



COLORADO

**Department of Health Care
Policy & Financing**

REQUEST FOR INFORMATION

Core Number: UHAA 2020*13

Drug Importation Questions for Wholesalers

Released: 10/11/2019

**THIS IS A REQUEST FOR INFORMATION (RFI) ONLY
THIS IS NOT A FORMAL BID SOLICITATION.**

NO AWARD WILL RESULT FROM THIS RFI

Modification 1 – Changes in red

1.1. OVERVIEW

- 1.1.1. The Department serves as the Medicaid Single State Agency. The Department develops and implements policy and financing for Medicaid and the Children's Health Insurance Program, called Child Health Plan *Plus* (CHP+) in Colorado, as well as a variety of other health care programs for Coloradans who qualify. For more information about the Department, visit www.Colorado.gov/HCPF.
- 1.1.2. The Department is a covered entity under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (United States Code [U.S.C.] Title 42 Sections 1320d through 1320d-8 [42 U.S.C. §§1320d – 1320d-8]) and its implementing regulations.
- 1.1.3. The Department operates the Colorado Medicaid Program, known as Health First Colorado, in accordance with the Colorado Medical Assistance Act (Section 25.5-4-104, *et seq.*, C.R.S.) and Title XIX of the Social Security Act. Colorado Medicaid is annually funded from appropriations authorized by the Colorado General Assembly and matched by federal funds.
- 1.1.4. The Colorado Health Programs Office (the Office), through the Department of Health Care Policy and Financing, has released a Request for Information (RFI) to assess interest among prescription drug wholesalers, distributors, repackers, relabelers, logistics providers, and importers (collectively, wholesalers) for participation in a wholesale prescription drug importation program from Canada and to receive public comment. Any individual, stakeholder group, vendor, or company is encouraged to offer written comments for consideration. Based on these requirements and comments, the RFI will be refined, finalized, and posted for open competitive bid as an RFP.

1.2. RFI TERMS AND CONDITIONS

- 1.2.1. This RFI is issued solely for information and planning purposes and does not constitute a solicitation. Information about costs and pricing is submitted voluntarily and is non-binding on the respondent. Responses to this RFI will not be considered legal offers nor will they result in an award of any type of contract.
- 1.2.2. The Department is not responsible for any costs incurred by a vendor organization for the development and provision of a response to this RFI.
- 1.2.3. The Department is subject to strict accountability and reporting requirements as a recipient of funds from public sources. Responses to this RFI are subject to disclosure by the Department as required by the Colorado Open Records Act (CORA).
- 1.2.4. The Department reserves the right to copy any information provided by responding vendor organizations for the purposes of facilitating the Department's review of use of the information.
- 1.2.5. The Department reserves the right to use information or ideas that are provided by responding vendor organizations in the vendor's response. By submitting information in response to this RFI, the vendor represents that such copying or use of information will not violate any copyrights, licenses, or other agreements with respect to information submitted.

- 1.2.6. The responses received from this RFI may be used for the development of a future solicitation. Should a solicitation be issued, further details on the solicitation process will be provided.

1.3. PROJECT BACKGROUND

- 1.3.1. The Colorado Department of Health Care Policy and Financing (Department) is soliciting competitive, responsive proposals from experienced and financially sound organizations to assess interest among prescription drug wholesalers, distributors, repackers, relabelers, logistics providers, and importers (collectively, wholesalers) for participation in a wholesale prescription drug importation program from Canada. This project will use this feedback to design the operational details of a future state program.
- 1.3.2. Drug importation is one of many potential strategies to bring down the cost of prescriptions for the American consumer. Colorado Senate Bill 19-005 was signed into law in 2019. The Federal Food Drug and Cosmetic Act (FDCA) Section 804, Congress permits importation and reimportation of prescription drugs from Canada by a pharmacist or wholesaler, provided the drugs meet certain minimum standards and the Secretary of Health and Human Services (HHS) certifies to Congress that implementation of such a program will (A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer. *See* 21 U.S.C. 384. For additional information, [click here](#). This provision is specifically designed to promote importation of drugs to make them available at lower cost to American citizens while not increasing the risks to health and safety that do not already exist within the current drug supply. For additional background about importation, please see the [FDA's Safe Importation Action Plan released 7.31.19](#):
- 1.3.3. The exact role may vary but could entail the following:
 - 1.3.3.1. Establishing a relationship with a Canadian wholesaler
 - 1.3.3.2. Performing or subcontracting for repacking and relabeling
 - 1.3.3.3. Performing or subcontracting for batch testing
 - 1.3.3.4. Record keeping, including pedigree and track and trace obligations
 - 1.3.3.5. Recall management
 - 1.3.3.6. Responsiveness to state audits
- 1.3.4. In pursuit of the aim of creating a Request for Proposal that will attract responsive bidders, the Department is releasing this Request for Information (RFI) in order to elicit assistance from industry leaders in the feasibility of the work, to design the operational details of a future state program.

1.4. VENDOR FEEDBACK

- 1.4.1. The Department is requesting vendors to send any comments or answers, no matter how minor, to the Department. Vendors are encouraged to address the questions listed below.

1.4.2. The Department encourages vendors to submit feedback regarding the RFI as soon as possible. Vendors do not need to wait until ~~October 25, 2019~~ **November 1, 2019** to submit comments. In addition, vendors may have multiple submissions, as not all comments and answers need to be under a single submission. The Department appreciates receiving any and all comments from vendors.

RFI RESPONSES (We encourage answering all questions, however feel free to skip questions you prefer not to answer.)

RFI RESPONSE 1. Would you be interested in contracting with Colorado to provide wholesale importation services from Canada? Why or why not?

RFI RESPONSE 2. What factors would encourage your participation?

RFI RESPONSE 3. What factors would prohibit your participation or decrease your interest in participating?

RFI RESPONSE 4. Do you have locations in Canada?

RFI RESPONSE 5. Do you already purchase medications from Canadian or other foreign sources?

RFI RESPONSE 6. What is the breakdown by percent of your existing volume of maintenance vs specialty medications over the past 12 months?

RFI RESPONSE 7. What parts of electronic track and trace requirements in the DSCSA to be required in the future have you already implemented?

RFI RESPONSE 8. Do you have direct relationships with manufacturers? All manufacturers? No manufacturers? Mix of some manufacturers and other wholesalers?

RFI RESPONSE 9. How would the following potential requirements influence your decision to sign up for a state program? (Please state why you are supportive or opposed to each idea)

- a. **Separate warehouse space for Canadian stock?**
- b. **Creating a separate invoice/file for Canadian drugs?**
- c. **Requirement to obtain a separate license from the state for importation?**
- d. **Equal fee schedule for all pharmacies participating in the importation program**
- e. **Audit of financial records to ensure “substantial cost savings” to the consumer**
- f. **Additional inspections by the state and potentially federal level**
- g. **What other requirements not listed above could be a barrier?**

RFI RESPONSE 10. What payment models would work for you?

RFI RESPONSE 11. Would you be reluctant to participate in a wholesale importation program from Canada out of concern that it could impact your existing contracts with drug manufacturers or expose you to risks of retaliation from opposing market actors?

RFI RESPONSE 12. What other support would you need from the State of Colorado?

RFI RESPONSE 13. What other information do you want to share with the State of Colorado?

1.4.3. Point of Contact

1.4.3.1. The Department’s sole point of contact for this RFI is:

1.4.3.1.1. Nick Severn, Esq.

Department of Health Care Policy and Financing

Purchasing and Contracting Services Section

1570 Grant Street

Denver CO, 80203-1818

(303) 866-3085

RFPQuestions@hcpf.state.co.us

1.5. NOTICES AND COMMUNICATIONS

1.5.1. All official communication with vendor organizations will be via notices on the CORE Web site at <https://codpa-vss.hostams.com/webapp/PRDVSS1X1/AltSelfService>. Vendors can view posted information by clicking on the “Public Access” button. It is the vendor’s responsibility to periodically check the Colorado CORE Web site for notices, changes, additional documents or amendments that pertain to this RFI.

1.6. TIMELINE

1.6.1. The timeline for this RFI is as follows:

ACTIVITY	DATE
RESPONSE SUBMISSION DEADLINE	No later than, October 25, 2019 November 1, 2019 at 11:59 pm, Mountain Time

1.7. RESPONSE FORMAT

- 1.7.1. Submit all responses to the RFI by e-mail to RFPQuestions@hcpf.state.co.us and show the RFI number and title listed in the e-mail subject line.
- 1.7.2. The responses should:
 - 1.7.2.1. Be provided in Microsoft Word and present writing that is self-explanatory on pages that are consecutively numbered in a consistent numbering format.
 - 1.7.2.2. Repeat the numbered 'RFI Response' items from the RFI in bold font with the vendor organization's response in normal font following the 'RFI Response' item.
- 1.7.3. We encourage answering all 'RFI Response' questions, however you are under no obligation to answer all questions and may skip any you prefer not to answer. Answer all RFI Responses in a concise manner.

1.8. TERMS AND CONDITIONS

- 1.8.1. This RFI is issued solely for information and planning purposes and does not constitute a solicitation. Information about costs and pricing is submitted voluntarily and is non-binding on the respondent. Responses to this RFI will not be considered legal offers nor will they result in an award of any type of contract.
- 1.8.2. The Department is not responsible for any costs incurred by a vendor organization for the development and provision of a response to this RFI.
- 1.8.3. The Department is subject to strict accountability and reporting requirements as a recipient of funds from public sources. Any response or other information provided during a demonstration of a product, system or solution is subject to disclosure by the Department as required by applicable law. The Department makes no agreements or representations of any kind, and expressly disclaims any requirement to maintain the confidentiality of any information provided in response to an invitation to demonstrate a product, system or solution. All material and information provided to the Department in response to the demonstration of a product, system or solution shall become the property of the Department upon receipt and will not be returned.
- 1.8.4. The Department reserves the right to copy any information provided by responding vendor organizations for the purposes of facilitating the Department's review of use of the information.
- 1.8.5. The Department reserves the right to use information or ideas that are provided by responding vendor organizations in the vendor's response or product, system or solution demonstration. By agreeing to demonstrate its product, system or solution the vendor represents that such copying or use of information will not violate any copyrights, licenses, or other agreements with respect to information submitted or product, system or solution demonstrated.