emissions such as dioxin;
- Recovers up to 90 percent of the available oil for reuse; and
- Reduces waste volume by over 90 percent (Gilliam, 2007).

EPA will continue to collect information on pharmaceutical destruction technologies during the 2009 annual review.

[14] Many common endocrine disruptors, such as estrogens, testosterone, progesterone, androgens, contraceptives, and oxytoxics are listed in the NIOSH Hazardous Drug Alert. Additional endocrine disrupting drugs, such as the anti-fungal ketoconazole, can be found at www.ourstolenfuture.org.

[15] The state of California requires health services facilities to obtain permission from their POTW prior to disposing of pharmaceutical waste down the drain. The POTW then has the authority to deny a facility's request based on local conditions.

Similarly the King County Industrial Waste Program in Washington issued industrial wastewater discharge authorizations to all King County hospitals stating that no pharmaceuticals may be discharged to the sewer as of 2002. King County hospitals use reverse distributors or dispose all pharmaceutical waste as hazardous waste (True, 2007).

6. PATHWAYS FOR ENVIRONMENTAL RELEASES OF UNUSED PHARMACEUTICALS

Health service facilities have three disposal options for pharmaceuticals that are identified as waste (i.e., that cannot be returned to manufacturer for credit):

- Disposal to sewer;
- Incineration (RCRA incineration or low temperature incineration); and
- Disposal to landfill.

Currently, EPA does not have information on the quantities of pharmaceuticals disposed by each option. Section 7 describes the status of EPA's information collection on disposal practices at hospitals and LTCFs. The remainder of this section describes each disposal pathway in more detail.

6.1 Disposal to Sewer

The vast majority of hospitals and LTCFs are indirect dischargers. Therefore, wastewater discharges from these facilities, including pharmaceuticals that are flushed down the drain, are treated at POTWs before they are discharged to surface waters. As described in Section 3.2 of this report, POTWs are not designed to remove pharmaceuticals that are present in discharges from hospitals and LTCFs. Many recent studies characterize treatment effectiveness of certain technologies, including secondary biological treatment, reverse osmosis, and several drinking water treatment technologies (AWWARF, 2007; Carballa, 2004; Drewes, 2006; Stephenson, 2007; and Thomas, 2007). The remainder of this subsection summarizes selected studies regarding the fate of pharmaceuticals at POTWs and the factors that affect their removal by POTW treatment operations.

6.1.1 Mechanisms for Removal

Studies show that removal of selected pharmaceuticals at POTWs is achieved through biodegradation and adsorption to solids (Stephenson, 2007)[16]. Sorption to solids is a major factor affecting removal efficiencies of pharmaceuticals by physical/chemical and biological treatment. As described in Section 6.2, sorption to solids is determined by the solid/liquid partitioning coefficient (Carballa, 2004). Pharmaceuticals with low solid partitioning coefficients will remain in the aqueous phase, making them available to POTW treatment processes, such as biodegradation, hydrolysis, and chemical oxidation with disinfectants such as chlorine and ozone.

6.1.2 Effect of POTW Operating Conditions

In a 2007 study sponsored by the Water Environmental Research Foundation (WERF), researchers sampled six conventional POTWs achieving secondary treatment and two pilot-scale membrane bioreactors. They investigated the fate of pharmaceutical and personal care products

[16] Carballa et. al. investigated 12 pharmaceuticals and personal care products, including musks, hormones, and pharmaceuticals.

(PPCP)[17] and examined the effects of changing operating parameters. The study authors concluded that:

- There was no significant difference in PPCP removals between conventional POTWs and the pilot-scale membrane bioreactors;
- Altering hydraulic retention time did not affect PPCP removals;
- Media filtration did not provide addition removals for PPCPs present in effluent from secondary treatment;
- Pure oxygen systems showed better removals than conventional aeration;
- Secondary treatment followed by reverse osmosis reduced all the analyzed PPCP[17] concentrations to less than the method detection limit; and
- Increasing the sludge retention time generally increased removals; however, some PPCPs still had no removal with increased sludge retention time (Stephenson, 2007).

6.1.3 POTW Removal Efficiencies

Table 6-1 presents a summary of the POTW removal efficiencies in selected published studies that EPA has obtained. These select studies provide an overview of the wider body of published technical literature related to the treatment of pharmaceuticals in water. Pharmaceuticals that were detected in POTW influent in these selected studies include 17 alpha-ethinylestradiol, 17 beta-estradiol, caffeine, estriol, estrone, ibuprofen, and testosterone. As shown in Table 6-1, most of these compounds have compound removals greater than 50 percent. However, the published removals for these compounds often range from negative removals to close to 100 percent removals (i.e., compound not detected in effluent). Several factors can contribute to the high variability of pharmaceutical removal rates found by various sampling studies (Thomas et al., 2007):

- Pharmaceutical concentrations can be highly variable in the POTW influent. Due to the design of the sampling program and retention times at the POTW, effluent samples may not be representative of influent samples.
- Excreted pharmaceuticals are often in their polar conjugate form (sulphates or glucuronides) and can reform the parent pharmaceutical during the treatment process at the POTW.
- High levels of organic matter at the POTW influent can cause interferences during analysis for pharmaceutical compounds.

Table 6-1. POTW Removal Efficiencies for Specific Pharmaceuticals in Selected Studies

Compound	Therapeutic Family	POTW Treatment	Compound Removal (%)	Reference
Acetaminophen (paracetamol)	Painkiller/anti-inflammatory	Secondary treatment	0 – 100 [a]	Thomas, 2007
Alpha-ethinylestradiol	Steroid	Secondary treatment	>92	Drewes, 2006
		Reverse osmosis (lab-scale)	100% removal	Drewes, 2006

[17] Stephenson and Oppenheimer investigated POTW removals for 21 PPCPs, two of which were pharmaceuticals (ibuprofen and caffeine).

Table 6-1. POTW Removal Efficiencies for Specific Pharmaceuticals in Selected Studies

Compound	Therapeutic Family	POTW Treatment	Compound Removal (%)	Reference
Beta-estradiol	Steroid	Secondary treatment	85 – >94	Drewes, 2006
			65	Carballa, 2004
			57 – 100	Thomas, 2007
		Reverse osmosis (lab-scale)	100% removal	Drewes, 2006
Caffeine	Stimulant	Secondary treatment	0 – >99.9 [a]	Stephenson, 2007
Ciprofloxacin	Antibiotic	Secondary treatment	0 – 100 [a]	Thomas, 2007
Diclofenac	Painkiller/anti-inflammatory	Secondary treatment	0 – 27 [a]	Thomas, 2007
Estriol	Steroid	Secondary treatment	>99	Drewes, 2006
			94 – 100	Thomas, 2007
Estrone	Steroid	Secondary treatment	98	Drewes, 2006
			0 [b]	Carballa, 2004
			42 – 100	Thomas, 2007
		Reverse osmosis (lab-scale)	100% removal	Drewes, 2006
Ibuprofen	Painkiller/anti-inflammatory	Secondary treatment	0 – >96 [a]	Stephenson, 2007
			40 – 65	Carballa, 2004
			0 – 100 [a]	Thomas, 2007
Metoprolol	Cardiovascular drug	Secondary treatment	0 – 50 [c]	Thomas, 2007
Naproxen	Painkiller/anti-inflammatory	Secondary treatment	40 – 65	Carballa, 2004
Sulfamethoxazole	Antibiotic	Secondary treatment	60	Carballa, 2004
			0 – 100 [a]	Thomas, 2007
Testosterone	Steroid	Secondary treatment	96 – >99	Drewes, 2006
Trimethoprim	Antibiotic	Secondary treatment	0 – 100 [c]	Thomas, 2007

Sources: Drewes et al., 2006; Stephenson and Oppenheimer, 2007; Carballa et al., 2004; Thomas et al., 2007.
NA — Not applicable.
a – One or more samples showed zero (or negative) removals (effluent concentration was greater than influent concentration); however, the majority of data indicated removal of the compound.
b – The concentration of estrone increased through the treatment works due to the partial oxidation of 17(beta)-estradiol.
c – Majority of samples showed zero (or negative) removals (i.e., effluent concentration higher than influent concentration).

6.2 Incineration

Incineration is the thermal destruction of waste. Modern incinerator systems operate at high temperatures and use controlled air and mixing to alter the chemical, physical, or biological characteristics of the waste material. The major benefit of incineration over disposal to landfills and sewers is that the incineration process destroys the pharmaceutical waste, rather than storing it or transferring it to another medium. 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 still be released to the atmosphere through the incinerator exhaust, discharged to wastewater via wet

air pollution control technologies (e.g., scrubbers), or disposed to landfill with the incinerator ash (Santoleri, 2006).

Hazardous waste incinerators and medical waste incinerators are currently available for destruction of pharmaceutical waste. Differences between these incinerators include permitting, oversight, operating temperatures, emissions control, and final disposition of the resulting ash (Chemical Disposal Services, 2008). Hazardous waste incinerators are subject to stringent regulations promulgated under the authority of the following statutory authorities:

- Resource Recovery Act (1965);
- Clean Air Act (1970);
- Resource Conservation and Recovery Act (1976); and
- Hazardous and Solid Wastes Amendments (1984).

These regulations require operators of hazardous waste incinerators to install and maintain proper combustion and air pollution controls. Air pollution control systems typically include scrubbers designed to remove particulate, heavy metals, hydrocarbons, dioxins and furans, and acid gases produced from waste containing chlorine, sulfur, phosphorus, and nitrogen (Santoleri, 2006). The ash recovered from hazardous waste incinerators must be sent to a lined hazardous waste landfill (Chemical Disposal Services, 2008).

Medical waste incinerators are not as strictly regulated. For example, ash recovered from medical waste incinerators may be stored in a municipal landfill (Chemical Disposal Services, 2008). In 1997, EPA found that medical waste incinerators were among the top emitters of mercury and dioxin, and adopted new source performance standards and emission guidelines for hospital/medical/infectious waste incinerators (see 65 FR 49739). The regulations required the implementation of good combustion practices to promote complete waste destruction and limit formation of air pollutants. The regulations, which are still in effect, also required the use of wet or dry scrubbers to control emissions of particulate matter, dioxins and furans, hydrochloric acid, and metals. Many medical waste incinerators have closed because they decided to implement alternative disposal methods rather than meet the new requirements of the standards.

Different incinerator configurations exist for thermal treatment of gases, liquids, and solids. The vast majority of pharmaceutical waste is expected to be in liquid or solid form. Incinerators designed to treat solid and liquid feed include fixed-hearth and rotary kiln incinerators. Fixed-hearth systems, commonly used for medical and municipal waste, burn solid and liquid waste in a stationary chamber. The rotary kiln incinerator uses a rotating cylindrical chamber to mix the solid and liquid waste and ensure even distribution of heat. In both systems, waste enters the primary combustion chamber (which operates at extremely high temperatures, i.e., 1,300 to 2,000°F), where the air in the combustion chamber volatilizes and oxidizes the waste. Carbon monoxide and unburned volatiles exit the primary combustion chamber and enter the secondary combustion chamber, where additional air or oxygen is added to further oxidize the vapor and ensure complete combustion (Santoleri, 2006). Hazardous waste incinerators must achieve 99.99 percent destruction and removal of principal organic hazard constituents.[18]

[18] Principal organic hazard constituents are selected based on their toxicity, prevalence in the waste mix, and difficulty to burn.

6.3 Disposal to Landfill

Unused pharmaceuticals that are disposed of as solid waste may be sent to a hazardous waste landfill or a municipal solid waste (MSW) landfill. Unused pharmaceuticals in landfills generally include pills, tablets, and trace amounts in spent containers. The main concern about using landfill disposal is the potential for pharmaceuticals to enter surface water and groundwater through landfill leachate. RCRA regulations include two types of requirements to control leachate: treatment prior to disposal on land and landfill construction requirements.

Hazardous waste landfills are regulated under RCRA Subtitle C. The RCRA Land Disposal Restrictions require hazardous wastes to be treated prior to disposal in the landfill. For example, liquid wastes containing hazardous pharmaceuticals such as epinephrine, nicotine, or nitroglycerine, are treated using wet air oxidation, chemical oxidation, carbon adsorption, or combustion. Solid wastes containing these pharmaceutical ingredients must be treated using high-temperature combustion. Treatment standards for hazardous waste are described in 40 CFR Part 268. The treatment standards for pharmaceuticals are expressed as a treatment method rather than as a concentration. For these standards, the waste must be treated using the technology described in Table 1 of the regulation. For example, chemical oxidation ("alkaline chlorination") requires:

- Using the following oxidation reagents (or waste reagents) or combinations of reagents: hypochlorite (e.g., bleach), chlorine, chlorine dioxide, ozone or UV (ultraviolet light) assisted ozone, peroxides, persulfates, perchlorates, permanganates, and/or other oxidizing reagents of equivalent efficiency; and
- Operating the treatment unit to substantially reduce the concentration of the surrogate compound or indicator parameter (e.g., total organic carbon).

Once waste is disposed of in a hazardous landfill, 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 soil and a geomembrane liner. All leachate is collected in a sump and treated (Zhao and Richardson, 2003).

MSW landfills are regulated under RCRA Subtitle D, which requires that the landfill have a liner and a leachate collection and treatment system. Unlike Subtitle C, Subtitle D does not require waste to be treated prior to disposal. In addition, Subtitle D requires only a single lining with a geomembrane and compacted clay liner. States have the authority to set more stringent requirements for Subtitle D landfills. As of 2003, seven states required double-liner systems at Subtitle D landfills (Zhao and Richardson, 2003).

EPA performed a literature search for studies or reports on pharmaceuticals disposed of in landfills. EPA found that in 2007, the Pharmaceutical Research and Manufacturers of America (PhRMA) evaluated the potential for 24 active pharmaceutical ingredients to leach from MSW landfills and their potential releases to surface water (Tischler, 2007). PhRMA compared the modeled landfill leachate releases to estimates of surface water releases from disposal of unused pharmaceuticals down the drain. PhRMA selected the 24 example pharmaceutical ingredients to represent a range of sales per year in the U.S. (i.e., high quantities and low quantities) and a

range of physical-chemical properties. These pharmaceutical ingredients were also evaluated in the 2002 USGS study of pharmaceuticals in surface waters (Kolpin et al., 2002).

The PhRMA study calculated that the landfill disposal pathway to surface water accounted for an average of 0.03% to 0.10% of the estimated aggregate annual surface water releases for the 24 active pharmaceutical ingredients. Therefore, the study estimated that over 99.9% of active pharmaceutical ingredient surface water releases would be due to patient excretion, not landfill disposal of unused medicines, assuming that landfill disposal were used for all unused medicine disposal. The evaluation was based on the assumption that the efficiency of the pharmaceuticals partitioning to solids in the landfill is 50% of the efficiency of partitioning in a biological wastewater treatment unit (Tischler, 2007).

7. DATA COLLECTION STATUS

As part of this study, EPA is collecting information on disposal practices, quantities of pharmaceuticals disposed, alternatives to disposal of pharmaceuticals down the drain, and pharmaceutical waste minimization and management practices. To accomplish this, EPA will collect data directly from hospitals, LTCFs, hospices, and veterinary facilities and review data available in scientific literature. EPA plans to use these data to identify and evaluate potential BMPs or alternative disposal methods; and determine the need for pretreatment standards for unused pharmaceuticals. EPA will compare disposal practices across the United States and estimate the amount and types of drugs discharged to surface water.

7.1 Site Visits

In June 2008, EPA visited a reverse distributor in Milwaukee, WI and two hospitals in Minneapolis, MN. The objectives of these site visits included:

- Observe the reverse distribution process;
- Observe pharmaceutical waste management practices at two hospitals;
- Collect information about available tools and resources for waste characterization and disposal recommendations;
- Gather data on pharmaceutical identities and quantities disposed to various waste streams;
- Collect information on costs of pharmaceutical waste management;
- Discuss factors that limit disposal options for some pharmaceuticals, such as hazardous pharmaceutical waste and controlled substances; and
- Collect general information to improve EPA's questionnaire for health services facilities.

7.1.1 Capital Returns, Milwaukee, WI

Capital Returns, a national reverse distributor, processes creditable pharmaceutical returns for pharmacies and pharmaceutical manufacturers. Its customers include:

- Hospital, long-term care, mail order, and retail pharmacies;
- Pharmaceutical manufacturers; and
- Independent and institutional customers.

The facility ensures the proper disposal of expired medications for two major types of returns (ERG, 2008a):

- *Pharmacy returns.* Capital Returns receives expired pharmaceuticals that are eligible for credit, or "creditable," from its pharmacy clients. Staff identify the expired pharmaceuticals, determine the amount of creditable pharmaceuticals, identify the manufacturer of the pharmaceuticals, process the return, and either ship the pharmaceuticals to the manufacturer (if the manufacturer is not a Capital Returns customer) or send them to incineration for disposal (if the manufacturer is a Capital Returns customer).

- *Manufacturer returns.* Capital Returns receives the creditable expired pharmaceuticals that pharmacies return to their pharmaceutical manufacturer clients. Staff identifies the expired pharmaceuticals, determines the amount of creditable pharmaceuticals, identifies the pharmacy that made the return, processes the return, and sends the expired pharmaceuticals to incineration for disposal.

7.1.2 North Memorial Hospital, Robbinsdale, MN

North Memorial Medical Center is a 518-bed, non-profit hospital. North Memorial developed its hazardous waste management program in response to a 2003 initiative by the Minnesota Pollution Control Authority (MPCA) to assist hospitals in Minnesota to improve their hazardous waste management practices and come into compliance with RCRA.[19] Following implementation of the program, North Memorial tracked pharmaceutical waste disposal for two years. The data indicated that North Memorial disposed of a total of 100,000 pounds of non-hazardous waste, 20,000 pounds of hazardous waste, and 8,000 pounds of dual waste[20] for the two-year period. The pounds include the weight of vials, tubes, and containers.

The key goal of North Memorial's program is to properly manage pharmaceutical waste through incineration and avoid flushing. North Memorial uses a pre-sort system to segregate pharmaceutical waste. Under a pre-sort system, the determination of type of waste is made at the point of generation. The facility's onsite pharmacy uses a proprietary program to identify proper disposal practices for each of its 3,000 to 4,000 formularies. These disposal methods are integrated with the facility's dispensary system. When nurses log into the system, they enter the national drug code for the medication that they need. The system then displays a message to indicate whether the pharmaceutical requires special disposal. The North Memorial nursing staff is trained to place pharmaceutical waste with special disposal requirements into black hazardous waste bins. Pharmaceuticals without special disposal requirements are placed in white non-hazardous waste bins. All waste that is disposed of in black bins is logged in for manifesting purposes, prior to disposal using a hazardous waste transporter. Waste in white bins is not tracked because it is not regulated, and it is disposed as municipal solid waste. Controlled substance waste is flushed down the drain.

Pharmaceutical waste minimization practices at North Memorial include managing inventory, using unit dose vials, ordering pharmaceuticals in unit doses, and repackaging bulk pharmaceuticals into unit doses. The onsite pharmacy also does not accept pharmaceutical samples from sales representatives (ERG, 2008b).

7.1.3 Abbott Northwestern, Minneapolis, MN

Abbott Northwestern Hospital is a 640-bed facility and is the largest not-for-profit hospital in Minnesota. Abbott Northwestern began to develop its hazardous waste management program in 2005 in collaboration with the MPCA Hazardous Waste Compliance and

[19] MPCA's environmental guidance for the health services industry is available online at http://proteus.pca.state.mn.us/industry/healthcare.html.
[20] MPCA refers to pharmaceutical waste and chemical waste that are hazardous and infectious as "dual waste."

Enforcement department. Abbott's focus was to develop a waste disposal program compliant with RCRA hazardous waste and Minnesota Lethal guidelines.[21]

Abbott's hazardous waste management program uses a "post-sorting" model. Under this model, nursing staff disposes of all pharmaceutical waste into black hazardous waste containers. Once full, the waste bins are transferred to a central storage and sorting area. A waste vendor contracted by Abbott, sorts the pharmaceutical waste into hazardous and non-hazardous. Abbott Northwestern, with assistance from an independent contractor, compiled a list of wasted pharmaceuticals and categorized each as either hazardous or non-hazardous waste (ERG, 2008c).

Based on pharmaceutical waste data for 2006 and 2007, approximately 75 percent of the sorted pharmaceutical waste generated at Abbott Northwestern is disposed of as non-hazardous waste (non-hazardous waste and municipal garbage), and 25 percent is disposed of as RCRA hazardous (P-listed drugs, dual waste, and Minnesota Lethal drugs. Hazardous waste is disposed using a hazardous waste transporter, while non-hazardous waste is disposed as municipal solid waste. Controlled substance waste is flushed down the drain (ERG, 2008c).

7.2 Pharmaceutical Disposal Information from Technical Literature

EPA has reviewed available literature on quantities and identities of pharmaceuticals disposed to wastewater, reasons why pharmaceutical waste is generated, how often facilities use different disposal methods, and examples of reductions in pharmaceutical discharges to wastewater through implementation of pharmaceutical waste minimization or alternate disposal methods. EPA reviewed the following studies and summarized their information in this subsection:

- Survey of 17 LTCFs located in the Commonwealth of Massachusetts (Paone et al., 2007);
- Bren School survey of LTCFs, hospitals, and pharmacies in Santa Barbara, CA (Bren School, 2007);
- Kansas State University survey of 59 LTCFs in Kansas (KSU, 2008);
- City of Newberg, OR, pharmaceutical collection program (Bateman, 2007); and
- Pharmaceutical waste management program at a 274-bed LTCF (Conkle, 2008).

7.2.1 Quantities and Identities of Pharmaceuticals

The Massachusetts Society of Consultant Pharmacists surveyed 17 Massachusetts LTCFs from 1992 to 1994 to evaluate the scope and costs of medication waste in Massachusetts LTCFs. The survey collected information on the costs of medications that were wasted and the reasons why medications became waste. The survey did not specify the method of destruction. Therefore, the quantity of destroyed medications that are disposed to wastewater is unknown. The survey found that, combined, the 17 facilities destroyed approximately $0.15 of medications per patient per day. This amount accounts for 6.7 percent of the total value of prescribed medications. The highest-cost medications destroyed were central nervous system drugs, gastrointestinal drugs, cardiovascular drugs, and anti-infective drugs (Paone et al., 2007).

[21] More information on Minnesota Lethal Guidelines can be found at http://www.pca.state.mn.us/publications/w-hw2-04.pdf

The Bren School of Environmental Science and Management conducted surveys to determine household and institutional disposal practices in Santa Barbara County and to estimate the public's willingness to pay for a pharmaceutical disposal program. The survey results indicated that most facilities dispose of only a small percentage of their pharmaceutical stock, and that the drain and trash are the most common disposal practices for households. Therefore, the Bren School researchers recommend implementing an education campaign and disposal program for the public (Bren School, 2007).

The Bren School survey of institutions included hospitals, pharmacies, and LTCFs located in Santa Barbara. The survey asked facilities to report the percent of their pharmaceutical stock that is typically wasted. The vast majority of all three types of facilities reported that between 0 and 5 percent of their pharmaceutical stock is wasted. No hospital or pharmacy reported more than 10 percent of their pharmaceutical stock as wasted. LTCFs reported the highest percentage of waste, with at least one facility reporting more than 30 percent of their pharmaceutical stock wasted. LTCFs commented that their residents' prescriptions changed as frequently as every six months. The Bren School researchers stated that the frequency of prescription changes at LTCFs may explain why this category of facilities produces the highest percentage of pharmaceutical waste (Bren School, 2007).

7.2.2 Reasons for Pharmaceutical Waste

The survey of 17 Massachusetts LTCFs found that prescribed pharmaceuticals were unused for the following reasons:

- Resident died: 35.5 percent;
- Medication was discontinued: 34.2 percent;
- Resident was transferred: 7.3 percent;
- Resident was hospitalized: 6.8 percent;
- Medication was changed: 6.3 percent;
- Medication was decreased: 3.4 percent;
- Other: 2.6 percent;
- Medication was increased: 2.0 percent; and
- Medication expired: 1.9 percent.

7.2.3 Disposal Methods

The Bren School survey asked hospitals, LTCFs, and pharmacies in Santa Barbara to rank, on a scale of 1 to 5, how often their facilities use different pharmaceutical disposal methods, where 5 is very frequently and 1 is never. Table 7-1 presents the average of responses for each type of facility. All three facility categories reported infrequent drain disposal of unused pharmaceuticals. The disposal methods most frequently used by hospitals in Santa Barbara are reverse distribution, biohazard waste disposal, and hazardous waste disposal. For LTCFs, the most frequently used disposal methods are reverse distributors, trash, and "other." Pharmacies indicated that reverse distribution is their primary disposal method (Bren School, 2007).

Table 7-1. Average Use of Disposal Practices Reported by Santa Barbara Hospitals, LTCFs, and Pharmacies

Disposal Method	Average Response for Hospitals	Average Response for LTCFs	Average Response for Pharmacies
Reverse distributor	3–4	3–4	4–5
Trash	1–2	2–3	1
Drain	1–2	1–2	1–2
Biohazard waste	3–4	1–2	1–2
Return to manufacturer	2–3	1–2	1–2
Onsite incinerator	1	1	1
Hazardous waste	4	1–2	1–2
Other	1	2–3	1–2

Source: Bren School, 2007.
1 — never;
5 — very frequently.

Kansas State University researchers asked 59 local LTCFs how they dispose of unused pharmaceuticals (KSU, 2008). The survey found the following usage rates for disposal methods:

- Drain disposal: 46 percent;
- Return processors: 24 percent;
- Trash: 20 percent; and
- Other: 10 percent.

7.2.4 Examples of Pharmaceutical Waste Management and Alternate Disposal Methods

At this time, EPA has reviewed information on two example programs that were implemented at LTCFs to reduce pharmaceutical wastewater discharges. These programs include a disposal program implemented by the City of Newberg, OR, and implementation of pharmaceutical waste minimization practices at an unnamed 274-bed LTCF. These case studies are described below.

Alternate Disposal Case Study

In 2007, the City of Newberg, Oregon implemented a program to collect and incinerate controlled and non-controlled substances (take-back program) from four adult care facilities (Bateman, 2007). Oregon state law allows the return and redispensing of unused pharmaceuticals from LTCFs that are:

- Non-controlled substances;
- In unopened, tamper-evident packaging;
- Under supervision of a pharmacist;
- In packaging that uses the original labeling; and
- Stored under conditions specified by the U.S. pharmacopeia standards.

Medications that cannot be returned are stored for disposal. The facilities used mailbox-like containers to hold unused pharmaceuticals in medication storage areas. The mailboxes are

locked and bolted to the floor or wall. Controlled substances are picked up by the Newberg-Dundee Police Department during their quarterly disposal of evidence at a local incinerator. The non-controlled substances are collected by the franchised hauler, Newberg Garbage Service. Information is not available regarding the disposal practices at the LTCFs prior to implementation of the take-back program. Therefore, EPA cannot estimate reductions to wastewater discharges that result from this program.

Pharmaceutical Management Case Study

In July 2002, a nurse at a 274-bed LTCF monitored the amount of prescriptions that were destroyed by flushing.[22] The facility flushed unit doses of narcotic pills, individually wrapped Duragesic patches, and sealed liquid containers. These unused medications were destroyed even though they were never opened. The total cost of medications disposed to wastewater at this facility totaled almost $2,000 per week ($99,000 per year). The destruction policy at this facility required nurses to count and log all unused medications and flush the medications in the presence of two nurses and a consultant pharmacist.

The facility implemented policies to reduce the generation of pharmaceutical waste. The facility worked with the pharmacy to reduce the quantity of narcotics dispensed to the facility to one week's supply. Patches were limited to three doses. The facility also asked the pharmacy to limit the amounts of fluids dispensed for oral medications. These efforts dramatically reduced the amount of waste requiring destruction at the facility by 90 percent to $200 per week. In addition, the amount of time required for the LTCF staff and consultant pharmacist to destroy the unused pharmaceuticals decreased, and the frequency of destruction was decreased to once every three months because of the reduction in waste generation (Conkle, 2008).

[22] In providing information to EPA, the nurse did not name the LTCF or give its location.

8. NEXT STEPS

EPA continues to study the issue of how health services facilities are managing and disposing of unused pharmaceuticals and POTW treatment effectiveness in an effort to identify the root cause and potential solutions to address the issue of pharmaceuticals in our waterways. Over the coming year EPA expects to:

- Submit an ICR to the Office of Management and Budget (OMB) for their review and approval of an industry survey under the Paperwork Reduction Act (PRA), 33 U.S.C. 3501, et seq.;
- Collect additional data through site visits at hospitals, LTCFs, hospices and/or veterinary facilities;
- Gather more technical and economic information on unused pharmaceutical management in the Health Services Industry via the industry survey;
- Work closely with industry representatives and other affected stakeholders; and
- Solicit comment on this interim report and the 2009 ELG annual plan.

8.1 Industry Questionnaire

During EPA review of currently available data for the health services industry study, EPA did not find a national source of information on the disposal of unused pharmaceuticals. Therefore, EPA is considering an Information Collection Request (ICR), as discussed in detail in the federal register notice dated August 12, 2008 (see 73 FR 46903, available at http://www.epa.gov/guide/304m/index.html).

As described in the supporting statement to the ICR, EPA will use the ICR to collect technical and economic information on unused pharmaceutical management and identify technologies and BMPs that reduce or eliminate the discharge of unused pharmaceuticals to POTWs (EPA-HQ-OW-2008-0517, DCN 06103). EPA is collecting data from medical and veterinary facilities about unused pharmaceutical disposal practices. To collect this information, EPA will distribute a questionnaire to a nationally representative sample of medical and veterinary facilities. EPA plans to use two versions of the questionnaire, one tailored to facilities that treat people (i.e., hospitals, hospices, and LTCFs) and one tailored to facilities that treat animals (i.e., veterinary facilities). Overall, the goal of these questionnaires is to gain a thorough understanding of unused pharmaceuticals disposal practices at medical and veterinary facilities at a national level including:

- The factors driving current disposal practices;
- Information on the amount of unused pharmaceuticals currently disposed of via the drain or flushing; and
- The alternatives to drain disposal and flushing. In addition, EPA will request information on alternative management options for unused pharmaceuticals and the costs associated with alternative management practices.

In the ICR notice, EPA solicited comments about the scope of the ICR and whether EPA adequately described the industry sectors that would be subject to the data collection. EPA also solicited comments on what additional entities, if any, should be included in the scope of the ICR. EPA plans to include health services establishments including hospitals, hospices, LTCFs,

and veterinary facilities. EPA may consider including veterinary clinics, medical and dental offices, as well as university and prison health clinics within the scope of inquiry and encouraged these groups to comment and meet with EPA to discuss their practices.

8.2 Site Visits

EPA also plans to conduct additional site visits to facilities to obtain more detailed information on how pharmaceuticals are managed, tracked, and disposed as well as influences on behavior. EPA will continue to work with industry trade groups to identify the best facilities to visit to identify BMPs and current practices.

8.3 Additional Review of Technical Literature

In addition to the many articles documenting the presence and removal of pharmaceuticals in water, there are even more ongoing studies currently underway. EPA will continue collecting data on pharmaceuticals in water as the publications from these studies become available.

9. REFERENCES

Albany Medical Center. 2007. *Policy and Procedure: Medication Distribution — Medication Delivery and Return.* January 23. Docket EPA-HQ-OW-2006-0771, DCN 06078.

Alvarez, et. al. 2007. Reconnaissance of Persistent and Emerging Contaminants in the Shenandoah and James River Basins, Virginia, During Spring of 2007. U.S. Geological Survey (USGS). Docket EPA-HQ-OW-2006-0771, DCN 06102.

APhA. 2006. American Pharmacists Association. *Re-Distribution of Medications.* APhA Policy Committee Background Information. November. Docket EPA-HQ-OW-2006-0771, DCN 04953.

ASCP. 2003. American Society of Consultant Pharmacists. *Policy Statement: Statement on the Return and Reuse of Medications in Long-term Care Facilities.* July 11. http://www.ascp.com/resources/policy/upload/ASCP%20Policy%20Statement%20on%20Return%20&%20Reuse.pdf. Accessed September 2007. Docket EPA-HQ-OW-2006-0771, DCN 04873.

AWWARF, 2007. American Water Works Association Research Foundation. *Removal of EDCs and Pharmaceuticals in Drinking and Reuse Treatment Processes*. Denver, Co. Prepared by Shane A. Snyder, Eric C. West and Hongxia (Dawn) Lei, Southern Water Authority, Henderson, NV and Paul Westerhoff and Yeomin Yoon, Arizona State University, Tempe, AZ. Docket EPA-HQ-OW-2006-0771, DCN 06118.

Bateman. 2007. "Pharmaceutical Take-Back Programs in Adult Care Facilities: A Pilot Project in Newberg, Oregon." Oregon Take-Back Steering Committee Meeting. February 9. Docket EPA-HQ-OW-2006-0771, DCN 05477.

Bren School. 2007. Donald Bren School of Environmental Science and Management. Pharmaceuticals in Wastewater Streams: Disposal Practices and Policy Options in Santa Barbara. University of California, Santa Barbara. May. Docket EPA-HQ-OW-2006-0771, DCN 06075.

California. 2002. State of California Department of Health Services. Letter to Directors of Environmental Health and Medical Waste Program Managers. October 15. Docket EPA-HQ-OW-2006-0771, DCN 06076.

Carballa, M., et al. 2004. "Behavior of Pharmaceuticals, Cosmetics and Hormones in a Sewage Treatment Plant." *Water Research* 38. Docket EPA-HQ-OW-2006-0771, DCN 06077.

Census. 1997a. U.S. Census Bureau. *1997 Economic Census: Bridge Between NAICS and SIC Health care & social assistance* (NAICS 622). Docket EPA-HQ-OW-2006-0771, DCN 06125.

Census. 1997b. U.S. Census Bureau. *1997 Economic Census: Bridge Between NAICS and SIC Health care & social assistance* (NAICS 623). Docket EPA-HQ-OW-2006-0771, DCN 06126.

Census. 1998. U.S. Census Bureau. County Business Patterns: 1998. Docket EPA-HQ-OW-2006-0771, DCN 04532.

Census. 2002. U.S. Census Bureau. County Business Patterns: 2002. Docket EPA-HQ-OW-2006-0771, DCN 04534.

Census. 2005a. U.S. Census Bureau. County Business Patterns: 2005. *Industry Code Comparison.* http://censtats.census.gov/cgi-bin/cbpnaic/cbpsel.pl. Docket EPA-HQ-OW-2006-0771, DCN 04531.

Census. 2005b. U.S. Census Bureau. Establishment and Firms Size: 2002 (Including Legal Form of Organization). "Receipts/Revenue Size of Establishments for the United States: 2002." *2002 Economic Census, Health Care and Social Assistance.* Subject Series. EC02-62SS-SZ. November. Docket EPA-HQ-OW-2004-0032, DCN 02943.

Census. 2007. U.S. Census Bureau. Statistics of U.S. Businesses — 2002. *Tabulated by Receipt Size*. http://www.census.gov/csd/susb/susb02.htm. Accessed August 10, 2007. Docket EPA-HQ-OW-2006-0771, DCN 04577.

Chemical Disposal Services. 2008. *A Guide to Pharmaceutical Waste Disposal.* http://www.medicalwastesolutions.com/pharm_update.pdf. Date accessed: April 2008. Docket EPA-HQ-OW-2006-0771, DCN 06080.

CMS. 2007. Centers for Medicare & Medicaid Services, Web site. Available online at: http://www.cms.hhs.gov/default.asp. Date accessed: August 2007. Docket EPA-HQ-OW-2006-0771, DCN 05074.

Collier, 2007. Collier, AC. *Pharmaceutical Contaminants in Potable Water: Concerns for Pregnant Women and Children*. Journal of Public Health. 2007. Docket EPA-HQ-OW-2006-0771, DCN 06119.

Conkle, C. 2008. "Narcotic Waste Report." Email correspondence between Cindy Conkle of Traditions Management and Meghan Hessenauer of EPA. April 4. Docket EPA-HQ-OW-2006-0771, DCN 06081.

Cunha, B. 2007. *Comments on the Preliminary 2008 Effluent Guidelines Program Plan.* EPA-HQ-OW-2006-0771-0829.

Daughton, C.G., and T.A. Ternes. 1999. "Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?" *Environmental Health Perspectives* 107(Suppl 6). Docket EPA-HQ-OW-2006-0771, DCN 06120.

Daughton, 2007. Daughton, C.G. *Pharmaceuticals in the environment: sources and their management.* A non-copyrighted chapter of *Analysis, Fate and Removal of Pharmaceuticals in the Water Cycle*. Edited by Petrovic, M., D. Barcelo, et al. Elsevier Science. Available at http://www.epa.gov/nerlesd1/bios/daughton/Chap1_Petrovic&Barcelo.pdf. Docket EPA-HQ-OW-2006-0771, DCN 06121.

DEA. 1997. Drug Enforcement Administration, Office of Diversion Control. *Code of Federal Regulations: Disposal of Controlled Substances*. 62 FR 13967; March 24, 1997. http://www.deadiversion.usdoj.gov/21cfr/cfr/1307/1307_21.htm. Accessed September 2007. Docket EPA-HQ-OW-2006-0771, DCN 04929.

DEA. 2005a. Drug Enforcement Administration, Office of Diversion Control. *Rules — 2005. Definition and Registration of Reverse Distributors.* 83 FR 22591; May 2, 2005. http://www.deadiversion.usdoj.gov/fed_regs/rules/2005/fr0502.htm. Accessed September 2007. Docket EPA-HQ-OW-2006-0771, DCN 04931.

DEA. 2005b. Drug Enforcement Administration, Office of Diversion Control. *Preventing the Accumulation of Surplus Controlled Substances at Long Term Care Facilities.* 92 FR 25462; May 13, 2005. http://www.deadiversion.usdoj.gov/fed_regs/rules/2005/fr0513.htm. Accessed December 2007. Docket EPA-HQ-OW-2006-0771, DCN 06082.

DOJ. 2006. U.S. Department of Justice. "Tenet Healthcare Corporation to Pay U.S. More Than $900 Million to Resolve False Claims Act Allegations." News release. June 29. http://www.usdoj.gov/opa/pr/2006/June/06_civ_406.html. Docket EPA-HQ-OW-2006-0771, DCN 06083.

DOL. 2007. U.S. Department of Labor. *NAICS to SIC Employment Ratios for 4-Digit SIC Series.* http://www.bls.gov/ces/naicstosic4.htm. Accessed August 6, 2007. Docket EPA-HQ-OW-2006-0771, DCN 04552.

Drewes, J.E., et al. 2006. *Removal of Endocrine Disrupting Compounds in Water Reclamation Processes*. Water Environment Research Foundation. 01-HHE-20T. Docket EPA-HQ-OW-2006-0771, DCN 06084.

EC Workgroup. 2005. Emerging Contaminants Workgroup. "Discussion Paper on Pharmaceutical Disposal to Sewer Systems." Emerging Contaminants Workgroup of the Santa Clara Basin Watershed Management Initiative. February. Docket EPA-HQ-OW-2004-0032, DCN 02324.

Environment Canada.2007. *Endocrine Disrupting Substances in the Environment*. http://www.ec.gc.ca/eds/fact/eds_e.pdf. Accessed November 28, 2007. Docket EPA-HQ-OW-2006-0771, DCN 06085.

EPA. 2006a. U.S. Environmental Protection Agency. Notice of Availability of Final 2006 Effluent Guidelines Program Plan. Federal Register 71:76644-76667. December 21.

EPA. 2006b. U.S. Environmental Protection Agency. *Final Guidance for EPA Rule Writers: Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act.* November. Docket EPA-HQ-OW-2006-0771, DCN 04509.

ERG. 2007. Eastern Research Group. Memorandum: *Industry Profile for Long Term Health Care Facilities, Hospitals, Clinics, and Veterinary Service*. Prepared for EPA Office of Water. August 20, 2007. Docket EPA-HQ-OW-2006-0771, DCN 04511.

ERG. 2008. Site Visit Report for Capital Returns, Milwaukee, WI. July. Docket EPA-HQ-OW-2006-0771, DCN 06086.

ERG. 2008a. Site Visit Report for North Memorial Hospital, Robbinsdale, MN. July. Docket EPA-HQ-OW-2006-0771, DCN 06087.

ERG. 2008b. Site Visit Report for Abbott Northwestern Hospital, Minneapolis, MN. July. Docket EPA-HQ-OW-2006-0771, DCN 06088.

Garvin, M.G. 2007. *Comments on the Preliminary 2008 Effluent Guidelines Program Plan.* EPA-HQ-OW-2006-0771-0851. December 21.

Gilliam, A. 2007. *Comments on the Preliminary 2008 Effluent Guidelines Program Plan.* EPA-HQ-OW-2006-0771-0824.

H2E. 2006. Hospitals for a Healthy Environment. *Managing Pharmaceutical Waste: A 10-Step Blueprint for Health Care Facilities in the United States.* April 15. Docket EPA-HQ-OW-2006-0771, DCN 04876.

Hessenauer, M. 2007. U.S. Environmental Protection Agency. Memorandum to the Public Record for the 2008 Effluent Guidelines Program Plan. "Health Services Outreach Meeting with the Center of Excellence in Assisted Living (CEAL) Advisory Council (18 October 2007) — Final." 17 December. Docket EPA-HQ-OW-2006-0771, DCN 05961.

Holman, S. 2007a. Telephone conversation with Darrell McKigney of Long Term Care Pharmacy Alliance and Sarah Holman of Eastern Research Group. "Disposal of Unused Pharmaceuticals from Long-Term Care Facilities." August 31. Docket EPA-HQ-OW-2006-0771, DCN 04946.

Holman, S. 2007b. Email to Darrell McKigney, Acting Executive Director, Long Term Care Pharmacy Alliance. "Pharmaceutical Disposal from Long-Term Care Facilities." September 3. Docket EPA-HQ-OW-2006-0771, DCN 04947.

Kolpin, D., et al. 2002. "Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams 1999-2000: A National Reconnaissance." *Environmental Science and Technology* 36:1202-1211. Docket EPA-HQ-OW-2006-0771, DCN 04958.

Koltz, B.J. 2007. *Compounds of Emerging Concern Source Control Programs: Components and Results.* CEC Symposium. Docket EPA-HQ-OW-2006-0771, DCN 05009.

KSU. 2008. Nancy J. Larson. *Pharmaceutical Waste Outreach Project.* January 31. Docket EPA-HQ-OW-2006-0771, DCN 06089.

Lee, G.F. 1998. "Deficiencies in Subtitle D Landfill Liner Failure and Groundwater Pollution Monitoring." National Water Quality Monitoring Conference. http://acwi.gov/monitoring/conference/98proceedings/Papers/61-lee.htm. Accessed May 2008. Docket EPA-HQ-OW-2006-0771, DCN 06090.

Lewin Group. 2004. *CMS Review of Current Standards of Practice for Long-Term Care Pharmacy Services.* Prepared for Centers for Medicare and Medicaid Services. December 30. http://www.cms.hhs.gov/Reports/downloads/LewinGroup.pdf. Accessed September 2007. Docket EPA-HQ-OW-2006-0771, DCN 04952.

McGurk, J. 2003. Environmental Management Branch, State of California Department of Health Services. Letter to Directors of Environmental Health, Medical Waste Program Managers, and California Health Care Associations: "Sewerage Disposal of Pharmaceutical Waste." September 5. Docket EPA-HQ-OW-2006-0771, DCN 06091.

MNTAP, 2007. Reducing Pharmaceutical Waste from Patient Care Settings. Minnesota Technical Assistance Program, University of Minnesota. Available online at http://mntap.umn.edu/health/94-PharmWaste.htm. Date accessed February 2007. Docket EPA-HQ-OW-2006-0771, DCN 05046.

Myers, P., and W. Hessler. 2007. "Does 'the Dose Make the Poison'?" *Our Stolen Future*. May 25. http://www.ourstolenfuture.org Docket EPA-HQ-OW-2006-0771, DCN 06092.

NERC. 2005. Northeast Recycling Council, Inc. *Best Practice Recommendations for the Disposal of Unwanted Medications Not Controlled by the U.S. DEA.* September 20. http://www.nerc.org/documents/bmp_disposal_of_unwanted_medications_final.pdf. Accessed September 2007. Docket EPA-HQ-OW-2006-0771, DCN 04879.

OSW, 1991. Sylvia Lowrance, Office of Solid Waste. Letter to Mark Shultz of Pharmaceutical Services, Inc. 16 May. Docket EPA-HQ-OW-2006-0771, DCN 06093.

OSW. 1997. David Bussard, Office of Solid Waste, Hazardous Waste Identification Division. Letter to William Warren, Drinker Biddle and Reath. 10 March. Docket EPA-HQ-OW-2006-0771, DCN 06171.

Paone, 2007. RP Paone, Vogenberg FR, Caporello E, Rutkowski J, Parent R, Fachetti F. *Medication Destruction and Waste Measurement and Management in Long-term Care Facilities*. http://www.ascp.com/public/pubs/tcp/1996/jan/mdwm.html . Accessed December 11, 2007. Docket EPA-HQ-OW-2006-0771, DCN 06094.

PharmEcology. 2005. *Pharmaceutical Waste: Frequently Asked Questions.* http://www.pharmecology.com/pedd/jsp/static/b3_faqs_waste.jsp. Accessed September 2007. Docket EPA-HQ-OW-2006-0771, DCN 04943.

Pomati, 2007. Francesco Pomati, Chiara Orlandi, Moira Clerici, Fabio Luciani, and Ettore Zuccato. *Effects and Interactions in an Environmentally Relevant Mixture of Pharmaceuticals*. Toxicological Sciences 2008. Docket EPA-HQ-OW-2006-0771, DCN 06122.

Premier. 2007. *Pharmaceutical Waste Management*. http://www.premierinc.com/safety/topics/pharma-waste/. Accessed September 2007. Docket EPA-HQ-OW-2006-0771, DCN 04944.

PSI. 2008. Product Stewardship Institute. *Product Stewardship Project Summary: Pharmaceutical Wastes*. February 13. Docket EPA-HQ-OW-2006-0771, DCN 06095.

RMA. 2007. Risk Management Association. *Annual Statement Studies 2006/2007*. Docket EPA-HQ-OW-2006-0771, DCN 04572.

Ruhoy, 2007. Ruhoy, I.S. and C.G. Daughton. *Types and Quantities of Leftover Drugs Entering the Environment via Disposal to Sewage - Revealed by Coroner Records*. Science of the Total Environment. 2007. http://www.epa.gov/nerlesd1/bios/daughton/SOTE2007.pdf. Docket EPA-HQ-OW-2006-0771, DCN 06123.

Saljoughian, M. 2004. "Disposal of Hazardous Pharmaceutical Waste." *US Pharmacist* 29:06. http://www.uspharmacist.com/index.asp?show=article&page=8_1296.htm. Accessed September 2007. Docket EPA-HQ-OW-2006-0771, DCN 04881.

Santoleri, J.J. 2006. *Incineration — Combustion, Types of Incinerators, Emission Control Systems*. http://www.pollutionissues.com/Ho-Li/Incineration.html. April. Docket EPA-HQ-OW-2006-0771, DCN 06096.

SBA. 2006. U.S. Small Business Administration. *Table of Small Business Size Standards Matched to North American Industry Classification Codes.* Effective July 31, 2006. Docket EPA-HQ-OW-2006-0771, DCN 04573.

Sedlack, D.L., and K.E. Pinkston. 2001. "Factors Affecting the Concentrations of Pharmaceuticals Released to the Aquatic Environment." *Water Resources* 131.230.120.11. Docket EPA-HQ-OW-2006-0771, DCN 06097.

S&P. 2006. Standard & Poor's. Industry Surveys. *Healthcare: Facilities*. December 26. Docket EPA-HQ-OW-2006-0771, DCN 04574.

Stephenson, R., and J. Oppenheimer, 2007. *Fate of Pharmaceuticals and Personal Care Products Through Municipal Wastewater Treatment Processes*. Water Environment Research Foundation. 03-CTS-22UR. Docket EPA-HQ-OW-2006-0771, DCN 06098.

Tenet. 2006. Tenet Healthcare Corporation. "Tenet Reaches Partial Settlement with Internal Revenue Service." Press Release. November 22. http://www.tenethealth.com/TenetHealth/PressCenter/PressReleases/Tenet+Reaches+Partial+Settlement+with+Internal+Revenue+Service.htm. Docket EPA-HQ-OW-2006-0771, DCN 04576.

Thomas, K.V., et al. 2007. *Occurrence of Selected Pharmaceuticals in Wastewater Effluents from Hospitals (Ullevål and Rikshospitalet) and VEAS Wastewater Treatment Works.* Oslo. March. Docket EPA-HQ-OW-2006-0771, DCN 05475.

Tischler, 2007. Tischler/Kocurek. *Potential Contributions of Unused Medicines to Environmental Concentrations of Pharmaceuticals.* December 21. EPA-HQ-OW-2006-0771-0851.2.

True, 2007. Christie True. *Comments on the Preliminary 2008 Effluent Guidelines Program Plan*. 19 December. EPA-HQ-OW-2006-0771-0860.

Vestara, 2008. Vestara Launches EcoRexNS To Reduce Pharmaceutical Waste (22 April). Docket EPA-HQ-OW-2006-0771, DCN 05483.

VPC. 2007. Veterinary Practice Consultants. *Reverse Distributors for Controlled Substances.* http://www.safetyvet.com/images/revdist.pdf. Accessed September 2007. Docket EPA-HQ-OW-2006-0771, DCN 04973.

U.S. EPA Region 2, 2007. Understanding the Hazardous Waste Rules: Guidance for Hospital Environmental Health & Safety Professionals. http://www.epa.gov/Region2/healthcare/presentations/rcra.pdf. Accessed August 2008. EPA-HQ-OW-2006-0771, DCN 06124.

USEPA Region 3, 2007. Summary of Pharmaceutical Collection Programs. 19 January. Docket EPA-HQ-OW-2006-0771, DCN 05403.

Zhao, A., and G.N. Richardson. 2003. "US Regulations on Solid Waste Containment Facilities." The Second China International Exhibition on Solid Waste Treatment and Technology Equipment, Beijing. Docket EPA-HQ-OW-2006-0771, DCN 06099.

Appendix A

GLOSSARY

Best Management Practices (BMPs) – BMPs include methods to prevent toxic and hazardous pollutants from reaching rivers, lakes and other surface water and sewage treatment plants. For example, BMPs for this industry could include, but are not limited to, practices to reduce the amount of ***pharmaceuticals*** generated that are not used or alternatives to ***disposal*** of ***unused pharmaceuticals***. Example BMPs include dispensing ***pharmaceuticals*** as unit doses and using a ***reverse distributor*** for managing returns of ***unused pharmaceuticals***.

Clean Water Act (CWA) – Federal legislation enacted by Congress to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters" (Federal Water Pollution Control Act of 1972, as amended, 33 U.S.C. 1251 et seq.).

Controlled Substances – ***Pharmaceuticals*** and certain other chemicals, both narcotic and non-narcotic, whose possession and use are regulated within "schedules" under the Controlled Substances Act.[23]

Discharge – The conveyance of ***wastewater*** to: (1) United States ***surface waters*** such as rivers, lakes, and oceans, or (2) a publicly owned, privately owned, federally owned, combined, or other treatment works (i.e., municipal wastewater treatment plant).

Disposal – Intentional placement of ***unused pharmaceuticals*** as waste into drain or toilet or into municipal, medical, or hazardous waste for permanent treatment or disposition.

EDCs – endocrine disrupting chemicals

Facility – Facilities include ***hospitals*** and ***long-term care facilities***.

Hospital – An institution that provides medical, surgical, or psychiatric care and treatment for the sick or the injured.

Long-Term Care Facility – A ***facility*** that provides rehabilitative, restorative, and/or ongoing skilled nursing care to ***patients*** or ***residents*** in need of assistance with activities of daily living. Long-term care ***facilities*** include nursing homes, rehabilitation ***facilities***, inpatient behavioral health ***facilities***, and long-term chronic care ***hospitals***.

Organization – An organization that operates one or more ***hospitals*** or ***long-term care facilities***. Organizations may include government-owned, religiously affiliated, nonprofit, and for-profit organizations.

Patient – Any person receiving medical, surgical, or psychiatric care or treatment at a ***hospital***.

Pharmaceuticals – Any chemical or biological substance, synthetic or non-synthetic, that when taken by the ***facility patient*** or ***resident*** will cure or reduce the symptoms of an illness or ongoing medical condition. Additionally, this definition refers to substances taken by the ***facility patient*** or ***resident*** for preventive medicine. This includes over the counter medication, as well as those prescribed by a physician. Table 1 of Attachment B includes a list of the ***pharmaceuticals*** most

[23] See http://www.usdoj.gov/dea/pubs/csa.html for information on the Controlled Substances Act.

frequently prescribed according to http://www.rxlist.com/. The definition of ***pharmaceutical***s includes, but is not limited to, the ***pharmaceuticals*** listed in Table 1 of Attachment B.

Pharmacy – Any unit or organization dispensing pharmaceuticals, whether located within the facility or outside of the facility.

Pollution Prevention – The use of materials, processes, or practices that reduce or eliminate the creation of ***pollutants*** or wastes. It includes practices that reduce the use of hazardous and nonhazardous materials, energy, water, or other resources, as well as those practices that protect natural resources through conservation or more efficient use. For example, ***pollution prevention*** for this industry could include but is not limited to reducing the amount of ***unused pharmaceuticals*** generated at ***hospitals*** or ***long-term care facilities***.

PPCPs – Pharmaceuticals and Personal Care Products

Publicly Owned Treatment Works (POTW) – Any state or municipality-owned sewage treatment plant that is used to recycle, reclaim, or treat liquid municipal sewage and/or liquid industrial wastes (e.g., municipal wastewater treatment plant).

Resident – Any person receiving rehabilitative, restorative, and/or ongoing skilled nursing care at a ***long-term care facility***.

Reverse Distributor – A company engaged primarily in the business of accepting outdated/expired ***pharmaceuticals*** from pharmacies and drug wholesalers for the primary purpose of returning them to the manufacturer for credit.

Surface Waters – Waters of the United States including, but not limited to, oceans and all interstate and intrastate lakes, rivers, streams, creeks, mudflats, sand flats, wetlands, sloughs, prairie potholes, wet meadows, playa lakes, and natural ponds.

Unused Pharmaceuticals – Any ***pharmaceutical*** purchased or prescribed for a patient or resident that is not taken by or administered to the patient or resident. These ***pharmaceuticals*** may be returned to the pharmacy, taken back by a ***reverse distributor***, ***pharmaceutical*** manufacturer, or an organization accepting donations (***non-disposal***). Alternatively, ***pharmaceuticals*** may be intentionally placed into a drain or toilet at the facility or into the facility's municipal trash, medical waste, or hazardous waste (***disposal***). This definition does not include any ***pharmaceutical*** ingredients or metabolites excreted or washed from patient or residents.

Wastewater – Water that is generated from any source at a ***hospital*** or ***long-term care facility*** that includes, but not limited to, restrooms, cafeterias, showers, domestic activities, and any healthcare activity.