

**Consumer Generated Sharps Waste  
Stewardship Plan**

**Santa Clara County, California**

**Submitted by:  
Novo Nordisk Inc.  
October 2, 2018**

## 1. Introduction

Novo Nordisk Inc. ("Novo Nordisk"), submits this Product Stewardship Plan ("Plan") to Santa Clara County, CA for seeking approval under Ordinance No. NS-517.92. While all manufacturers of Sharps, or drugs that lead to the use of Sharps, have an obligation to participate in takeback initiatives on some level, it is inappropriate for manufacturers to replicate the Product Stewardship Work Group ("PPSWG") program through their efforts. Replicating the program would create unnecessary financial burden and potential create confusion for patients. Novo Nordisk believes that approaches that complement the PPSWG Program are necessary to ensure that all individuals regardless of their circumstances have access to safe and effective disposal methods for Sharps. Therefore Novo Nordisk has created a program that focuses specifically on Sharps takeback at the individual consumer level and seeks opportunities to continue to offer options to consumers outside of those existing PPSWG locations.

## 2. Contact Information

The primary contact person for information related to the Plan is:

Amie Phillips Pablo  
Director, Government Reporting

Novo Nordisk Inc.  
800 Scudders Mill Road  
Plainsboro, NJ 08536  
609-786-4427 (Direct)  
ampp@novonordisk.com

## 3. Plan Definitions

**Consumer** means any Person who uses Sharps outside a healthcare setting, or any Person who assists another person in using Sharps outside a healthcare setting.

**Municipality** means the unincorporated and incorporated areas of Santa Clara County, CA.

**Municipality Residents** means a resident of the Municipality.

**Department** means the Municipality Department of Environmental Health.

**Mail-Back Services** is the provision of pre-paid, pre-addressed mailers for the collection and disposal of Unwanted Sharps.

**Plan or Product Stewardship Plan** is the product stewardship plan presented in this submittal by Novo Nordisk.

**Program or Product Stewardship Program** is the product stewardship program set forth in this Plan.

**Sharps** are defined as devices with sharp points or edges that can cut or puncture the skin and includes needles, pen needles, syringes, lancets, auto-injectors, infusion sets, intravenous catheters, connection needles/sets, and other devices.

**Stewardship Organization** is an organization designated by a group of Producers to act as an agent on behalf of the Producers to develop, implement, and operate a Product Stewardship Plan and Program

**Vendor** is PureWay Compliance, Inc. ("PureWay"), the collection and transportation vendor for this Plan, and any other such vendor as retained by Novo Nordisk to carry out its obligations under the Program.

#### **4. Collection of unwanted Sharps**

The Program provides services to collect Sharps. The Program, including collection methods and applicable legal requirements are described below.

##### **a. Program Implementation**

Novo Nordisk, through the Program began collecting any unwanted Sharps on 12/11/2017 ("Implementation Date"). Since the implementation date, Novo Nordisk has distributed 366 collection containers.

##### **b. Summary Plan**

Novo Nordisk plans to promote the program through the company website which consumers have access to and request a Sharps disposal container through a third party, Pure Way. Novo Nordisk will provide options for the return of the container.

##### **c. Patient Enrollment**

Consumers can enroll in the Program by logging onto the Program website (NovoCare.com). Spanish speaking Consumers can call 1-877-438-0564 to enroll. The Program is open to all Consumers with a valid California address, regardless of whether or not Consumers utilize Novo Nordisk products. Upon enrollment, Consumers will be sent a UN/DOT Certified Sharps Container, instructions for safe use and disposal of Sharps and instructions for pick-up once the Sharps Container is full.

##### **d. Patient Education**

Consumers can obtain information about the safe use and disposal of Sharps through the Program website (<https://www.novocare.com/psp/safe-needles-program.html>). Such patient information shall include, but not be limited to safety reminders, how to create your own container and what to do with containers that have been filled. Consumers that visit the Program website are also encouraged to visit [safeneedledisposal.org](http://safeneedledisposal.org) to learn more about safe disposal and to find a disposal location in their area

Novo Nordisk published a press release on 1/8/2018 in efforts to drive awareness of the program.

The Program messaging will focus on two main goals:

- Educating Residents about the appropriate use, storage, and disposal of Sharps and

- Providing Residents with clear steps to properly manage the disposal of their Sharps, including the use of Mail-Back Packages.

**e. Call Center**

Consumers may call the Call Center (1-877-765-3030) to seek assistance in preparing the container for destruction, schedule a pick up or reorder a new container.

**f. Mail-Back services**

The Program will offer Mail-Back Services for Sharps, free of charge, to any Consumer residing in California that enrolls in the Program through the methods described above. The packaging the Container arrives in includes all the necessary materials to safely return the full Container for destruction. Materials include an instruction sheet describing how to properly dispose of Sharps, explains what materials may be placed in a Sharps container, how to use the Sharps container, and how to return the container. A pre-paid/pre-addressed is also included for convenience.

Mail-back services shall comply with all applicable local, state, and federal requirements.

**i. Sharps Mail-Back Package Specifications**

A UN/DOT Certified Sharps Container and a pre-paid, pre-addressed Mail-Back Package for returning the Sharps container

**ii. Mail-back Package Collection and Disposal**

All packages will be logged upon shipment to Consumers as well as upon delivery to the approved disposal facility using a unique identifier. Consumers will be directed to follow the instructions provided with the container and to place their Sharps in the pre-addressed, pre-paid package. Mail-Back Packages shall be sent to the treatment and disposal facilities listed in section VI. Upon arriving at the disposal facility, the Mail-Back Packages shall be scanned for receipt verification. Sharps returned in Mail-Back Packages will be disposed of using an incineration process.

Patients will receive email communication each step of the process:

- Registration
- Container has been shipped (with tracking number)
- Container has been picked up
- Container has been destroyed (includes certificate of destruction)

**5. Patient Privacy**

Novo Nordisk takes patient privacy very seriously, in addition to the vendor having protections in place for keeping personally identifiable information safe and secure. Additional information regarding Novo Nordisk’s privacy terms may be found at: <http://www.novonordisk-us.com/disclaimer-privacy.html>.

## **6. Mail-Back, Processing and Destruction Facility Information**

### **a. Mail-back Vendor**

PureWay, Inc.  
20501 Katy Freeway  
Suite 206  
Katy, TX 77450

### **b. Medical Waste Processing Facility**

Daniels Health Medical Waste  
4144 E Therese  
Fresno, CA 93725

### **c. Incineration Facility**

Covanta  
Environmental waste solution site  
4040 Fink Road  
Crows Landing, CA 95313

## **7. Compliance with Applicable Federal, State and Local Legal requirements**

As described in more detail below, the Program is designed such that all entities participating in the Program shall comply with the laws and regulations listed below, and all other applicable federal, state, and local laws, rules, and other legal requirements.

### **a. United States Department of Transportation (USDOT)**

When transporting Sharps, Vendor will ensure compliance with the USDOT Hazardous Materials Regulations (HMR). Shipments of Sharps will comply with applicable shipping papers, packaging, placarding, and other HMR requirements associated with shipment by ground.

### **b. California Medical Waste Management Act**

California comprehensively regulates the transportation, storage, treatment, and disposal of Sharps under the Medical Waste Management Act, Ca. Health & Safety Code § 117600 et seq. Many of these requirements apply to "home-generated sharps waste," meaning "[h]ypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications derived from a household, including a multifamily residence or household." § 117671. Among other requirements, the Medical Waste Management Act requires that home-generated Sharps shall "be transported only in a sharps container, or other containers approved by the enforcement agency..." § 118286(b). These home-generated Sharps may only be managed at certain facilities, including but not limited to a "home-generated sharps consolidation point[s]" or facilities through mail-back services. See *id.* The Medical Waste Management Act also requires specific "treatment" methods for Sharps to render them non-infectious before disposal. See CMWMA § 118225(a) (requiring treatment by incineration, steam sterilization, or another approved method).

## **8. Annual Report**

Within six months after the end of the first 12-month after the Implementation Date, and annually thereafter, Novo Nordisk will submit a report to the Department describing Plan activities during the previous reporting period. This annual report will include:

- The number of Consumers participating in the Program;
- The amount by weight of Sharps collected
- The transporters used and the disposal facility or facilities used for all Sharps;
- A statement whether any safety or security problems occurred during collection, transportation, or disposal of Sharps and, if so, what changes have or will be made to alleviate these problems and improve safety and security;
- A description of public education, outreach, and evaluation of activities implemented; and,
- A summary of the Product Stewardship Plan's goals, the degree of success in meeting those goals in the past year, and, if any goals have not been met, what effort will be made to achieve the goals in the next year.