

303 East 17th Avenue

Denver, CO 80203

Colorado's Drug Importation Program

Partner Fact Sheet, February 2024

Colorado's Importation Program is designed to import lower cost prescription drugs from Canada without posing additional risk to public health or safety. The program will work with supply chain partners to ensure access to drugs that will benefit consumers and employers the most—high cost brand name and specialty drugs.

The importation of certain prescription drugs was made possible through a change in federal policy in November 2020. This federal <u>final rule</u> implements a <u>provision of a federal law</u> from 2003 that allows FDA-authorized programs to import certain prescription drugs from Canada to U.S. states. In 2019, the Colorado General Assembly passed <u>SB19-005</u>, which authorized the Colorado Department of Health Care Policy & Financing (HCPF) to seek approval from the federal government to establish an Importation Program (Program) that will provide access to Canada's lower priced drugs for Colorado employers and consumers in the commercial market. Colorado submitted a formal application to FDA on December 5, 2022 and submitted an amended application on February 26, 2024.

Our Partners

To implement Colorado's Program, HCPF has developed a supply chain to support a new marketplace in our state. Each partner has been carefully vetted through numerous interviews, site visits, and assessments conducted by our Program consultants who are experts in different areas of the pharmaceutical supply chain. Each partner was chosen for their willingness to tackle a broken industry where profits are consistently put ahead of patients and their innovative thinking around how to solve these systemic problems.

AdiraMedica LLC, a U.S. wholesaler, and its subsidiary located in Ontario, Canada, will fulfill the role of Colorado's Foreign Seller. The Foreign Seller serves as the primary conduit with Canadian manufacturers. AdiraMedica will purchase eligible drugs for Colorado's Program and ensure they meet specifications for exportation to the United States. AdiraMedica has been in business for 15 years, specializing in supply chain management including import/export for global clinical trials. They are accustomed to working with products that require the utmost care and attention to detail and are well-versed in navigating the exportation process into the United States.

<u>Premier Pharmaceuticals Mid-America, LLC</u>, located in Bowling Green, Ohio, will serve as Colorado's importer. They will be the primary distributor once medications come into the U.S. and will sell the medications to participating Colorado pharmacies. Additionally,



Premier manages key aspects of the Program including partnering with a qualified laboratory and they will relabel products for the Colorado market. They pride themselves on transparency, innovation, and integrity.

Premier has chosen <u>Q Laboratories</u> to be the Program's Qualified Laboratory. Located in Cincinnati, Ohio, Q Laboratories is registered with FDA for pharmaceutical testing and is cGMP/GLP Compliant and ISO/IEC <u>17025 Accredited</u>. They are an independent laboratory with over 50 years of experience. Discussions with a Program Relabeler are ongoing.

Denver's <u>Rocky Mountain Poison and Drug Safety</u> (RMPDS), which has been serving the public since 1956, will be responsible for all FDA required adverse event reporting and will respond to consumer inquiries. One of the leading poison control centers in the nation, RMPDS can fully integrate safety reporting intake processes with many different solutions for pharmacovigilance database and reporting as required by the final rule. The Colorado team of pharmacists and nurses are rigorously trained to ensure they identify and capture appropriate information about any adverse events or product quality complaints.

Additionally, HCPF has developed a team of consultants and supply chain experts who are integral to the success of the Program. Our consultants are experts in federal and state health care policy, FDA policy and importation law, the pharmaceutical supply chain, and laboratory testing and processes.

For more information, contact:

hcpf_005drugimportation@state.co.us Colorado.gov/hcpf/drug-importation

