PRODUCT STEWARDSHIP ACTION PLAN FOR MEDICAL SHARPS

FINAL

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About the Product Stewardship Institute, Inc.
The Product Stewardship Institute, Inc. (PSI) is a national non-profit organization located in Boston, Massachusetts. PSI develops partnerships with manufacturers, retailers, government agencies, environmental groups, and other stakeholders to reduce the health and environmental impacts from the production, use, and end-of-life management of consumer products. PSI membership includes 44 states, 56 local governments, and over 21 businesses, environmental groups, and other organizations. By forging partnerships with all participants involved in the lifecycle of a product, PSI opens channels of communication that lead to sustainable product stewardship systems. PSI has conducted pilot projects, national dialogues, and/or other initiatives in the following product categories: electronics, paint, mercury thermostats, fluorescent lamps, pharmaceuticals, medical sharps, phone books, tires, pressurized gas cylinders, beverage containers, and radioactive devices.

The Product Stewardship Institute's Approach
All of PSI's projects take a product stewardship, shared responsibility approach that involves those responsible for the manufacture, distribution, use, and end-of-life management of medical sharps. PSI's collaborative method entails presenting the entire issue, developing trust among participants, honoring existing partnerships, and finding each participant's role within the context of an overall solution. PSI will identify areas where innovation is most needed and develop a plan to fill the void, with projects, policies, or other initiatives.

For Updates and More Information
PSI's project web pages will be updated regularly during the project and can be viewed at: www.productstewardship.us/MedicalSharpsProject

Project Contacts
For more information or to participate in this project, please contact Sierra Fletcher, PSI Associate, at sierra@productstewardship.us, or 617-236-4886, or Scott Cassel, PSI Executive Director, at scott@productstewardship.us, or 617-236-4822.

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PRODUCT STEWARDSHIP ACTION PLAN

FOR

MEDICAL SHARPS

I. Purpose of this Action Plan

The intent of this *Product Stewardship Action Plan for Medical Sharps* is to prepare participants for the dialogue phase of PSI's Medical Sharps Product Stewardship Initiative. The *Action Plan* proposes a draft issue statement, project goal, and dialogue process, and presents key issues, potential solutions, and other information derived through interviews and discussions with key stakeholders, as well as other documentation. The contents of the *Action Plan* reflect varying perspectives on the management of medical sharps disposal and not a unanimous approach. *Prior to* the first dialogue meeting, PSI will seek to refine this document so that the information presented is as comprehensive, objective, and accurate as possible. *At* the first dialogue meeting, PSI will seek to gain consensus on the issue statement, project goal, and dialogue process, and will begin to prioritize strategies for implementation.

This issue has been studied and discussed by the American Medical Association (AMA), American Pharmaceutical Association, U.S. Centers for Disease Control, and other public and private stakeholders collectively since a multi-stakeholder meeting convened by the AMA in 2001. This meeting ultimately resulted in the founding of the Coalition for Safe Community Needle Disposal, an advocacy organization with the backing of the American Association of Diabetes Educators, American Medical Association, Association of State and Territorial Health Officials, American Diabetes Association, American Pharmaceutical Association, and the National Alliance of State and Territorial AIDS Directors,[1] with funding from Waste Management and Becton, Dickinson, and Co. since 2002.

This *Action Plan* does not attempt to repeat the extensive, though somewhat outdated, literature from the 1990s and early 2000s on this issue, but highlights key findings here along with information gathered from PSI's interviews.

II. Consumer Benefits of Medical Sharps

Medical sharps (including syringes, pen needles, and lancets[2]) are a safe, convenient, and cost-effective resource for consumers to self inject medications at home or away from traditional health care settings. Advances in needle design have made them extremely small, sharp, and a relatively pain-free means for administering often life-saving medications quickly and easily, without the need to travel to a hospital or doctor's office.

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[1] "Safe Community Disposal of Needles and Other Sharps," a letter issued on August 5, 2002 by the American Association of Diabetes Educators, American Medical Association, Association of State and Territorial Health Officials, American Diabetes Association, American Pharmaceutical Association, and the National Alliance of State and Territorial AIDS Directors.

[2] A lancet is a surgical knife with a short, wide, pointed double-edged blade, used especially for making punctures and small incisions. It is widely used by people with diabetes to test blood.

III. Issue Statement

It is estimated that over 3 billion[3] disposable needles and syringes and an additional 900 million[4] lancets (collectively called "medical sharps") are used outside of the healthcare setting in the U.S. each year. Most of these enter the municipal solid waste (MSW) stream. A roughly estimated two thirds of these medical sharps are used by those managing their own (or their pet's) health care at home by injecting medication (primarily for the treatment of diabetes) while the remainder are used by injection drug users. As self-injection of medications becomes an increasingly popular mechanism for drug delivery, the number of home medical sharps is expected to increase significantly.

Self-injectors in all groups are known to discard medical sharps in trash containers in homes and public places, and in other public settings such as hotel rooms, air ports, recycling bins (in plastic containers), and flushed down toilets. These disposal methods create the potential for injury or the transmission of infectious diseases to homeowners, as well as sanitation workers, sewage treatment plant operators, and waste management personnel at transfer stations, recycling facilities, and disposal facilities. They are a potential hazard for hospitality workers when left at restaurants, hotels, airports, and other public locations. In addition, since people dispose of needles almost everywhere, sharps can pose a basic hazard to the general public. They also create costly maintenance problems when loose sharps become jammed in equipment, posing a potential hazard to anyone trying to remove them, or to the equipment itself.

IV. Project Focus and Goal

This project will **focus** on sharps generated outside the traditional health care setting, including households, hotels, casinos, restaurants, airports, and other public venues.

The primary **goal** of the project is to maximize the safe and environmentally sound disposal of waste sharps that is financially sustainable.

V. PSI Dialogue Process

The Product Stewardship Institute (PSI) has developed a Project Summary and this *Product Stewardship Action Plan on Safe Needle Disposal* in preparation for conducting four national dialogue meetings designed to lead to stakeholder agreements on the development and implementation of collaborative projects.

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[3] This estimate was derived for a 1998 article: Peter Lurie, T. Stephen Jones, and Jill Foley, "A Sterile Syringe for Every Drug User Injection: How Many Injections Take Place Annually, and How Might Pharmacists Contribute to Syringe Distribution?" in *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology, Volume 18, Supplement 1, 1998*. Official Publication of the International Retrovirology Association, Lippencott-Raven Publishers. This estimate has been cited widely by the American Medical Association, Coalition for Safe Community Needle Disposal, and other groups. However, it is an estimate and is now 10 years out of date.

[4] Robert J. Singley, Becton Dickinson and Co., letter to Sierra Fletcher, PSI, May 16, 2008.

Proposed Timeline

PSI's dialogue process involves a four-phased approach to defining, developing, and meeting the project goal. PSI proposes to conduct this project according to the timeline below to allow participants time to seek the internal approvals necessary among their constituencies to be effective dialogue participants. According to the proposed timeline, meetings will be scheduled every three months. However, if dialogue participants want to expedite this timeline, PSI can mobilize resources to meet participant needs.

ACTIVITY	***TIMELINE***
Develop Project Summary	December 2007 – February 2008
Develop Product Stewardship Action Plan	February – May 2008
Convene 1st National Dialogue Meeting	May 21-22, 2008 in Boston
Convene 2nd National Dialogue Meeting	September 2008 in Sacramento
Convene 3rd National Dialogue Meeting	December 2008 (location TBD)
Convene 4th National Dialogue Meeting	February/March 2009 (location TBD)
Develop Agreements on Priority Initiatives	June 2008 – March 2009
Ratification of Agreements and Refining of Initiatives	April/May 2009

Phase 1: Research and Outreach

PSI conducted a literature review and interviewed stakeholders involved with the manufacture, sale, use, and recovery of medical sharps. Those interviewed expressed a high level of support for the dialogue and shared their own interests and perspectives for improving the management of medical sharps. (See Appendix B for a list of stakeholders interviewed.) PSI summarized the research, including existing pilot projects and initiatives, into this *Product Stewardship Action Plan for Medical Sharps,* which will serve as the basis for four face-to-face meetings with key stakeholders. PSI has compiled a database of stakeholder contacts from around the country. This group will be invited to participate in the national dialogue and/or be updated on the project's progress. Jenny Schumann of the Coalition for Safe Community Needle Disposal has provided extensive support to this phase, including data and documentation, consultation, and contacts.

Phase 2: National Dialogue Meetings/Negotiations

PSI will convene four national dialogue meetings over one year, as well as separate workgroup discussions via conference call to address specific issues. PSI will facilitate the meetings, track next steps, follow relevant issues and opportunities as they emerge, and mediate agreements.

- Meeting Design: For each meeting, PSI will develop an agenda, attendance list, PowerPoint presentations, supplemental meeting materials, and follow up meeting notes. PSI will design the series of meetings so that each one addresses a different set of strategies identified during the interview phase. At the meetings, PSI will work with

stakeholders to identify the top strategies they want to pursue. PSI staff will manage all meeting logistics, including meeting space, meals, and a possible informal reception, and will seek public and private sponsors to defray costs. Meetings are usually held in partnership with a host government agency.

- Workgroups: PSI will convene workgroup conference calls between meetings to further develop priority solutions that emerge from the meetings. These workgroups will refine solutions for discussion and subsequent decision by the full group of stakeholders. It is possible that the group, or a segment of participants, may want to immediately embark on one or more strategies while the dialogue is still underway. Implementation of good ideas should occur as soon as possible. PSI expects that additional funding will be required to employ these strategies and will depend on the type of agreements that are developed.

- Agreement on Priority Initiatives: At the fourth dialogue meeting, PSI expects that stakeholders will reach agreements on the development and implementation of joint initiatives. If the stakeholder group decides that subsequent ratification of this agreement is needed by their respective companies, agencies, and organizations, the schedule includes one month for this to take place, although several more months might be necessary. PSI's goal will be to find common ground and develop "actionable items" as quickly as possible. If the group can reach agreement on certain priority actions prior to the last meeting, we will move ahead with those initiatives.

- Stakeholder Communication: Throughout the project, PSI will act as a clearinghouse of information associated with managing medical sharps used in the community. PSI will maintain an extensive stakeholder database and communicate with stakeholders continually throughout the dialogue via email and conference calls. It will also initiate a list serve to promote daily communication, and will develop a comprehensive webpage on the PSI website to post up-to-date reports, articles, and other information on the management of used medical sharps.

Phase 3: Implementation

PSI will hold conference calls and meetings with stakeholders to implement agreements reached in Phase 2. PSI expects that additional funding will be required for this implementation phase, depending on the nature of the agreement(s).

Phase 4: Evaluation

Pending available resources, PSI will assist stakeholders in evaluating projects implemented, using the metrics of success established in earlier dialogue phases. Throughout the phases, participants will gather data to subsequently evaluate initiatives.

Relationship to the PSI National Dialogue on Waste/Unwanted Pharmaceuticals

As part of this project, PSI will identify areas in which the sharps disposal issue overlaps with the broader pharmaceutical disposal issue. For example, many pharmaceutical return and hazardous waste collection operations around the country receive sharps as part of their intake, even when consumers are specifically instructed not to bring them. PSI has begun a separate

effort on pharmaceuticals disposal management. It has conducted over 30 interviews with a range of key stakeholders, including representatives from pharmaceutical companies, long-term care facilities, reverse distributors, pharmacies, retailers, water quality and wastewater treatment organizations, and government agencies. Based on the interviews and other research, PSI developed a Project Summary and a draft *Product Stewardship Action Plan for Unwanted/Waste Pharmaceuticals*. PSI will hold its 1st national pharmaceutical dialogue meeting in Sacramento, California, on June 19-20, 2008.

As feasible, PSI will coordinate the sharps dialogue with the pharmaceuticals project, since many stakeholders for the two efforts have similar goals. PSI will offer the opportunity for stakeholders in this sharps dialogue to work on the pharmaceuticals project and vice versa. PSI will also identify sharps disposal strategies that may also be applicable as solutions for the safe management of pharmaceuticals. Should both issues be fully funded simultaneously, PSI will streamline efforts and develop a combined cost-effective approach.

Benefits of a National Approach

The billions of medical sharps disposed of each year outside the traditional healthcare setting represent a public health and safety threat. Several state agencies have taken different approaches to address the problem. Companies and organizations are also moving to develop solutions. While each represents progress, they threaten to create a patchwork of inefficient and conflicting programs. This project will coordinate separate existing efforts and enlist the support of key players in a national dialogue to develop priority solutions that are effective, affordable, and sustainable in the long-term. Developing a national consensus on best management practices and funding options for safely disposing of needles will save money, create goodwill among stakeholders, and solve a public health and safety issue. The goals for the national dialogue will be established during the first phase of the project.

VI. Stakeholders

Table 1 below describes the primary stakeholder groups relevant to PSI's national dialogue.

Table 1. Overview of stakeholder groups

Stakeholder Category	General Description	Examples of Specific Companies, Agencies, Associations, and Other Groups
Manufacturers: Medical Sharps	These companies manufacture needles, syringes, and lancets for use both within the traditional healthcare setting and elsewhere.	Becton, Dickinson and Co. Covidien Terumo Medical Corporation UltiMed Artsana B. Braun Facet Technologies Owen Mumford Novo Nordisk UltiCare VetRx
Manufacturers: Pharmaceuticals and Other Medications	These companies manufacture medications that are administered by the patient outside the traditional healthcare setting.	*Insulin:* Eli Lilly and Company Novo Nordisk Roche Sanofi-Aventis Vetsulin *Biologics:* GlaxoSmithKline Hoffman-La Roche Novo Nordisk Schering-Plough and InterVet, Inc. (part of Schering-Plough) *Other:* Pharmaceutical Research and Manufacturers of America (PhRMA) Biotechnology industry (BIO – Biotechnology Industry Organization)
Pharmaceutical	Pharmaceutical wholesalers supply and	Amerisource Bergen

Stakeholder Category	General Description	Examples of Specific Companies, Agencies, Associations, and Other Groups
Wholesalers	distribute medications that are administered by patients outside the healthcare setting	Cardinal McKesson Medline
Pharmacy Benefit Managers and Mail Order Pharmacies	These companies provide products (including medical supplies such as sharps and pharmaceutical drugs) and other services to pharmacies, health insurance providers, and/or directly to consumers.	Caremark (now part of CVS) Express Scripts Inc. – CuraScript Medco (Accredo) WHI (Walgreens Health Initiatives) – OptionCare
Insurers/Payers	Insurers provide full or partial payment for prescription drugs and related supplies. They are also subject to the risks associated with covering the cost of accidental sticks.	America's Health Insurance Plans (national association) Aetna Blue Cross/Blue Shield Centers for Medicare/Medicaid Services Cigna Humana Kaiser Permanente UnitedHealthcare Workers' compensation insurers
Retail Pharmacies	Retail pharmacies sell medications, medical equipment, and other supplies to consumers. They may be small and independently-owned, regional/national chains, free-standing or part of a larger store, or online. These are the primary retailers of medical sharps directly to the consumer.	*National chains, including* Walgreens, Rite Aid, CVS *National retailers that include pharmacies:* Wal-Mart, Target, Costco Academy of Managed Care Pharmacy (AMCP) American Pharmaceutical Association National Association of Chain Drug Stores National Community Pharmacists Association State retail associations
Healthcare Providers/ Pharmacists	Healthcare providers have direct access to most sharps consumers and are well-positioned to provide information on safe	American Medical Association American Association of Clinical Endocrinologists American Association of Diabetes Educators

Stakeholder Category	General Description	Examples of Specific Companies, Agencies, Associations, and Other Groups
	disposal of medical sharps, or collection locations.	Home Health Nurses Association National Association for Home Care and Hospice Family practice groups Internal medicine doctors
Workers Potentially at Risk	Some individuals are at a higher risk for accidental needlesticks because of the nature of their work.	Service and Food Worker Union Service Employees International Union (SEIU) Employees of waste management industry Hotel/hospitality workers
Consumers and Associations	The "general public" includes medical sharps consumers (people with diabetes, people taking self-injected biologic or other prescription pharmaceutical drugs, and injection drug users) and those at risk of exposure from improperly disposed of sharps.	American Association of Diabetes Educators American Diabetes Association Children with Diabetes Coalition for Safe Community Needle Disposal Diabetes Research and Wellness Foundation AIDS prevention groups
Government	Local, state, and federal government agencies promote public health and proper management of waste.	U.S. Centers for Disease Control and Prevention U.S. Environmental Protection Agency U.S. Indian Health Services State and local agencies working on environmental and waste-related issues
Waste Management Officials/Industry	These individuals, companies, and groups oversee and implement the handling of waste and wastewater in various settings. Some companies provide medical waste hauling and treatment services.	*Waste management officials:* American Public Works Association Association of State and Territorial Solid Waste Management Officials (ASTSWMO) Solid Waste Association of North America (SWANA) National Solid Wastes Management Association (NSWMA) National Association of Clean Water Agencies (NACWA) *Waste management industry (including those that provide*

Stakeholder Category	General Description	Examples of Specific Companies, Agencies, Associations, and Other Groups
		medical waste management services): Chrysalis Environmental Solutions, LLC. Healthcare Waste Solutions Sharps Compliance, Inc. Medical Waste Solutions, Inc. Stericycle Sure-Way Systems, Inc. Waste Management, Inc.

VII. Manufacturing of Medical Sharps

Medical sharps sold in the U.S. are manufactured in Asia,[5] Europe,[6] and North America, and in some cases are assembled in different locations from the manufacture of their components.[7] Products manufactured in the U.S. may be sold in Europe, and vice versa.

Medical sharps are classified as syringes, pen needles, cannula, and lancets. The manufacturers (listed in Table 1) sell their products to hospitals or other traditional healthcare facilities (through group purchasing organizations). However, the products ultimately used for self-injection are sold to pharmaceutical or third party companies where they are combined with the drugs they are designed to deliver, or are sold directly to retail or mail order pharmacies and/or wholesalers.

VIII. Overview of the Use of Medical Sharps

Types of Medical Sharps

The term "medical sharps," as used here, includes several different types of medical products that have the potential to puncture skin, or have a component with this potential. See Appendix A for photos of medical sharps products.

The three primary products in this category are the syringe, pen needle, and lancet. Syringes and pen needles are used to inject a drug, while lancets are used by those with diabetes when measuring blood glucose levels.

Pen needles are accounting for a growing portion of the sharps used for injection of medications, which are already more common outside the U.S. With this device, only the needle needs to be replaced after each use.

Since the Needlestick Safety and Prevention Act of 2000 came into effect, health care facilities are required to use safety-engineered devices to minimize the risks of needlesticks as long as the syringe remains intact.[8] However, this requirement does not extend to sharps used in the community because it is assumed, however incorrectly, that the only person at risk for a needlestick is the person using the needle on themselves so there is no risk of disease transmission. Health care facilities and providers are also required to follow certain procedures and dispose of their sharps as medical waste, whereas in most states there are no such requirements for individuals in the community.

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[5] China, Korea, Japan, Philippines

[6] Germany, Italy, Ireland

[7] For example, Becton Dickinson assembles most of their syringes in Nebraska and their pen needles are made in Ireland. UltiMed assembles their syringes in South Dakota and Korea while their pen needles are made only in South Dakota.

[8] 29 CFR 1910.1030. Furthermore, Becton, Dickinson and Co. recommends that even "safe" needle devices should be disposed of in a sharps container, as described in: Council on Scientific Affairs, "Safe Community Syringe Disposal: Understanding the Barriers and Creating Solutions," American Medical Association, 2001.

Medical Sharps Consumers

Medical sharps use can be considered in several general categories as shown in Table 2: people with diabetes, patients self-injecting biologics or other drugs, injection drug users (IDU), and animals (home pet care and agriculture).

Table 2. Consumers of Medical Sharps[9]

Consumer Group	Sharps Used	Associated Pharmaceuticals	Usage
People with diabetes	Syringes/pen needles for insulin injection; transition to pen needles Lancets when measuring blood glucose levels[10]	Insulin 15-16% of insulin is dispensed through the mail by companies such as Medco or the Veterans' Administration system[11]	20.8 million people have diabetes in the U.S. today, or 7% of the population[12] 0.9 - 1.4 billion insulin injections/year[13] 900 million lancets[14]
Patients self-injecting biologics and other drugs	Syringes, pen needles	Wide ranging, expensive, fragile drugs typically made of molecules too large for ingestion, and often used for treatment of chronic conditions Often distributed through specialty pharmacies; may require refrigeration	Number of injections per day/month, and length of treatment vary greatly Some medications provided with "safety-engineered" syringes Fast-growing sector
Injection drug	Syringes	Illicit drugs	920 million-1.68 billion

[9] There are approximately 3.5 billion diabetes syringes and pen needles sold each ear. However, reuse of these products is common practice, thus the actual number of injections is much higher. (Robert Singley, Becton, Dickinson and Co., Letter to Sierra Fletcher, PSI, 12 June 2008.)

[10] Approximately 5-15% of people with diabetes have Type I, requiring them to take insulin all the time. The remainder have Type II diabetes, which typically comes on later in life and can be managed for years without insulin injections. Kathy Gold, Diabetes Research and Wellness Foundation, interview with PSI, April 17, 2008.

[11] Interview with Pat Quinn, NovoNordisk, March 31, 2008.

[12] American Diabetes Association webpage, available at: http://www.diabetes.org/about-diabetes.jsp.

[13] This 1996 estimate remains widely cited (as part of the "3 billion" estimate referenced in the Issue Statement), though updated data may be necessary. T.S. Jones and P. Lurie, "Can Enough Syringes be Provided to Allow Drug Injectors to Use a New Syringe for Every Injection?" International Conference on AIDS, July 7-12, 1996 as cited in Grace E. Macalino *et al.*, "Community-Base Programs for Safe Disposal of Used Needles and Syringes," in *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology, Volume 18, Supplement 1, 1998*. Official Publication of the International Retrovirology Association, Lippencott-Raven Publishers, SS111-S119.

[14] Robert Singley, Becton, Dickinson and Co., letter to Sierra Fletcher, PSI, May 16, 2008.

Consumer Group	Sharps Used	Associated Pharmaceuticals	Usage
users			injections annually across the U.S.[15] A single user injects about 1,000 times per year.[16]
Agricultural uses	Syringes, needles with a "gun" or "animal injection system"	Antibiotics, supplements, hormones	
Home/private pet care	Syringes, lancets	Insulin for diabetic household pets; pain medications, antibiotics, relaxants, and analgesics for horses	Estimated 2.5 million per day (0.9 billion per year) for diabetic pets[17] Number used for other animals (such as horses) and in private practice where medical facility disposal may not apply is unknown

Trends in Medical Sharps Use

It is anticipated that both the biologic and diabetes-related sharps use will increase dramatically. The prevalence of diabetes in the U.S. grew an average of 5% each year from 1990-2007[18], with no indication that the trend will change. An estimated 418 biologic drugs are in the biotechnology development pipeline. Furthermore, the aging American population and the increased treatment of chronic diseases (including through self-care) portend a probable increase in the use of medical sharps outside the traditional healthcare setting.[19] Diabetes is also increasing in pets (dogs and cats) and pet owners have demonstrated a willingness and commitment to treating their pets' ailments.[20]

[15] Lurie, Jones, and Foley, p. S46.

[16] Centers for Disease Control, "Syringe Exchange Program," CDC.gov, December 2005, available at: http://www.cdc.gov/IDU/facts/AED_IDU_SYR.pdf.

[17] Calculated using the number of household cats and dogs in the U.S. (according to the American Veterinarian Medical Association, information available at: http://www.avma.org/reference/marketstats/ownership.asp) multiplied by the rate of diabetes in dogs and cats (Rand *et al*., Canine and Feline Diabetes Mellitus: Nature or Nurture? *The Journal of Nutrition*. 134: 2072S–2080S, 2004), using the estimate that pets are injected twice daily.

[18] Abstract of a study conducted by Jing Wang and Edward Gregg of the U.S. Centers for Disease Control: "Prevalence of Diabetes Rose 5% Annually Since 1990," In Diabetes Today, American Diabetes Association, February 23, 2007, available at: http://www.diabetes.org/diabetesnewsarticle.jsp?storyId=15351710&filename=20070623/ADA20070623118262585664 1EDIT.xml.

[19] Interview with L.J. Tan, American Medical Association, May 5, 2008.

[20] Rand *et al*., Canine and Feline Diabetes Mellitus: Nature or Nurture? *The Journal of Nutrition*. 134: 2072S–2080S, 2004

IX. Medical Sharps Disposal

Many people who use medical sharps on their own do not utilize or do not have access to a safe disposal option and so discard their used medical sharps in household trash (MSW), flushing down the toilet, or leaving them in a public place. The exact number of sharps disposed of improperly is not known, but there are a few available data points—albeit a bit outdated and not inclusive of all sharps consumer groups—that illustrate the potential extent of the problem:

- 83% of patients taking insulin who were surveyed in New York City for a 1988 study indicated that they disposed of their needles in the trash.[21]

- 93% of patients taking insulin who were surveyed in Atlanta disposed of their sharps in the trash, and 3% flushed them. Thirty-five percent of those who discarded their sharps in the trash made no effort to contain them, though 54% did break or bend the needles to prevent their use by someone else.[22]

Potential Problems Caused by Improper Disposal

Populations at Risk and Exposure Routes

The general public may be at risk for injuries from medical sharps that are left in public places such as parks or playgrounds,[23] but a more focused risk potential exists for people who handle waste, including custodial or hospitality workers emptying trash bins, waste haulers, recycling facility personnel, or anyone working in or around landfills.[24]

Though largely anecdotal, there are documented instances of waste workers contracting illnesses believed to be the result of a needlestick on the job. An EPA pamphlet describes a trash collector who is stuck with a needle and is diagnosed a year later with hepatitis C, leading to chronic liver failure.[25]

The Solid Waste Association of North America (SWANA) provides training materials for local governments to use with their employees that include best management practices to prevent needlesticks. SWANA's main concern is with curbside pickup as the primary place where waste haulers could come in contact with used sharps. However, this contact with sharps may also happen when waste loads are dumped at the "working face" of the landfill if a driver needs to

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[21] J. Jagger, E.H. Hunt, J. Brand-Elnaggar, and R.D. Pearson, "Rates of Needle-stick Injury by Various Devices in a University Hospital," *New England Journal of Medicine, Vol. 319,* August 1988, pages 284-288, as cited in Dawn Satterfield and Julie Kling, "Professional Development: Diabetes Educators Encourage Safe Needle Practice," *The Diabetes Educator, Vo. 17, No. 4,* 1991.

[22] Dawn Satterfield and Julie Kling, "Professional Development: Diabetes Educators Encourage Safe Needle Practice," *The Diabetes Educator, Vo. 17, No. 4,* 1991.

[23] Waste haulers have found syringes in parking meters and tree trunks, according to WESTAT, "Waste Workers and Bloodborne Pathogen Exposure: Executive Summary of Existing Literature, Revision 0" prepared for the National Institute for Occupational Safety and Health, February 26, 2004.

[24] Wastewater treatment workers represent another potential population at risk, but internal inquiries conducted by the National Association of Clean Water Agencies (NACWA) indicated that this is not a high level of concern: cleaning of screens and other equipment that used to be done by hand is now typically mechanized and there are best management practices in place to protect workers, per PSI interview with Chris Hornback, NACWA, March 13, 2008.

[25] "Safe Options for Home Needle Disposal," U.S. Environmental Protection Agency pamphlet, available at: www.epa.gov/epaoswer/other/medical/med-home.pdf.

dislodge material in the truck, or if a sharp punctures a work boot. Needles have also been found lodged in tires, which creates an injury risk for the person conducting the repair. Even sharps that have been collected in a detergent bottle, coffee can, or other container, according to best practice disposal recommendations, are likely to spill when the container breaks or opens during waste hauling and landfill operations. Needles that have been broken or bent to prevent their re-use still represent a potential needlestick hazard.

Risks and Costs

Medical sharps in the waste stream—or discarded in a public place—have the potential to "stick" someone who comes in contact with the product either through the course of their work or in other ways, such as in stories of used needles washing up on beaches or being found in parks or playgrounds. Any such event represents the *potential* transmission of bloodborne pathogens, but is at minimum a costly and potentially emotionally-difficult experience. If no disease is transmitted, the individual will most likely[26] receive extensive testing and vaccinations, and may suffer psychological trauma from the fear of the potential for disease transmission, even though this fear may or may not be related to the *actual* potential for disease transmission.[27,28] Regardless of secondary impacts, the individual will have a puncture wound or abrasion which will vary in severity depending on the location (e.g. hand vs. eye) and treatment.

The actual risk of disease transmission from a needle stick depends on several factors including the following: whether the initial user of the medical sharp had a bloodborne, infectious disease, the type of stick injury, the viability of the virus, the time passed since the medical sharp was used by an infected person, the person's level of immunity (depending on the disease), humidity, temperature, acidity, and whether or not a post-exposure preventive treatment is used. There is no "perfect" data on the issue of medical sharps, the costs associated with a needlestick, and the potential for disease transmission. Data on all groups tend to be limited by time, location, and scope. Table 3 provides some of the available, relevant data points.

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[26] Individuals will not receive treatment and follow-up testing if a) they do not report the injury; b) if they work for an employer who dismisses the incident; c) if they work for an employer who does not know about the BBP standard; d) if the occupational medical provider working with the employer is not trained in how to handle a sharps injury; e) the employee may refuse testing and/or follow-up prophylaxis. (Angela Laramie, MA DPH, email to Sierra Fletcher, PSI, 9 June 2008.)

[27] In New York City, a Department of Sanitation worker stuck by a needle is taken to a nearby hospital for a vaccination against hepatitis B, then referred to an infectious disease specialist and given the requisite follow-up dosages of hepatitis B vaccine. After six months, an HIV test is administered. Counseling is provided by the Employee Assistance Unit or outside counselors. All direct costs are paid by the Department, and the employee's time spent on medical treatment is considered "on the clock." Stephen Lawitts, "Needle Sightings and On-the-Job Needle-Stick Injuries Among New York Department of Sanitation Workers," in *Preventing Blood-Borne Infections through Pharmacy Syringe Sales and Safe Community Needle Disposal: Supplement to the Journal of the American Pharmaceutical Association*, November/December 2002 Issue, S92-S93.

[28] "Individuals who sustain a needlestick injury often suffer considerable anxiety and distress. Fear of blood-borne virus transmission following such injuries can be intense and protracted, considering the three or more months generally required to exclude infection," Sandra C. Thompson, Clem R. Boughton, and Gregory J. Dore, "Blood-borne Viruses and their Survival in the Environment: is Public Concern about Community Needlestick Exposures Justified?" *Australian and New Zealand Journal of Public Health, Vol. 27, No. 6, 2003.*

Table 3. Quantifying the risks

Needlesticks of Waste Workers[29]	Costs of a Needlestick	Data Applicable to Disease Transmission
New York City: 1 in every 11,000 truck-shifts in 1997; 1 in every 34,000 in 2002 (though spiked in 2001)[30] 109 sticks of metropolitan Atlanta sanitation workers in 1989 (no HIV transmission)[31] 6 sticks to San Francisco garbage collectors in 2001[32] 6 sticks of workers on recycling line in Rhode Island in 1999[33]	$600 for "medical evaluation and care" (1991)[34] Roughly estimated costs include up to $6,300 for initial testing/care up to hundreds of thousands of dollars if disease is contracted[35] Costs for treatment of HIV/AIDS and hepatitis B or C range into the hundreds of thousands of dollars, and include missed work time[36]	Hepatitis B virus can last up to 8 months at room temperature with no decline in sensitivity[37] Hepatitis C virus can last up to 8 months, with 9-fold *decrease* in sensitivity[37] HIV can last up to 30 days, but generally only 1-2 days[37] HIV viability depends on the temperature and quantity of blood in the syringe[38]

Treating Collected Sharps

Numerous companies provide medical waste hauling and treatment services, often for the regulated healthcare industry such as hospitals, clinics, ambulance services, doctor's offices, and professional medical services provided in the home. These companies, including those listed in

[29] There is no data available on the frequency and nature of "sticks" to hospitality, airline, or custodial personnel.

[30] There are 4,900 "truck-shifts" per week operated in New York City. As of this article, no New York City sanitation worker had contracted a blood-borne illness from an on-the-job stick. Stephen Lawitts, "Needle Sightings and On-the-Job Needle-Stick Injuries Among New York Department of Sanitation Workers," in *Preventing Blood-Borne Infections through Pharmacy Syringe Sales and Safe Community Needle Disposal: Supplement to the Journal of the American Pharmaceutical Association*, November/December 2002 Issue, S92-S93.

[31] C. Seabrook, "Study: Medical Wastes Pose Little Threat of Spreading AIDS," *Atlanta Journal and Constitution*, March 13, 1990, as cited in Dawn Satterfield and Julie Kling, "Professional Development: Diabetes Educators Encourage Safe Needle Practice," *The Diabetes Educator, Vo. 17, No. 4,* 1991.

[32] B. Drda, J.Gomez, R. Conroy, M. Seid, and Jacob Michaels, "San Francisco Safe Needle Disposal Program, 1991-2001," *Journal of the American Pharmaceutical Association, Vol. 42, No. 6, Supplement 2*, 2002 as cited in WESTAT, "Waste Workers and Bloodborne Pathogen Exposure: Executive Summary of Existing Literature, Revision 0" prepared for the National Institute for Occupational Safety and Health, February 26, 2004.

[33] PSI Interview with Cherie Fisher, Chrysalis, March 13, 2008.

[34] Dawn Satterfield and Julie Kling, "Professional Development: Diabetes Educators Encourage Safe Needle Practice," *The Diabetes Educator, Vo. 17, No. 4,* 1991.

[35] Fred Eilrich, "Sharps in the Waste Stream: An Oklahoma Perspective," Presentation given at the SWANA Oklahoma Symposium, Tulsa, Oklahoma, February 28, 2008.

[36] U.S. Department of Health and Human Services, Draft U.S. Department of Health and Human Services Strategic Plan Fiscal Years 2007 – 2012, 15 June 2007, available at: http://nastad.org/Docs/highlight/2007727_HHS_StratPlan_Comments_Final.pdf.

[37] Data on hepatitis B, hepatitis C, and HIV from Sandra C. Thompson, Clem R. Boughton, and Gregory J. Dore, "Blood-borne Viruses and their Survival in the Environment: is Public Concern about Community Needlestick Exposures Justified?" *Austalian and New Zealand Journal of Public Health*, *Vol. 27, No. 6, 2003.*

[38] Nadia Abdala, Rina Reyes, John M. Carney, and Robert Helmer, "Survival of HIV-1 in Syringes: Effects of Temperature during Storage," *Substance Use and Misuse, Vol. 35, No. 10*, 2000.

Table 1, may also provide services for programs designed for the collection of medical sharps used in the community.

Over 50 vendors offer different options for the "proper" disposal of medical waste, including sharps. Several different treatment methods may be used, depending on the collection service used, facilities available, and state and local regulations. However, they all fall in to the categories listed below.

- Incineration either separately or with MSW;
- Wet, low-temperature thermal technologies (autoclaves, microwaves, and other steam-based systems);
- Dry, low-temperature thermal technologies (dry heat systems);
- High temperature thermal technologies (depolymerization, pyrolysis, and others);
- Wet and dry chemical technologies (chlorine and non-chlorine systems); and
- Others (irradiation, e-beam, biological).[39]

X. Current Regulations and Recommendations on Home-Generated Sharps Disposal

Regulations and Recommendations

Federal Level

There are no federal requirements for the safe disposal of medical sharps generated outside the traditional healthcare setting, but U.S. EPA recommends use of one of several disposal options besides discarding sharps straight to MSW, which are discussed in the next section.[40]

The federal agencies and other groups shown in the table below reference sharps in their regulations, though not necessarily those used outside hospitals, clinics, doctor's offices, or commercial settings.

[39] Mark Iske, Healthcare Solutions WM, via email, May 9, 2008.

[40] Until working with the Coalition for Safe Community Needle Disposal starting in 2002, the EPA used to recommend just labeling a rigid container, taping it closed, and marking as "Do Not Recycle." However, the updated recommendations advise (albeit without the weight of regulation) against disposal in MSW and point to the range of recommendations described in the following section. See "Community Options for Safe Needle Disposal," U.S. Environmental Protection Agency, October 2004.

Table 4. Federal regulations applicable to disposal and handling of medical sharps[41]

Department	Regulation	Applicable to Community-generated Sharps?
U.S. Department of Transportation (DOT) 40 CFR 173.197	Sharps must be placed in rigid, leak-proof containers that are impervious to puncture or tearing in transport.	No, only applies to commercial activities.
U.S. Postal Service (USPS)	Sharps being mailed must be in USPS-authorized containers that meet DOT standards (see above) and be labeled with an authorization number, biohazard symbol, and as regulated medical waste.	Yes, if they are being mailed for disposal.
U.S. Food and Drug Administration (FDA) 21 CFR 800	Sharps containers are considered medical devices and subject to labeling and other requirements. Requires pre-market clearance of sharps disposal containers based on OSHA standards.	Yes; applies to all sharps containers.
U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) 29 CFR 1910.1030	OSHA's Bloodborne Pathogens Standard (BBPS) requires that engineering and work practice controls be employed to prevent sharps injuries and other exposures. Engineering controls may include sharps with engineered sharps injury prevention features, needle destruction devices, and appropriate sharps containers[42,43] designed to reduce exposure during or after disposal, and in waste handling.	No, does not apply to those using sharps in the community. However, the BBP Standard does apply to anyone that may come in contact with sharps in the work place.[44]

State Level

All states regulate medical waste. Table 5, below, describes pending legislation or existing laws and regulations at the state or local level that deal specifically with the safe disposal of medical sharps generated outside the traditional healthcare setting. Many states that do not have regulations specific to the issue recommend collecting sharps in a rigid container,

[41] Based on information in the Code of Federal Regulations, as cited in the table, and information compiled by the Coalition for Safe Community Needle Disposal, available at: http://www.safeneedledisposal.org/resfedreg.html.

[42] For more information, see "Selecting, Evaluating, and Using Sharps Disposal Containers," U.S. Department of Health and Human Services, NIOSH Publication No. 97-111, available at: http://www.cdc.gov/niosh/sharps1.html.

[43] The World Intellectual Property Organization describes one model of a biodegradable sharps container at: http://www.wipo.int/pctdb/en/wo.jsp?wo=2007130402&IA=WO2007130402&DISPLAY=DESC.

[44] OSHA, under the revised Bloodborne Pathogen Standard, requires that healthcare facilities explore the option of safer sharps devices. Though this project does not cover non-community used needles, this guideline may be a possible option for reducing needlesticks after community disposal. Information on multiple types of safety devices and options is available at: http://osha.gov/SLTC/etools/hospital/hazards/sharps/sharps.html.

taping it closed, and labeling it "Do Not Recycle" before disposing in the trash. For specific state recommendations and disposal options, please see the Coalition's website at: http://www.safeneedledisposal.org/dispcenters.html.

While there is no disposal ban for medical sharps in Florida, the state has one of the more comprehensive sharps collection programs in the country. Over 40 counties have collection programs for home-generated sharps. County programs vary, but all have locations where individuals can drop off and pick up sharps containers free or for a small fee. In counties where the collection takes place at a hospital or clinic, that facility usually pays all associated costs. In other counties, the household hazardous waste (HHW) facility collects the needles and pays for disposal. In still other counties, the "Voyager" (http://www.safemedical.com/) container can be purchased and used to deposit sharps directly in the solid waste stream, or mailed back to a medical waste treatment facility for an additional cost.[45]

[45] Information provided by Gina Vallone-Hood, Florida Bureau of Community Environmental Health, February 14, 2008. More information is available at: http://www.doh.state.fl.us/Environment/community/biomedical/home_sharps.htm

Table 5. State statutes, regulations, and legislation related to community medical sharps

State	Law or Legislation	Overview
California	Chapter 64, Statues of 2006[46] AB 501 (under review in Senate as of Feb. 2008)	Bans disposal of medical sharps as of September 1, 2008. Would require pharmaceutical manufacturers to provide consumers of "specified injection devices" with a mail-back container that is pre-paid for shipment to a processor. The container must be rigid plastic and approved by the U.S. Postal Service and California's Department of Public Health. The bill would apply only to pre-filled syringes, not other medical sharps.[47]
Louisiana	SB 226 (Amended State Sanitary Code)	Bans disposal of home-generated medical sharps; awaiting promulgation of regulations. Will regulate the packaging, storage, and transport of sharps, but does not specify collection options.
Massachusetts	Chapter 172, Acts of 2006	Bans disposal of medical sharps as of July 1, 2009. Departments of Public Health and Environmental Protection are developing collection options, which may involve both public and private groups. Development of the program is underway; it may include mail-back, collection at pharmacies, healthcare facilities, or municipal facilities. The law also specifies that both public and private sector groups may be involved in developing and implementing the system. Some aspects of collection are designated by the law, including the fact that sharps collection containers must meet OSHA criteria and that sharps must be dropped off in rigid, puncture-resistant containers.[48]

[46] The California Integrated Waste Management Board has conducted surveys on the barriers to home-generated sharps disposal, which will be presented at a "Sharps Summit" on March 17, 2008 and available at: http://www.ciwmb.ca.gov/HHW/Sharps/Survey/default.htm. This information will be used to improve collection programs. Currently, sharps used in the home are collected at some pharmacies, local HHW facilities, and some hospitals. They can also be mailed back for a fee in a container available at some pharmacies.

[47] Manufacturers oppose AB 501 on the grounds that they do not have direct relationships with the consumers and so would not know how to identify patients using sharps to provide them with the appropriate container. UltiMed opposes the bill, but recommends an alternative that would provide consumers who purchase syringes or pen needles with an approved sharps container for a $5.00 deposit that would be refunded when the container was returned. Under this alternative, all pharmacies in California would become authorized drop-off locations for the filled sharps containers. Text and analysis are available at: http://info.sen.ca.gov/pub/07-08/bill/asm/ab_0501-0550/ab_501_cfa_20080114_105656_asm_comm.html

[48] Information provided by Roy Petre, Massachusetts Department of Public Health, February 14, 2008.

State	Law or Legislation	Overview
Mississippi	SB 2730	This legislation calls for a range of collection options and a public education campaign to be in place by the time a disposal ban comes into effect July 1, 2010. The legislation is awaiting the Governor's signature.
New Hampshire	HB 1502-FN (introduced 2008)	Would ban disposal of used needles as of January 2009, with a $25,000 fine for violations and require pharmacy collection of used sharps.[49]
New Jersey	Regulated Medical Waste Law (N.J.S.A. 13:1E-48.1) Criminal Justice Law (N.J.S.A. 2C:36-6.1)	Does not set any requirements for home-generated medical sharps, but has provisions to allow regulated medical facilities to collect sharps from the community. Requires all sharps to be destroyed before disposal. [50]
New York	Chapter 438 of the Laws of 1993 Chapter 56 of the Laws of 2000	Hospitals and nursing homes are required to accept used sharps from the public as a free community service.[51] An Expanded Syringe Access Demonstration Program (ESAP) began under Chapter 56 of the Laws of 2000, created community-wide coalitions linking syringe access and safe disposal. The Department of Health has provided collection kiosks and wall-mounted units for 91 pharmacies, clinics, landfills, waste transfer stations, housing projects, a community college, a bus depot, an airport and a police station across 20 counties, as well as 8 mobile van programs.[52] [53]

The law is available at: http://www.mass.gov/legis/laws/seslaw06/sl060172.htm

[49] Available at: http://www.gencourt.state.nh.us/house/committees/billtext.aspx?billnumber=HB1502.html.

[50] Information provided by Robert Confer, New Jersey Department of Environmental Protection, February 21, 2008.

[51] Regulations available at: http://www.health.state.ny.us/facilities/waste/#managing_rmw_stream

[52] Information provided by Dr. Wesley Badillo, New York State Department of Public Health, including a "Safe Disposal Flyer." Sharps disposal options are listed at: http://www.nyhealth.gov/diseases/aids/harm_reduction/needles_syringes/sharps/docs/alternate_sites.pdf

[53] The kiosks are manufactured by Johnson Environmental in Ontario, Canada. Information provided by Dr. Alan Woodard, New York State Department of Environmental Conservation, February 20, 2008.

State	Law or Legislation	Overview
Oregon	Oregon Laws 1989, Chapter 459.486-405	Home-generated sharps are subject to the same requirements as those generated in a regulated healthcare setting. They must be treated by one of the methods approved by the Oregon Health Services, which include incineration or autoclaving after which they may be disposed of in a landfill or transfer station for a fee (which varies), but only if delivered there directly in a sealed, rigid plastic container without compaction. At the landfill, they must be placed in a separate area.[54]
Pennsylvania	House Bill No. 1320 (introduced 2008)	This legislation would have required the Department of Environmental Protection to pay for or subsidize sharps disposal opportunities through community drop-off sites, mail-back, home needle destruction devices, and/or special curbside pick-up, as well as associated public education efforts. It passed the House but no action was taken in the Senate.[55]
Wisconsin	Regulations at Chapter NR 526[56]	Requires used medical sharps to be clipped or re-sheathed/re-capped, and then closed securely in an approved sharps container or other rigid plastic container that can be securely closed. These containers are then labeled as "biohazard" and "non-recyclable" before being taken to a registered sharps collection site around the state. The state provides instructions for the safe packaging of sharps for incineration at a licensed medical waste facility. Over 450 healthcare facilities, pharmacies, and recycling centers are registered with the state to collect medical sharps from the general public.[57]

[54] Regulations available at: http://www.oregon.gov/DHS/ph/acd/infectwaste/infectw.shtml

[55] Information provided by Ron Hassinger, Pennsylvania Department of Environmental Protection, February 21, 2008.

[56] Regulations available at: http://www.legis.state.wi.us/rsb/code/nr/nr526.pdf

[57] Information provided by Barb Bickford, Wisconsin Department of Natural Resources, February 21, 2008.

Organizational level support/recommendations

The Coalition has identified the following critical components to a successful state-wide system: sustainable financing, ban on the disposal of untreated sharps in MSW, providing for an education campaign, and allowing time for the development and implementation of a set of collection options appropriate to the state's sharps user population. Please see the Coalition's website at: www.safeneedledisposal.org.

Enforcement

The enforcement of a disposal ban is always challenging, as the contents of trash bags and cans are unlikely to be readily visible at the point of collection, after which it is difficult to identify the source of prohibited items. In New York City, the Environmental Police are called when sanitation workers find any sharps in the trash and can levy a fine if it is possible to ascertain the source of the sharps.[58]

Safe Collection Options

Although there is no nationally-coordinated system, there are several proven models for the safe disposal of medical sharps generated in the community. A successful sharps collection program must consider the convenience, financial, and privacy needs of its target consumer group, and, most importantly, it must be safe for all involved. Its availability must also be communicated to the appropriate target groups. Variables including rural versus urban settings and the mobility of patients infer that a "one size fits all" approach may not be viable. Options for appropriate disposal may be necessary to ensure compliance.

Results from a 2007 State of California survey indicate that 33% of respondents acquire their sharps online, while 29% purchased them at a retail location (18% chain store, 8% independent pharmacy, and 3% big box store). Thirty-one percent of respondents indicated that not knowing where to take their sharps for proper disposal was the most significant barrier, demonstrating the importance of both convenient, accessible collection locations and the importance of communication and education of currently available options to the appropriate audience as part of a solution.[59]

Illustrative examples of existing collection models recommended by the U.S. EPA are described below, although many examples of each type of model exist.

- **Designated collection location.** A drop-box, kiosk, or collection bin may be placed at a retail location, public facility, or health facility for the collection of used sharps. The consumer would drop off used sharps in an approved collection container. Collection in hospitals is required by law in some states (e.g. New York).

[58] Stephen Lawitts, "Needle Sightings and On-the Job Needle-Stick Injuries Among New York City Department of Sanitation Workers," *Supplement to the Journal of the American Pharmaceutical Association, Vol. 42, No. 6, Suppl. 2,* November/December 2002, pages S92-93.

[59] California Integrated Waste Management Board, "Sharps Survey: Personal Use," 2007, available at: http://www.ciwmb.ca.gov/hhw/Sharps/Survey/PersonalRslt.pdf.

Public facilities, such as police or fire stations, provide for safe oversight in a location that is generally centrally-located within a community. Alternatively, household hazardous waste (HHW) collections are usually less convenient or open for limited hours but are often already equipped and identified within the community as a place to handle problem wastes. *Pharmacies* are typically very convenient, especially if the person dropping off used sharps is also picking up new medications or other supplies. Regardless of the type of collection point, the collection bin, drop-box, or kiosk needs to be emptied regularly by a waste hauler approved and trained to handle the material. This activity will be regulated by the state.

Underlying all of these options is the issue of what is an acceptable container for the collection and transport of the sharps to the collection point. Sharps containers adhering to OSHA, DOT, and FDA guidelines are ideal, although some states allow for the use of detergent bottles, coffee cans, or other containers that are rigid and leak-proof. However, the problem with these alternatives is that they may not be as durable as an approved container and, unless properly labeled, could become mixed in with recycling[60] or MSW. On the other hand, they are commonly available and do not require an additional cost to the consumer.

Examples:

Collection at Pharmacies
In Rhode Island, 28 pharmacies (including Walgreens, CVS, and independent pharmacies) collect medical sharps in automated kiosks provided by Chrysalis Environmental Solutions. These electronic kiosks have automatic lockdown functions, a light that indicates when the kiosk needs to be emptied, and a sonar signal to the waste hauler. Forty sites have collected an estimated average of 1 million syringes each year since 2000 with no incident. Over half of the syringes collected (by weight) were collected by the participating CVS stores. Corporate sponsorships from Stericycle and others cover the kiosks. Kiosks can be leased or $375/month, including twice-monthly pickups. Consumers provide their own rigid, leak-proof containers. [61]

Sharps containers, paid for by the county, are available at the pharmacy at the 15 Lewis Drug stores in the Sioux Falls area as part of a voluntary program that has been underway for the past 12-15 years. Once filled, the containers are returned to Lewis Drug and placed in a plastic bag that the customer ties closed. This bag is then deposited in a large, red trash-type container kept behind the counter. Once a week, Lewis Drug maintenance personnel transport the sharps collected to an autoclave facility at the Veterans' Administration hospital. Minnehana County pays the $2.13 cost of the sharps containers, and the rest of the services are provided in-kind by Lewis Drug. The program has been

[60] David Lamm and Sharon Adams, "Removing Needles from Trash in Indiana: A Necessary Effort," *Journal of Environmental Health*, September 2007.
[61] Information provided by Cherie Fisher, Chrysalis Environmental Services, in interview with PSI March 13, 2008.

well-received and replicated by other counties in the state and local pharmacies due to its apparent success and customer demand.[62]

Photo: **Automated kiosk, provided by Cherie Fisher, Chrysalis**

Photo: Kiosk used in New York, provided by Wesley Badillo, NY Department of Health

Photo: Collection bin with bagged sharps containers in Lewis Drug Store, provided by Tom Erickson, UltiMed

Collection at Public Facilities

In Boone County, IN [63] the Solid Waste District funds the County Health to distribute sharps containers and collect them free of charge. Providing and disposing of a 2-gallon sharps container costs approximately $6.00 through this program, and just fewer than 300 containers are disposed of annually for an average of about 130,000 needles/year since 2001. Stericycle collects the containers of used sharps for treatment. A citizens' advisory committee, including local trash haulers and interested citizens, agreed that such a program "was a good use of funds and should be done."[64]

[62] Information provided by Tom Erickson, UltiMed, to PSI on March 12, 2008.

[63] Population 50,000

[64] Email to Sierra Fletcher, PSI, from David Lamm, Boone County Solid Waste Management District, 22 May 2008.

Massachusetts Department of Public Health has placed 30 kiosks in public health departments, community health centers and HIV/AIDS prevention and education programs. An additional 30 will be placed in the coming year, mainly in local health departments. The local health departments are taking financial responsibility for the monthly disposal costs either through leasing the units or for their existing medical waste hauler contracts.[65]

- **Mail-back from the home.** When using a mail-back sharps disposal service, consumers order an approved sharps container on-line, which comes accompanied by a pre-paid mailing package that must be approved by the USPS. The consumer then completes a tracking form and returns this with the sharps container once it is filled. This may be the only convenient option for those for whom moving around the community is difficult or impossible as priority mail pick-up can be arranged, or the sealed package handed to the mail carrier directly.

  Example:

  Companies such as Sharps Compliance, Inc., Stericycle, and multiple others provide mail-back services that include the sharps container, mailer, shipping, and treatment costs upfront. Customers can choose from a range of container sizes (from about 1-quart to 6-gallons) for about $30 - $100. Some companies, such as Sharps Compliance, Inc. provide customers a way to re-visit the website to see proof of destruction of their container using the company's SharpsTracer system. This service is operated in conjunction with Waste Management, Inc. and Becton, Dickinson and Co.

- **Home needle destruction devices.** There are some FDA-approved devices that "treat" the needle in the home so that it can be discarded with MSW (unless the state requires specific disposal methods for both needles *and* syringes). This may be done by burning, melting, or cutting the needle.[66]

  Example:

  A small home incinerator unit, such as the Disintegrator, made by Pacific Medical Technologies and one made by NeedleZap, leaves a blunt syringe with no needlestick hazard that can be disposed of in MSW. The units cost from $100 - $250. There can be certain restrictions, for example it is not recommended for use in homes where compressed oxygen is in use. There have also been concerns with aerosolizing pathogens on the needle through heating. The needle is disintegrated by low-voltage electrical current down to a blunt end.

[65] Email to Sierra Fletcher, PSI, from Thera Meehan, MA DPH, 2 June 2008.

[66] Cutting the needle would not necessarily remove the potential for needlestick injuries, but this is one of the options recommended by the EPA in its booklet, "Protect Yourself, Protect Others: Safe Options for Home Needle Disposal," EPA530-F-08-004, 2004.

Photo: NeedleZap home incinerator, from http://www.needlezap.com/

- **Syringe exchange programs.** Syringe exchange programs have become popular over the past 20 years as a means of preventing HIV/AIDS and hepatitis B and C. These programs are typically provided free and designed to target the IDU community. The North American Syringe Exchange Network provides detailed information on the programs available in various states on its website at: http://www.nasen.org.

- **Residential waste pick-up.** Some communities provide medical waste collection services.

Costs of Current Disposal Options

The costs of appropriate disposal programs and services for home-generated medical sharps include the sharps container; collection container (kiosk, bin); transport, treatment and ultimate disposal of the waste; documentation (of mail-back, for example); outreach and education; and oversight at the collection location and of the program overall. Typically, these services have been provided by public agencies at the local, state, and tribal levels as a public safety and disease prevention service. In some cases, direct private sector contributions have supported the programs, as with the kiosk collection in Rhode Island and waste hauler support of syringe exchange programs in New York. Pharmacies and others have provided in-kind services by "hosting" a kiosk at no cost to provide additional services to their customer base. In other cases, hospitals or clinics may accept the used sharps for free and process them with their own waste. Finally, the sharps consumers themselves may be required--or choose--to pay for the disposal, as with a mail-back program or through a fee paid for the sharps container either at purchase or at the drop-off point.

The exact costs of any single option vary depending on the distance to a disposal site and the various in-kind contributions of public and private resources. Jessica Schwarz of the Indian Health Services (IHS) estimated the total annual costs for different disposal options for the estimated number of people with diabetes living on Louisiana reservations. Her estimation of the costs for one year of safe disposal concluded that the home incinerator (described above) was the least expensive option at just over $6,000, but there are some concerns with this product as it cannot be used safely in a home where a patient is on oxygen. The drop-off at an IHS clinic cost

twice as much as the home incinerator, but as compared to the mail-in (which came in over $80,000), it was still relatively accessible.[67]

Currently, the acquisition costs of medical sharps used for diabetes, such as syringes, pen needles, and lancets are covered under Medicare and most private insurance plans. Certain injection devices such as pre-filled pens or syringes for other medications, classified as Part B drugs, are also covered under Medicare and many private plans. However, the cost of an approved sharps disposal container and the safe disposal of that container are not included. In 2007, Senator Johnny Isakson (R-GA) and Congressman Mike Ferguson (R-NJ) introduced legislation that would include coverage for the cost of safe sharps disposal for insulin and pen needles associated with the injection of insulin under Medicare Part D.[68]

In California's 2007 survey, 72% of respondents reported that their insurance did not cover sharps disposal (16% did not answer).[69] These results indicate that 12% of respondents' insurance policies *did* cover disposal, or that people are uninformed and assume that free disposal options are paid for by their insurance when in fact they may be paid for by public funds.

XI. Options for Shared Responsibility

As demonstrated by the projects described previously, there are many ways for companies, agencies, and organizations committed to the safe use and disposal of medical sharps to share responsibility. Table 6 shows some examples, many of which have already been demonstrated in the projects described above, or are being implemented at the initiative of a company, agency, or organization, or by a statutory or regulatory requirement.

[67] Jessica Schwarz, Mitch Camarillo, and Robert Martel, "Disposal Proposal: Getting to the Point of Safe Tribal Needle Disposal," presentation for the Master's of Public Health program at Tulane, Spring 2008.
[68] Coalition for Safe Community Needle Disposal website, available at: http://www.safeneedledisposal.org/assets/pdf/hr3251.pdf.
[69] California Integrated Waste Management Board, "Sharps Survey: Personal Use," 2007, available at: http://www.ciwmb.ca.gov/hhw/Sharps/Survey/PersonalRslt.pdf.

Table 6. Potential stakeholder contributions (options for discussion)

Stakeholder	Potential Contributions to Product Stewardship of Medical Sharps
Manufacturers: Medical Sharps	✓ Develop/promote sale of devices with sharps injury prevention features and auto-disable features ✓ Produce/sell approved sharps disposal containers for sale with sharps products[70] ✓ Manage and/or finance safe collection and disposal, in full or in part ✓ Increase awareness of importance of safe disposal and collection
Manufacturers: Pharmaceuticals and Other Medications	✓ Develop/promote sale of devices with sharps injury prevention features and auto-disable features ✓ Require self-injected products to be accompanied by approved sharps disposal container ✓ Finance safe collection and disposal, in full or in part ✓ Increase awareness of importance of safe disposal and collection
Pharmaceutical Wholesalers	✓ Require self-injected products to be accompanied by approved sharps disposal container ✓ Finance safe collection and disposal, in full or in part ✓ Increase awareness of importance of safe disposal and collection
Pharmacy Benefit Managers	✓ Require self-injected products to be accompanied by sharps disposal container ✓ Increase awareness of importance of safe disposal and collection
Insurers/Payers	✓ Reimburse costs that include sharps disposal containers, collection, and disposal
Retail and Mail Order Pharmacies	✓ Increase awareness of importance of safe disposal and collection opportunities ✓ Collect used sharps on site or via mail-back ✓ Provide coupon as incentive to return used medical sharps for disposal ✓ Promote sale of devices with sharps injury prevention features
Government	✓ Require inclusion of safe sharps disposal with self-injected products ✓ Require use of devices with engineered safety features ✓ Coordinate projects locally, state-wide, or nationally ✓ Increase public awareness about importance of safe disposal and collection locations ✓ Recognize companies/groups taking leadership roles ✓ Regulation/enforcement to level playing field and maintain fairness ✓ Explore tax credits or other opportunities to encourage private sector participation in sharps disposal programs ✓ Explore public financing options
Consumers and Associations	✓ Increase awareness of importance of safe sharps disposal and collection ✓ Recognize efforts made by companies to promote safe disposal options
Waste Management Officials/Industry	✓ Increase awareness of importance of safe disposal and collection ✓ Provide safe transport and treatment for sharps disposal

[70] Not e that there are manufacturers of sharps disposal containers who do not make sharps and sharps manufacturers who do not make sharps disposal containers.

The cost of safe disposal of community-generated medical sharps was cited by most of the stakeholders interviewed by PSI as the primary obstacle to a nationally-coordinated system that meets the needs of the various sharps consumer groups.

Sustainable Financing[71]

Currently, most end-of-life management costs for HHW in the United States (e.g., collection, reuse, recycling, disposal) are largely borne by state and local agencies through government programs, and are paid for through taxes. Other ways of funding programs are through end-of-life fees charged to consumers when they return a product for recycling or disposal, or through solid waste utility rates. There are two basic types of product stewardship financing systems that seek to cover end-of-life product management costs by incorporating these costs into the purchase price of a new product: (1) Advanced Recycling Fees and (2) Cost Internalization (or "producer responsibility").

Europe and Japan have developed systems that share financial responsibility. In those countries, producers usually are financially responsible for the portion of the process on which they have influence, namely transportation and recycling of scrap products. Municipalities and retailers often pay for the collection of products at municipal depots or at retail, parts of the process on which they have most influence. In the U.S., producer responsibility systems are by far the dominant financing mechanism, and have been implemented for electronics, thermostats, rechargeable batteries, and paint. For each of these products, manufacturers have taken responsibility for the collection, transportation, and recycling of the products by creating an industry-run stewardship organization to contract for services, collect payments from producers, and manage the overall system.

Advanced Recycling Fee

An advanced recycling fee (ARF) is a separate charge placed on a new product and paid by a consumer at retail to cover the cost of the product's eventual end-of-life management. An ARF is paid in advance so that when a consumer is ready to recycle the product, a "free" system is available for its collection, transportation, and management. Buying a product and paying an ARF is like buying that product's recycling service in advance. In reality, the ARF paid on a current product pays for the recycling of a product bought years before. One advantage of ARF systems is that the fund created can immediately cover the costs of recycling these past products.

An ARF can be either visible or invisible to the consumer. In the U.S., many state governments have placed visible ARFs on products such as tires, motor oil, and lead acid batteries. California's 2003 electronics scrap recycling law, the first electronics product stewardship system in the U.S., is also based on a visible ARF. Some Canadian ARFs, however, are invisible to the consumer.

[71] Parts of this section appeared in a chapter written by Scott Cassel, Product Stewardship Institute, called "Product Stewardship: Shared Responsibility for Managing HHW," in *Household Hazardous Waste*, edited by Amy Cabaniss, Government Institutes (Lanham, Maryland) 2008.

Funds collected in ARF systems can go into a government-managed fund or an industry-managed fund (handled through a producer responsibility organization). While most ARFs in the United States are paid into government funds, ARFs in Canada are most often paid into an industry fund and managed by a stewardship organization. A key disadvantage of government-managed funds is the possibility of state legislatures seizing these dedicated funds for other funding purposes. Another downside is the need for additional government staff to manage the fund collection, grant distribution, contractor services, and other operational functions. Many people believe that, for an ARF to be considered as a product stewardship system, funding must be handled by industry, and that industry must play a significant role in managing the system.

Those supporting industry-managed funds believe that these functions can be provided more cost effectively when managed by the private sector. Some in Europe, however, believe that ARFs that pay into a single organization – whether public or private – provide little incentive to improve efficiency since central funds act as monopolies. These proponents believe that the most efficient systems are ones that provide competition among private organizations, which would exclude an ARF.

Cost Internalization

A second type of financing system involves manufacturers and importers that internalize end-of-life management costs into the cost of doing business so that they are invisible to the consumer, even though the costs may be passed on to the consumer. These are called "producer responsibility" systems. By internalizing end-of-life management costs, manufacturers and importers have direct management ability to increase efficiency, improve service, and cut costs. The ability to control management decisions is the biggest advantage for a producer responsibility system compared to an ARF, which does not become part of a company's profit and loss statement and therefore does not result in company actions toward greater efficiency.

The two most common voluntary industry-wide programs in the U.S. are run by the Rechargeable Battery Recycling Corporation (RBRC) and the Thermostat Recycling Corporation (TRC). Both of these programs were developed by manufacturers to fund collection and recycling programs that are free to consumers, who can bring their batteries and thermostats to participating public and private collection sites. These products do not have to be sorted by brand since the programs accept all manufacturer brands. Manufacturers' costs to collect and recycle the batteries and thermostats, and to publicize the programs, are included in the purchase price of the products. The entire program is paid for by funds derived from manufacturers that pay according to a formula based on market share and established by RBRC and TRC. Of the 12 scrap electronics recycling laws recently enacted in the U.S., all but one follow the producer responsibility model.

In most European countries, the Waste Electrical and Electronic Equipment (WEEE) Directive is implemented through cost internalization, which fosters competition among several stewardship organizations in one country. For example, the establishment of four stewardship

organizations in Austria in 2005 has reduced the take back cost from 75 cents per kilogram of electronic product placed on the market to 8 cents per kilogram within a 6-month period.[72]

Deposits

Deposit systems create an extra incentive for residents to bring their used product in for collection. Under such a system, consumers pay an extra charge, similar to an ARF, at the time the product is purchased at retail. However, unlike an ARF, if the consumer returns the used product, they will receive a return deposit, or a portion of the deposit. Deposits have been effective at increasing the rate of recycling, although they add significant costs and complexity to the program since part of the revenue must be paid back to consumers who return their products. Examples of deposit-related systems include state laws on beverage containers, and some state laws on automobile batteries, pesticide containers, and used motor oil.

End-of-Life Fees

End-of-life fees are charged by some government agencies and private entities at the point where a product is collected for recycling or disposal. They are used to obtain program revenue to collect used products. Government officials usually view these fees as inadequate long-term solutions because they charge residents for "doing the right thing" and often result in illegal disposal. Given a mandatory fee for collection, many consumers dispose of products in the garbage, a vacant lot, or the woods rather than take the product to a collection location. Fees are best used to jump-start programs, as a supplement to a product stewardship system, or to gain experience on a pilot project basis. In 2007, Staples became the first retailer to announce that it would take back computers, for an end-of-life fee, in all of its stores nationally.[73] This program is viewed as a supplement to, but not a substitute for, a funding system that will collect and recycle electronics equipment without an extra fee from residents.

Retail Coupons

Retail coupons offer additional incentives to the consumer to have them return the product. These could be provided by a retailer or manufacturer at a retail outlet, or at a municipal collection event or depot.

XII. Key Issues and Potential Strategies

PSI identified key issues, solutions, and potential strategies based on interviews with key stakeholders and other input received (see Table 7). During the meeting phase of the dialogue, participants will jointly determine which strategies show the most promise and develop specific steps to pursue these highest priority strategies. The PSI dialogue group will benefit from work already underway on these strategies. The potential strategies listed below are intended to launch discussion at the first national dialogue meeting.

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[72] Hans Korfmacher: "Some Learnings from the establishment of the first pan-European WEEE Compliance Scheme: The European Recycling Platform," presentation at Product Stewardship Institute Forum, San Francisco, May 2007, http://www.erp-recycling.org.

[73] For more information, see the Product Stewardship Institute's website at http://www.productstewardship.us.

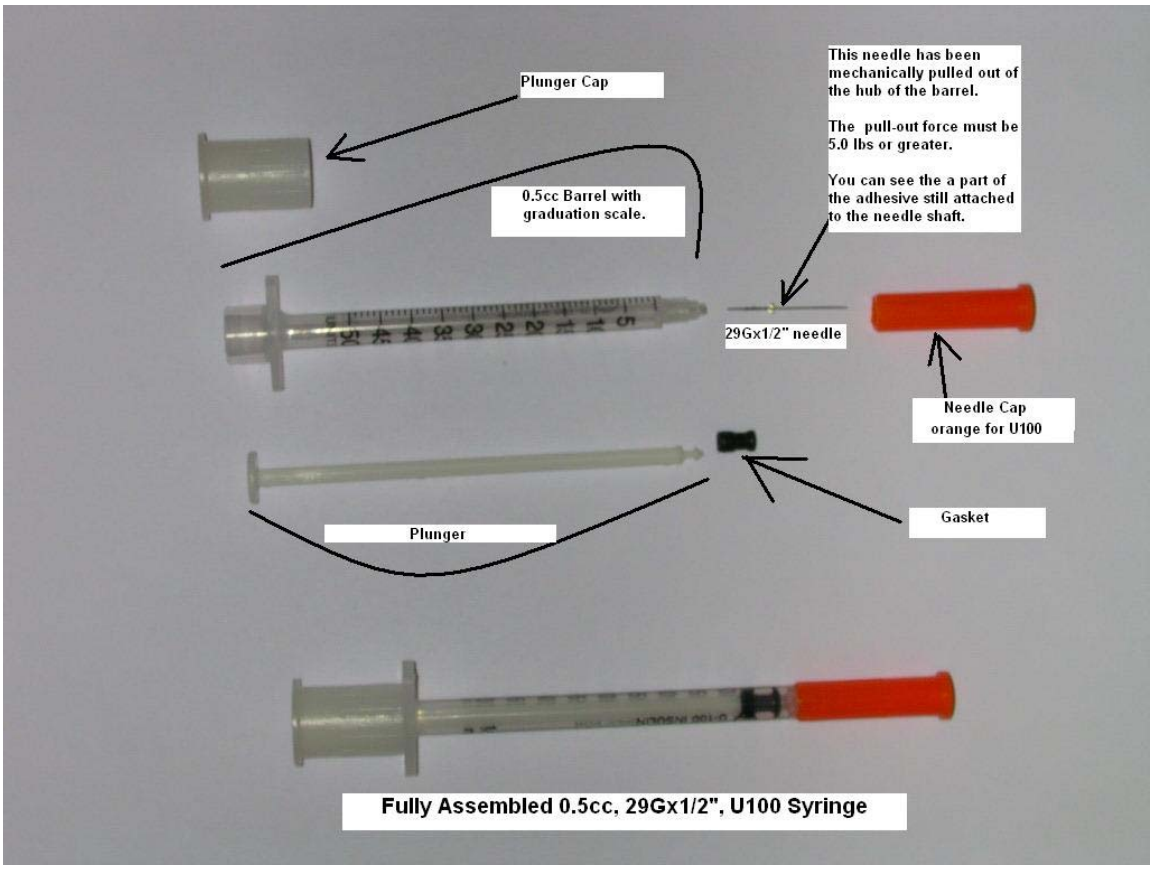
Table 7. Issues, solutions, and strategies for consideration by stakeholders

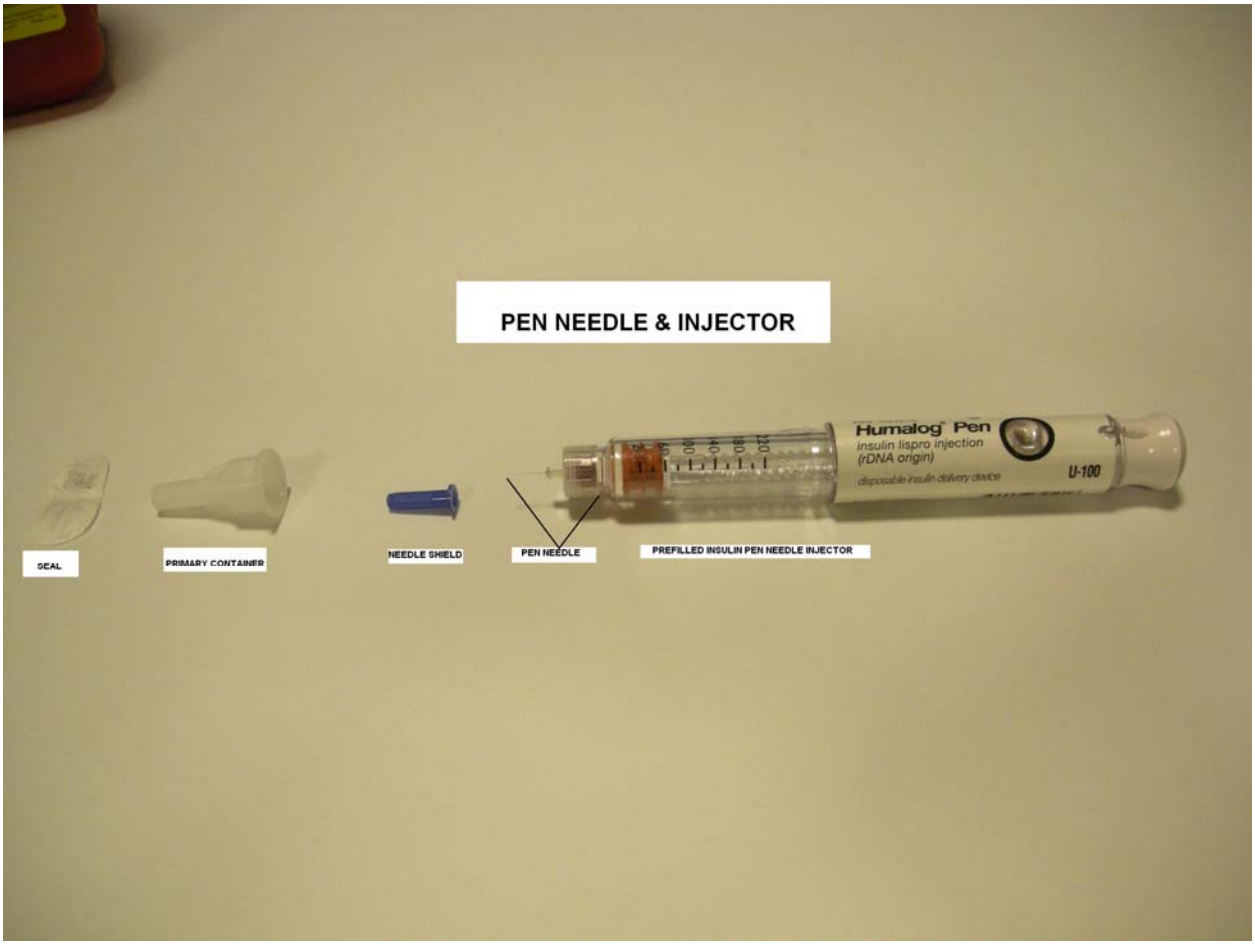
Issue	Potential Strategies
#1. Source reduction. Source reduction is the starting point for end-of-life management of any product. In the case of medical sharps, there are different types of syringes and needles that are designed to reduce the risk of a needlestick, as long as the unit remains intact. Use of devices with engineered safety features would help to prevent injuries to custodial/hospitality staff upstream from waste haulers. Various forms of medical treatment can reduce the injections required.	a) Investigate whether devices with sharps injury prevention features would remain intact during typical waste hauling and disposal processes. If they would, promote the financing and use of these alternatives outside of health facilities. (They are already required within health facilities).
#2. Collection, transportation, and disposal infrastructure. Maximizing the safe disposal of medical sharps requires safe, convenient, and comfortable (culturally and in terms of privacy concerns) collection opportunities. A range of options must be available to meet the needs of different sharps consumer groups and to address cultural /privacy concerns and mobility needs.	a) Determine precise numbers of sharps used by different consumer groups. b) Determine whether a sharps container that adheres to OSHA/FDA guidelines is necessary for safe collection at drop-off locations. c) Determine the target parameters for "convenient" collection locations based on population statistics (including urban/rural, # of people with diabetes, # IDUs, etc.). This information can be matched with the # and location of retail pharmacies, various public facilities, and syringe exchange programs. d) Develop best practices for collection locations, including parameters/standards for kiosks/bins used at collection sites.
#3. Regulation and enforcement. A growing number of states are developing statutes and regulations specific to medical sharps generated outside the traditional healthcare setting. Effective regulation requires effective enforcement, which is	a) Identify or develop key components of model state legislation, possibly to include financing, convenience, education, and an implementation schedule. b) Identify and overcome potential regulatory obstacles impacting the

Issue	Potential Strategies
particularly challenging.	collection, transportation, and disposal infrastructure. This may include requirements for staff at collection locations or waste handling requirements. c) Advocate for the FDA to require sharps disposal costs/methods to be included with all self-injected medications.
#4. Sustainable financing. A sustainable financing system is needed to conduct widespread safe collection, transportation, and disposal of medical sharps; current financing by governments and consumers at the end of life is not sustainable.	a) Develop a financing system that covers the collection, transportation, and disposal costs for medical sharps generated outside the traditional healthcare setting. b) Develop cost estimates for different options nationally. c) Advocate for Medicare Part D/ health insurance plans to cover cost of safe sharps disposal and sharps with engineered safety devices.
#5. Education, outreach, and risk communication. The successful collection of medical sharps requires the targeted dissemination of information about the importance of –and opportunities for—safe sharps disposal. It is important that risks are described clearly and accurately, and that communications are appropriate to their target audiences.	a) Develop educational materials for dissemination via medical professionals, diabetes educators, pharmacies/pharmacy benefit managers, and others through the various associations and organizations that represent these groups. b) Develop consensus on statement describing the medical sharps issue to be disseminated as part of public information campaign. c) Develop or add to training materials for populations at risk for needlesticks while on the job to inform them of the risks or actions to take in the event of a needlestick and prevention measures.

APPENDIX A

These photos of various medical sharps devices were provided by Tom Erickson, UltiMed.


Plunger Cap
This needle has been mechanically pulled out of the hub of the barrel.
The pull-out force must be 5.0 lbs or greater.
You can see the a part of the adhesive still attached to the needle shaft.
0.5cc Barrel with graduation scale.
29Gx1/2" needle
Needle Cap orange for U100
Gasket
Plunger
Fully Assembled 0.5cc, 29Gx1/2", U100 Syringe


PEN NEEDLE & INJECTOR
SEAL
PRIMARY CONTAINER
NEEDLE SHIELD
PEN NEEDLE
PREFILLED INSULIN PEN NEEDLE INJECTOR
Humalog Pen
insulin lispro injection
(rDNA origin)
U-100

APPENDIX B

INTERVIEWS, COMMENTS, AND CONTRIBUTIONS

PSI conducted interviews or focus group calls with the following individuals from February-May 2008.

Associations and Organizations
Brent Dieleman, Solid Waste Association of North America
Kathy Gold, Diabetes Wellness and Research Foundation
Chris Hornback, National Association of Clean Water Agencies
Jenny Schumann, Coalition for Safe Community Needle Disposal
Litjen Tan, American Medical Association

Device Manufacturers
Tom Erickson, UltiMed
Adrian Gilmore, Terumo Medical Corporation
Karl Schumann, Becton Dickinson and Co.
Robert Singley, Becton Dickinson and Co.

Pharmaceutical Manufacturers
Pat Quinn, NovoNordisk
David Trindell, Hoffman-La Roche Inc.

Pharmaceutical Wholesaler
Laurie Jamieson, McKesson

Waste Management Industry
Bob Barros, Healthcare Waste Solutions
Cherie Fisher, Chrysalis Environmental Solutions, LLC.
Ben Hoffman, Waste Management, Inc.
Burton Kunik, Sharps Compliance, Inc.

Ron Pierce, Waste Management, Inc.

Federal Government
Kit Grosh, Indian Health Services
Jessica Schwarz, Indian Health Services

State Government
Wesley Badillo, NY Department of Health (AIDS Institute)
James Ballin, MA Department of Public Health
Alma Candelas, NY Department of Health
Robert Confer, NJ Department of Environmental Protection
Del Courtney, NY Department of Health
Andy Epstein, MA Department of Public Health
Irene Gleason, FL Department of Environmental Protection
Angela Laramie, MA Department of Public Health
Thera Meehan, MA Department of Public Health
Roy Petre, MA Department of Public Health
Mary Lou Perry, OR Department of Environmental Quality
Denise Rondeau, NH Department of Health and Human Services
DeAnn Ryberg, CO Department of Public Health and Environment
Gina Vallone-Hood, FL Department of Health
Rachel Weinrich, IN Department of Health
Alan Woodward, NY Department of Environmental Conservation

Local Government
David Lamm, Boone County Solid Waste Management District (Indiana)

Other
Steve Jones, Consultant

APPENDIX C

Sharps Disposal Containers[74]

According the American Diabetes Association, an easy way to get rid of used lancets or needles is to put them in a heavy-duty plastic or metal container with a tight-fitting lid (such as an empty laundry detergent bottle). When the container is full, you dispose of it according to your local waste-disposal rules.

A sharps disposal container, which is any container that is intended to be used for sharps waste disposal, is a FDA-regulated medical device. Manufacturers must obtain premarket clearance before marketing the device to the public.

FDA describes the type of information and data that are needed for marketing clearance of sharps containers in the document, Guidance on the Content and Format of Premarket Notification [510(k)] for Sharps Containers (October 1993). For a copy of this document, use the following link:

Guidance on the Content and Format of Premarket Notification [510(k)] for Sharps Containers
http://www.fda.gov/cdrh/ode/895.pdf

The information is based on Occupational Safety and Health Administration (OSHA) requirements for sharps disposal containers. The container must be

- closable
- upright and stable during use
- puncture resistant
- leakproof at sides and bottom
- properly labeled with the biohazard symbol and legend or color coded.

The label on the container should clearly inform the user that the container holds sharps waste. Either a recognized symbol, the phrase "Infectious Sharps Waste," or a similar warning must be clearly visible on the container label.

In January 1998, NIOSH (the National Institute for Occupational Safety and Health) published a guidebook, “Selecting, Evalutating, and Using Sharps Disposal Containers,” for the purpose of “selecting sharps disposal containers and evaluating their efficacy as part of an overall needlestick injury prevention plan.” The full document is available at: http://www.cdc.gov/niosh/pdfs/97-111.pdf.

[74] This information taken directly from FDA website at: http://www.fda.gov/DIABETES/lancing.html#3.