

***Plan for Support of Safe Collection and Proper Disposal of Waste from Self-Injected Home Medications Including Sharps***

***Submitted to the California Department of Resources, Recycling and Recovery  
(CalRecycle)  
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kaleo, Inc. submits the following plan describing how we support the safe collection and proper disposal of waste from self-injected at home medications that include sharps.

This report is submitted consistent with the requirements of Chapter 1 of Part 7 of Division 30 of the Public Resources Code, beginning with Section 47115 for the limited number of prescription drug products for at-home use that include, or utilize a separate, hypodermic needle, pen needle, intravenous needle or similar device. It is important to note that physicians, healthcare providers and pharmacists all play an important role in instructing patients on the safe collection and proper disposal of needles.

kaleo, Inc. markets EVZIO® (naloxone HCl injection) auto-injector, a take-home naloxone auto-injector. EVZIO contains a retractable needle that is designed to present no sharps hazard before and after use. The needle is self-contained within the device and is only exposed very briefly (less than 1 second) during the activation of the injection. Prior to activation, the needle is completely contained inside the device, and after injection the needle completely retracts into the device, eliminating the sharps hazard.

The EVZIO device addresses disposal in its FDA approved product labeling and patient instructions. These instructions include: “DO NOT throw away EVZIO in household trash. DO NOT recycle. Put the used EVZIO back into its outer case. Used EVZIOs should be taken to a healthcare setting for proper disposal in a sharps container.” Since EVZIO also has audio prompts, it also speaks to the user, when it has been deployed, to call 911 for emergency medical attention and instructs the user how to properly dispose of the unit.

Finally, we have information on the kaléo website relating to proper disposal of sharps and prescription medicines including a link to the CalRecycle website which provides specific information on sharps disposal and a county-by-county guide for disposal of sharps in California:

<http://www.calrecycle.ca.gov/HomeHazWaste/Sharps/Household.htm>