



COLORADO

Department of Health Care
Policy & Financing

1570 Grant Street
Denver, CO 80203

Colorado Prescription Drug Importation Program

Program Overview and Opportunities

Winter 2021

In light of the COVID-19 pandemic and its unprecedented impact on the Colorado state budget and economy, the state's efforts to rein in prescription drug costs are more important than ever. Prescription drug importation from Canada is one tool the Department of Health Care Policy & Financing (Department) is deploying to address the burden that high drug costs pose to the Colorado health care market. An integral part of the success of this new program will be the participation of wholesalers in both Colorado and Canada that value innovation, seek to create a more consumer-centric pricing model for prescription drugs in Colorado, and tap into new business opportunities.

Program Background

In accordance with [Colorado Senate Bill 19-005](#), the Department submitted a [draft application](#) to the U.S. Department of Health and Human Services (HHS) in early March 2020 to establish a Canadian prescription drug importation program to bring significant reductions in the costs of prescription drugs to Colorado families and employers. We are now in the process of taking next steps to secure vendor partners as required to submit a final application to the federal government.

Colorado's proposed program establishes a framework to allow a Colorado registered importer (wholesaler or pharmacy) to contract with a registered foreign seller (a Canadian wholesaler) to safely import prescription drugs that have been approved by the Food and Drug Administration (FDA) for importation. The Department's preliminary estimate finds that such a program could save Colorado families and employers an average savings of 61% per imported drug.

The state's draft application, or Section 804 Importation Program (SIP), was designed to align with the federal government's [proposed rule](#) for Canadian importation, which provided extensive requirements to ensure the safety of the distribution system. The Department has also released an Invitation To Negotiate (ITN) to solicit vendors to manage the program and distribution of imported drugs. We have been working closely with stakeholders to refine our proposed program and will submit a final application once vendor partners are selected and

Our mission is to improve health care access and outcomes for the people we serve while demonstrating sound stewardship of financial resources.
www.colorado.gov/hcpf



in compliance with the [final rule](#) that is in place. We estimate that a program will be operational in Colorado by mid-2022.

Opportunities for Wholesalers

Partnership with many stakeholders is critical to ensuring Colorado can demonstrate significant cost savings in its application to HHS for a drug importation program. Wholesalers, in particular, have the opportunity to play an important role in supporting the success of an importation program. Our program will task a participating wholesaler (or pharmacy) with bringing prescription drugs into the state of Colorado in compliance with all federal and state regulations, coordinating the testing of these drugs, and eventually distributing them to participating Colorado pharmacies, as laid out in the FDA's final rule. Through our released ITN the Department is seeking proposals from interested wholesalers through the state procurement process.

Wholesalers are invited to submit proposals to serve in one of three vendor roles. The ITN seeks an administrative vendor that will work closely with the Department and other vendor(s) to manage programmatic, compliance and communications aspects of the program which may or may not be a wholesaler. A second vendor, a Foreign Seller, a Canadian wholesaler, will purchase prescription drugs for the Colorado market. A third vendor, an Importer, will contract with the Foreign Seller to facilitate the importation of the prescription drugs into Colorado. An Importer will also manage the drug distribution system in the U.S., which includes ensuring that imported products are tested to meet safety standards through the use of a qualified laboratory, all imported products are appropriately labeled and packaged for the Colorado market, and contracting with Colorado pharmacies to ensure Colorado consumer access to imported products.

Our preliminary analysis has demonstrated significant reductions in costs for many prescription drugs, which accounted for generous markups across the supply chain. We believe this program presents a unique opportunity for wholesalers to tap into a new line of business that will not only allow for additional profit in current business models but achieve lower drug costs for Coloradans.

We look forward to the opportunity to work with partners on the state's importation program to design a strategy that can best meet the needs of Colorado wholesalers, pharmacies, employers, and consumers during this very challenging time.

For information about the bidding process and to view the ITN, please visit Colorado's [Vendor Support Services website](#) and search for Colorado's Drug Importation Program. Please direct any questions to Purchasing and Contracts Specialist, Kate Rusk, at Kate.Rusk@state.co.us. Learn more about our drug importation program at Colorado.gov/hcpf/drug-importation.

