

***Kaléo's 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. ("kaléo") 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 plan 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 play an important role in instructing patients on the safe collection and proper disposal of needles.

Kaléo sells EVZIO® (naloxone HCl injection), a take-home naloxone auto-injector, and AUVI-Q® (epinephrine injection, USP), a take-home epinephrine auto-injector. EVZIO and AUVI-Q contain a retractable needle that is designed to eliminate sharps hazards before and after use. The needle is self-contained within the device and is only exposed briefly (less than 1 second) during the activation of the injection. Prior to activation, the needle is completely contained inside the device. After injection, the needle completely retracts into the device, eliminating the sharps hazard.

The EVZIO and AUVI-Q devices address disposal in their respective FDA-approved product labeling and patient instructions. The EVZIO patient information includes:

Put the used EVZIO back into its outer case. Do not throw away the EVZIO in household trash. Do not recycle EVZIO. Used EVZIO should be taken to a healthcare setting for proper disposal in a sharps container.

Similarly, the AUVI-Q patient information includes:

Replace the outer case and talk to your healthcare provider about the right way to throw away your AUVI-Q.

EVZIO and AUVI-Q also have audio prompts that tell the user, after injection, to call 911 for emergency medical attention, and instruct the user in how to properly dispose of the unit.

Finally, kaléo's website contains information related to the proper disposal of sharps and prescription medicines, including the following link to the CalRecycle website, which provides specific information on sharps disposal, as well as a county-by-county guide for disposal of sharps in California: <http://www.calrecycle.ca.gov/HomeHazWaste/Sharps/Household.htm>.