

Appendix I: Importer Stakeholder Engagement



Request for Information - Pharmacy Questions

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. For additional background about the Colorado bill, please see the bill in its entirety [here](#):

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](#):

Purpose:

The primary goal of this Request for Information (RFI) is for Colorado to assess interest among pharmacies whether they would consider participation in a prescription drug importation program from Canada. Colorado will use this feedback to design the operational details of a future state program. We encourage answering all questions. However, feel free to skip questions you prefer not to answer.

Pharmacy compensation:

The current price differential between US and Canadian wholesale acquisition costs for drugs that are likely to be favored for importation is large. For pharmacies considering pursuing this importation opportunity, savings were achieved including the assumption of a mark-up on the Canadian wholesale acquisition costs. Though it will be up to Colorado to determine allowable profit margins during contracting, the significant price differential allows for consumers to capture substantial savings while the pharmacies capture positive margins.

1. What are your general thoughts on importing drugs from Canada or another country?
2. What positive outcomes could result from foreign drug importation?
 - a. For consumers?
 - b. For businesses?
3. What factors would prohibit your participation or decrease your interest in participating?
4. What drugs would you like to see included in Canadian importation? (Excluded drugs include controlled substances, biological products, infused drugs, intravenously injected drugs, drugs inhaled during surgery, and certain parenteral drugs). Please explain your reasoning for each drug/drug class



5. What specific recommendations do you have to ensure safety as required by federal law?
6. What payment models would work for you?
7. 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 shelf space for Canadian drug stock
 - b. Separate file for Canadian drug invoices
 - c. Separate file for Canadian drug hard copies
 - d. Additional inspections by the state and potentially federal level
 - e. Obtaining a separate license for importation
 - f. Using a separate wholesaler just for Canadian drugs
 - g. What other potential requirements would influence your decision?
8. What are your thoughts on limiting distribution of Canadian imported drugs to a defined set of pharmacies or a single pharmacy, for example, a mail order only option?
9. What other support would you need from the State of Colorado?
10. What other information do you want to share with the State of Colorado?



Request for information Wholesaler Questions

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Wholesaler role:

The exact role may vary but could entail the following:

- Establishing a relationship with a Canadian wholesaler
- Performing or subcontracting for repacking and relabeling
- Performing or subcontracting for batch testing
- Record keeping, including pedigree and track and trace obligations
- Recall management
- Responsiveness to state audits

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Questions:



1. Would you be interested in contracting with Colorado to provide wholesale importation services from Canada? Why or why not?
2. What factors would encourage your participation?
3. What factors would prohibit your participation or decrease your interest in participating?
4. Do you have locations in Canada?
5. What is the breakdown by percent of your existing volume of maintenance vs specialty medications over the past 12 months?
6. Do you already purchase medications from Canadian or other foreign sources?
7. What parts of electronic track and trace requirements in the DSCSA to be required in the future have you already implemented?
8. Do you have direct relationships with manufacturers?
 - a. All manufacturers
 - b. No manufacturers
 - c. Mix of some manufactures and other wholesalers
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?
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 - d. Audit of financial records to ensure “substantial cost savings” to the consumer
 - e. Additional inspections by the state and potentially federal level
 - f. What other requirements not listed above could be a barrier?
10. What payment models would work for you?
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?
12. What other support would you need from the State of Colorado?
13. What other information do you want to share with the State of Colorado?



Drug Consumer Importation Survey

Responses Question 1: Please select all that apply:

	Number of Response(s)	Response Ratio
I purchase prescription drugs for myself or someone else.	25	64.1%
I am a physician, nurse, or other health care provider who has direct contact with patients.	5	12.8%
I am a pharmacist.	6	15.3%
I work in health care in an administrative capacity.	7	17.9%
I am a stakeholder.	7	17.9%
I am a lobbyist, lawmaker, or policy maker.	4	10.2%
Other	8	20.5%
Total	39	100%

"Other" responses include:

- Healthcare policy consultant
- Consumer advocate
- I am a former pharmaceutical industry analyst
- Family member used Canadian pharmacy
- Insurance Broker
- I am a volunteer lobbyist
- Insurance Broker
- Consultant

Question 2: Please explain your interest in a Canadian drug importation program.

reduce costs for high-cost diseases such as certain cancers, to avoid the health effects of "financial toxicity." High drug costs result in patient noncompliance or dropout from therapeutic regimens, resulting in unnecessary morbidity and mortality.

The National MS Society is committed to stopping MS in its tracks, restoring what's been lost, and ending MS forever. Until that happens, we help people living with MS live their best lives. Evidence shows that early and ongoing treatment of MS with a disease modifying therapy is the best way to prevent disability in the brain and body. However, these MS drugs are exorbitantly expensive. The first drug came to market at approx. \$10,000 a year- that same drug, no changes to formula, is now over \$80,000 a year. People with MS struggle to afford these life changing drugs, which can literally be the difference between walking and using a wheelchair. The National MS Society has no position on Canadian Importation and neither supported nor opposed SB19-005. However, we are interested in seeing how this program can bring relief to people living with MS in terms of lowering drug costs.

cheaper prices, less finagling with insurance copays and coinsurance



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Competition from Canada, like any threat to the market, should bring down prices for all consumers as well as for public programs paid for by the taxpayer.

Lowering premiums.

would like to see any program that would help reduce cost

It feels like the Pharma charges prices that aren't justified and beyond the scope of doing business.

Worried about drug re-labeling and FDA's ability to oversee in cases of drug adverse effects.

I would like to understand what is possible from a legal and logistics point of view, the savings a program would be expected to achieve (both for the State and for consumers), and what response the State anticipates will come from the Federal government, industry and the domestic supply chain. I hope to be helping develop policy for Colorado, and this is information germane to my interests.

Anything we can do to keep medicine affordable is a good thing. Also with the large profits pharmaceutical companies make it doesn't seem fair to the people, these companies do have the ability to do research and provide medicines at affordable rates, they choose not to. Maybe more competition will help even out our market. Plus I'm also in support of price transparency so consumers can make educated choices i have concerns with quality control issues that may arise from importing medications. i do not believe it is possible to have qualified oversight necessary to ensure safety and ingredients

Our health-system is currently opposed to general importation of drugs from Canada due to concerns with logistics, costs of importation, safety, and overall feasibility given the limited supply of drugs in Canada. In addition, these drugs may not comply with NDC standards and will not be available in drug databases (FDB, Medispan, etc.) to allow for appropriate charging & drug interaction checking.

In cases where US approved product is not available, we would support importation. However, we do not support importation based solely on cost and strongly recommend that cost/contracting issues be addressed with a cost/contracting strategy."

Not interested

I like the lower cost option.

I'm skeptical as to whether or not this will work. The pharmaceutical companies will just reduce the supply into Canada to drove prices back up.

My regular birth control (Seasonique) is incredibly expensive in Colorado, and I cannot take generic (it messes up my body too much).

When living in Boston, MA, I belonged to a community health center which participated in the Federal 340B drug pricing program. The difference in price (cash pay) - \$50 in Boston, \$450 in Colorado for the same drug. This is a huge cost savings due to negotiation, so I can only assume what the price would be for the Rx if imported from Canada.



My interest is both professional and personal. I have several medical conditions that require me to be on medications to maintain my health and quality of life. Recently I was prescribed a medication that is still hundreds of dollars a month even with my private insurance. This is not an option for me so I have to go without. I'm not sure how sustainable this decision is. But I have no choice. That is one example of how prescription drug prices impact my life and health. I also am a psychotherapist and work with clients that have to choose to pay rent, buy food, pay utilities, pay medical bills etc. over getting a prescription they need. Unfortunately having to forego taking a medication keeps my clients sick. Both physically and mentally. We need help. We need a better way.

Families, and individuals, across Colorado are cost-burdened with the high cost of medication... especially for diabetes, stroke prevention, and cancer treatment. Recommend Canada to some of my Medicare clients and they have found Canada a viable option.

None I do not want to Canadian drugs. If industry and the Government can not come to some agreement then we should not go to other countries for supplies

Most of the cost of medicine is paid for through our taxes several of the drugs were developed at NIH A lot of the cost of the drugs we buy goes to pay for advertising, lobbying in DC and local government. So many people as they get older have to choose between their medicine or food. There is just too much greed and waste in this country

I need for life lengthening and life saving drugs to be available, safe and within the payment ability of all of those who need them.

Some of these drugs are manufactured in the US and shipped to Canada. To solve the problem by then purchasing from Canada and shipping back to US seems a very convoluted way to solve a problem that resides here in the US.

Seems like a way for politicians to avoid solving this directly here at home in an attempt to avoid loss of donations by big pharma"

I am actively involved in all matters related to bringing down the cost of care.

Put pressure on Big Pharma to behave in consumer interest.

People are having difficulty purchasing prescription drugs because of cost. Canadian drugs are more reasonable. People living on Social Security cannot afford needed drugs in the U.S. where pharmaceutical companies are out of control. We need to find a solution, and importation would be a first important step.

I want to purchase cheaper drugs

It is important to lower the increasingly high cost of prescription medications so everyone can afford the treatments they need. Most of the US pharmaceutical manufacturers have plants in Canada. FDA inspects these plants as the US pharma imports from Canada and sells here or labels for export. Thus I believe Canadian drugs are safe. The current problem with carcinogens in some products are not from Canadian sourced prescription drugs. If this action encourages the US HHS to formulate regulations for direct importation, we could broaden the scope and use any FDA approved product source in our effort to lower prices.



Well...I need a prescription for Xifaxin and it costs 1600 for a 2nweek treatment...300 from Canada. My daughters epi pen was over 300. I have patients everyday that without.

If it can be safe and efficient, it would disrupt the current system that gives drug companies too much power. That could have both positive and negative impacts, but would change the dynamics of policy and negotiations.

Drug prices are a huge burden on our communities. It's unfair that we are mandated to bear such a burden when our neighbor to the North has better options.

why reimport meds that are already available in America. I struggle to understand why drug companies sell to other nations at such reduced prices and charge extremely high prices to Americans...?

If market share is what these companies seek, sell at the same AWP worldwide.

At this point Americans are subsidizing other nation's health care costs as well as our own which is completely unfair.

The result is people are not compliant with their medication regimens and health care costs accelerate as a result.

It would certainly drive the cost of prescriptions downward a little bit and help to reduce the cost of health insurance including the federal government's cost of Medicare and Medicaid insurance which would help us all in the long run.

Save my patients money on certain prescription drugs and possibly make a profit for a change.

I do not understand the point of the entire industry jumping through the hoops to comply with the DSCSA track and trace laws just to allow people to get their drugs from another country outside of the US supply chain.

I am interested in a short term project centering around a pharmaceutical issue. I am very interested in the Canadian Prescription Drug Importation legislation. I am a pharmacist with experience as Director of Pharmacy for BCBS of Wyoming, Vice President of Sales for Prime Therapeutics (PBM), Perform Cost Management (PBM). Vice President of Sales for ComCoTec (Prescription Processing software). Owner of Haraseks Pharmacy in Berwyn Illinois. Pharmacy Manager Banner Health Greeley Colorado. I would like to focus on a single project like Canadian Drug Importation. A project of one year or less would be ideal. I can work as a contract employee. Can you direct me to the appropriate person or agency?

As a matter of public health, access to prescription drugs is very important to the population. Not all individuals are able to afford the prescriptions that they need, therefore they place not only themselves, but others around them at risk for increased illness. Many individuals are forced to choose between putting food on their tables or taking necessary medications, thus the high costs of prescription drugs contributes to nutritional deficits that can lead to increased illnesses. Reducing prescription drug costs will help increase access and ultimately lead to a healthier population.

I am curious to see if it will actually help patients. The drug industry has been aggressively raising prices and entering into exotic lobbying arrangements for years in order to unethically extort patients and public entities. I am hopeful this will present an actual threat to these practices.



The current state of the prescription marketplace in Colorado is oligopolistic and profit-driven. The exorbitant prices paid for prescription drugs in this country is an outrage. This needs to change. We need additional sources of supply, and we need actors who are not driven by profit. This law is a good step in that direction.

Question 3: I think the quality and safety of drugs imported from Canada would be:

	Number of Response(s)	Response Ratio
More safe	2	5.1%
Less safe	5	12.8%
The same	25	64.1%
I'm not sure	7	17.9%
No responses	0	0.0%
Total	39	100%

Question 4: Tell us what you would expect from a Canadian prescription drug importation program.

Lower prices.

The ability to acquire therapeutically equivalent drugs at a significantly lower cost. cheaper prices, less finagling with insurance copays and coinsurance

Have every belief that Canada exercises the same oversight over pharmaceuticals as the U.S. does through the FDA. Quality would remain the same. US residents would not be prompted to go across the border and purchase expensive medications and bring them back to the U.S. as is happening now, even though technically against the law.

I would expect more open market in Canada to have an effect on US drug prices by bringing them down.

assurance that the medications were equal want to was available domestically.

An easy process for patients to obtain medications via mail

Lower costs

Tampering

For cash pay customers, the cost of drugs obtained in Canada ought to be lower. If Colorado is the only state (or one of just a few) to engage in a formal importation program, it's possible supply/access would be reliable. However, I believe manufacturers would respond by restricting supply to Canada as well as upping the paperwork quotient for persons obtaining pharmaceutical products (especially those in the "specialty" category) while covered by health insurance. I worry that important customer service functions will be impacted adversely as well. If there's a side effect and the lot is Canadian, how will the manufacturer work with the patient, physician and FDA to remedy the situation?

I would expect a third choice at the pharmacy: name brand, generic or imported or something similar to that.



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People are having difficulty purchasing prescription drugs because of cost. Canadian drugs are more reasonable. People living on Social Security cannot afford needed drugs in the U.S. where pharmaceutical companies are out of control. We need to find a solution, and importation would be a first important step.

I want to purchase cheaper drugs

It is important to lower the increasingly high cost of prescription medications so everyone can afford the treatments they need. Most of the US pharmaceutical manufacturers have plants in Canada. FDA inspects these plants as the US pharma imports from Canada and sells here or labels for export. Thus I believe Canadian drugs are safe. The current problem with carcinogens in some products are not from Canadian sourced prescription drugs. If this action encourages the US HHS to formulate regulations for direct importation, we could broaden the scope and use any FDA approved product source in our effort to lower prices.



Well...I need a prescription for Xifaxin and it costs 1600 for a 2nweek treatment...300 from Canada. My daughters epi pen was over 300. I have patients everyday that without.

If it can be safe and efficient, it would disrupt the current system that gives drug companies too much power. That could have both positive and negative impacts, but would change the dynamics of policy and negotiations.

Drug prices are a huge burden on our communities. It's unfair that we are mandated to bear such a burden when our neighbor to the North has better options.

why reimport meds that are already available in America. I struggle to understand why drug companies sell to other nations at such reduced prices and charge extremely high prices to Americans...?

If market share is what these companies seek, sell at the same AWP worldwide.

At this point Americans are subsidizing other nation's health care costs as well as our own which is completely unfair.

The result is people are not compliant with their medication regimens and health care costs accelerate as a result.

It would certainly drive the cost of prescriptions downward a little bit and help to reduce the cost of health insurance including the federal government's cost of Medicare and Medicaid insurance which would help us all in the long run.

Save my patients money on certain prescription drugs and possibly make a profit for a change.

I do not understand the point of the entire industry jumping through the hoops to comply with the DSCSA track and trace laws just to allow people to get their drugs from another country outside of the US supply chain.

I am interested in a short term project centering around a pharmaceutical issue. I am very interested in the Canadian Prescription Drug Importation legislation. I am a pharmacist with experience as Director of Pharmacy for BCBS of Wyoming, Vice President of Sales for Prime Therapeutics (PBM), Perform Cost Management (PBM). Vice President of Sales for ComCoTec (Prescription Processing software). Owner of Haraseks Pharmacy in Berwyn Illinois. Pharmacy Manager Banner Health Greeley Colorado. I would like to focus on a single project like Canadian Drug Importation. A project of one year or less would be ideal. I can work as a contract employee. Can you direct me to the appropriate person or agency?

As a matter of public health, access to prescription drugs is very important to the population. Not all individuals are able to afford the prescriptions that they need, therefore they place not only themselves, but others around them at risk for increased illness. Many individuals are forced to choose between putting food on their tables or taking necessary medications, thus the high costs of prescription drugs contributes to nutritional deficits that can lead to increased illnesses. Reducing prescription drug costs will help increase access and ultimately lead to a healthier population.

I am curious to see if it will actually help patients. The drug industry has been aggressively raising prices and entering into exotic lobbying arrangements for years in order to unethically extort patients and public entities. I am hopeful this will present an actual threat to these practices.



The current state of the prescription marketplace in Colorado is oligopolistic and profit-driven. The exorbitant prices paid for prescription drugs in this country is an outrage. This needs to change. We need additional sources of supply, and we need actors who are not driven by profit. This law is a good step in that direction.

Question 3: I think the quality and safety of drugs imported from Canada would be:

	Number of Response(s)	Response Ratio
More safe	2	5.1%
Less safe	5	12.8%
The same	25	64.1%
I'm not sure	7	17.9%
No responses	0	0.0%
Total	39	100%

Question 4: Tell us what you would expect from a Canadian prescription drug importation program.

Lower prices.

The ability to acquire therapeutically equivalent drugs at a significantly lower cost. cheaper prices, less finagling with insurance copays and coinsurance

Have every belief that Canada exercises the same oversight over pharmaceuticals as the U.S. does through the FDA. Quality would remain the same. US residents would not be prompted to go across the border and purchase expensive medications and bring them back to the U.S. as is happening now, even though technically against the law.

I would expect more open market in Canada to have an effect on US drug prices by bringing them down.

assurance that the medications were equal want to was available domestically.

An easy process for patients to obtain medications via mail

Lower costs

Tampering

For cash pay customers, the cost of drugs obtained in Canada ought to be lower. If Colorado is the only state (or one of just a few) to engage in a formal importation program, it's possible supply/access would be reliable. However, I believe manufacturers would respond by restricting supply to Canada as well as upping the paperwork quotient for persons obtaining pharmaceutical products (especially those in the "specialty" category) while covered by health insurance. I worry that important customer service functions will be impacted adversely as well. If there's a side effect and the lot is Canadian, how will the manufacturer work with the patient, physician and FDA to remedy the situation?

I would expect a third choice at the pharmacy: name brand, generic or imported or something similar to that.



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the same scrutiny as medications allowed within US

We are generally opposed to importation due to the complex logistics. I would support a program when drugs are on shortage in the US. Ideally, these drugs would be available through our standard wholesalers and distribution channels to minimize the potential for diversion and adulteration.

Not interested

Monitored.

I would expect it to bring additional competition to the market, more reasonably priced prescription drugs and a safe option to Colorado.

To begin, Timeliness and education.

Lower cost and potentially increased selection.

There are companies in Canada that people can currently use to fill their prescriptions. Expanding the education of state side clients could prove to a cost savings for everyone and PBM's companies would have to learn to accept they need to become competitive to stay in business.

No I am not in favor

I would expect the program to start with some of the most prescribed drugs high blood pressure, simvastatins, depression medicine, if all goes well then slowly expand the program to include more medications

Please see #2 above. I would expect that we proceed in full agreement with Canada. I don't think it is wise to move forward without Canadian (policy makers and general population) agreement.

The program should provide protections to physicians and other clinicians from lawsuits that could stem from supply chain, quality, and safety issues.

The buyer of the medications should have a choice and be well informed from where the medications originate. Once the information obligation has been met then responsibility is transferred to the buyer/patient since they are making an informed choice.

Hopefully lower prices without sacrificing quality and safety.

Lower costs directly from Canada and pressure on Big Pharma.

Lower costs for people of all ages. Relief for parents of children who have diabetes and other life-threatening diseases.

cheaper drugs

Colorado would be able to offer considerable savings to patients for some medications that are 40-60% cheaper in Canada than in the US. I would expect a Board, a State office and a contractor to ensure that the products are FDA approved, purchased from a reliable source and that state-wide pharmacies could provide savings to their pockets as well as to consumers.

Cheaper prices

Lower costs

No impacts on access

Equivalent or better safety than current system

Flexibility for policy discussions



Consideration of impacts on US pharmacies, especially in small, rural, or underserved communities

Cheaper prescriptions that sent to my home

Nothing. Keep the products here so that the consumer can be confident in pedigree, no tampering or storing meds in poor conditions - either in actual storage (climate control) or transporting.

Most of it would be run through mail order programs of course.

Be able to buy and dispense brand name medication below current wholesale costs.

It's going to complicate things more in the US. I do not understand how Canada would be able to sustain all the extra products being shipped out of their country to the US. How will DEA regulate for controlled substances?

Competition for U.S. pharmaceutical companies and lower costs to the consumer.

I hope the state will choose the classes of drugs that have seen the greatest increases in price without new innovation, such as insulins, doxycycline or other ancient drugs that have seen absurd price increases. Then purchase vast quantities, return those to retail in the state and depress the price of similar medications. Drug companies function as cabals and hide behind claims of innovation and caring for patients, by targeting older drugs with inflated prices the state can both save lives and lay bare industry lies.

Lower prices for the identical or chemically identical product.

Question 5: How many prescriptions does your household purchase each month?

8 - 10

People living with MS may use upwards of 10 symptom management drugs in addition to a disease modifying therapy.

6

8

1

2

2

8

2-3

2-3

11

2

5

2

0

I purchase one. I have cut back on others due to the cost.

6 approx

5

None

4



Eight per month

5

2

3

2

Seven.

6

one

2

6

4

none due to the cost

4

N/A

2

12

2

It's around 7 different products.

Question 6: How much does your household pay each month for prescription medicine?

\$100 more or less

People living with MS pay anywhere from \$200-\$3000 per month for their prescriptions.

\$100

approx \$70

\$8

100

\$100+

\$80

\$100

Not a huge amount but I have paid over \$100 for antibiotics in the past and that is a terrible burden when you are already sick and choice would help.

\$200

\$5 - Our drugs are very cheap - \$1-2 per prescription typically....

\$100

\$25.00

0

I am currently lucky that after 4 months of appeals, phone calls, and paperwork, my insurance company now covers part of the cost of my RX, so \$20/month.

\$100 aprox

369

Nothing

Insurance and co pays



I am Medicare so I have reached catastrophic cost by March

About \$80

100

Under \$30

\$15

We are very fortunate because my husband who is disabled vet gets his medications from the VA. We pay about \$80 a month on average.

\$400

\$15

200

usually about \$50, but one drug (intermittently filled) can cost upwards of \$100 per month alone

\$180

we would pay over \$2,500 in unreimbursable cost or pay exorbitant premiums to cover these meds.

450

Business purchases \$150,000 per month for resale.

20

\$75-\$100 as co-pays to medical insurance. We are among the lucky ones that can afford good health insurance coverage.

\$8

After insurance coverage, somewhere in the range of \$400.

Question 7: How much does your most expensive prescription cost?

During my spouse's bouts with cancer, we often faced COPAYS of \$600 / week

Some people living with MS have a 40% coinsurance, meaning their therapy can cost \$2500 a month.

\$27

\$20 for 90 days

\$8

60

\$100/month

\$10 (with insurance.)

\$100/mo.

The cozy fluctuates with insurance and that is a separate and equally problematic issue. If not for chp I would not be able to afford my sons asthma medicine

"cost to me: \$35

actual cost \$1,200"

\$3

\$25

\$35.00

0



\$450 for 3 months at full retail price in Colorado (which I would be paying if I didn't convince Anthem to cover it).

\$250

280

50.00

The most expensive drug cost is 7246 dollars. Per month.

New prescription is \$50 out of pocket. Retail price is \$600, at least that is what is printed on the packaging.

50

\$15

\$15

\$60 copay

\$350/month

Epipen for \$148/year OOP, after deductible or \$370 if deductible not met.

The antibiotic I need is \$1600

when filled, \$80-100/month, per above, but routinely \$20-25/month.

\$180

\$1,800 for biologicals

200

N/A

Not sure due to my copay costs

Without insurance coverage, the most expensive prescription would cost just over \$600 per month.

\$4

Several thousand dollars before insurance, for a three-month supply.

Question 8: What's the most you have ever had to pay out of pocket for a prescription drug?

\$600 per dose for Neupogen

\$2500/month on the extreme end.

\$189

\$45

\$70

200

none of our prescriptions are covered in our drug plan, so we plan full price

\$90

\$100/mo.

Something around \$100

\$50

\$40

\$80

Over \$100.00.

500



\$450

I cant remember

480

Can't recall

Yes

\$2578 dollars, I am still paying on that charge card for this years first months co pay for it. I will have to add 2020 first months on to the same charge card it charges me 28% interest.

As far as I remember, this new drug at \$40 is the most expensive one that I paid for. I did not fill the one with a co-pay of \$200.

1000

A couple hundred.

\$100

\$60

\$350

\$370

Trying not to pay the above. Epi pens 430

\$100

\$675

\$1,800

600

N/A

125.00

\$435.

\$50-60

One time I had to pay full retail for one of these extremely expensive drugs, something like \$30 or more per DAILY DOSAGE.

Question 9: What type of pharmacy do you use today? Please select all that apply.

	Number of Response(s)	Response Ratio
Chain drug store (Walgreens, CVS, Rite Aid, etc.)	21	53.8%
Independently owned pharmacy	7	17.9%
Grocery store pharmacy (King Soopers, City Market, Safeway, etc.)	13	33.3%
Kaiser Permanente (outpatient or mail order)	6	15.3%
Mail order	11	28.2%
Hospital outpatient (Denver Health, UCHHealth, Children's Hospital, etc.)	3	7.6%
I get samples from my doctor	3	7.6%
Other	3	7.6%



Total 39 100%

Question 10: How important is it for you to be able to continue using the pharmacy you use today for all of your prescriptions?

Top number is the count of respondents selecting the option. Bottom % is percent of the total respondents selecting the option.					
	I Don't Care	Not Important	Neutral	Important	Very Important
	5	7	12	9	5
	13%	18%	32%	24%	13%

Question 11: Would you be willing to change where you get your prescriptions if it meant you could purchase cheaper Canadian drugs?

	Number of Response(s)	Response Ratio
Yes	22	56.4%
No	9	23.0%
I'm not sure	7	17.9%
No Responses	1	2.5%
Total	39	100%

Question 12: Would having a choice of pharmacy influence your decision whether to purchase Canadian imported drugs? Please explain your answer.

	Number of Response(s)	Response Ratio
I want to be able to choose my pharmacy	10	25.6%
I don't care what pharmacy I use	16	41.0%
I'm not sure	12	30.7%
No Responses	1	2.5%
Total	39	100%
17 Comment(s)		

Comments include:

I don't understand the question.

Pharmacies are irrelevant to me. I use goodrx.com as drug/price vetting comparison site to see who is charging what for a drug. Apps and online access to information is what is now key to drug purchases, not pharmacies.



Ours are only oral meds. For brand, the pharmacy is just a distribution node. For generics, the manufacturer can be important, but we monitor that.

I'd be willing to change my pharmacy but I don't want to go to a pharmacy that I feel takes advantage of people like Walgreens or to king Soopers who has the worst customer ser Also what would systems like kaiser do? They don't give their members a choice and I would hope if it saved the people money they would have to participate.

not likely to purchase Canadian imported drugs

I may avoid pharmacies that preferably import Canadian drugs due to cost only.

Choice is always good.

With different insurance plans over my lifetime, I have been bounced around among many different pharmacies/mail order options. If you wanted your Rx, you did what the insurance company says.

Would US pharmacy's control the use of Canadian pharmacy's, if so then the process could become a very cumbersome mess. Clients could become confused, frustrated and discouraged, not wanting to use the program.

As I ride the bus, it needs to be somewhere I can get to easlily

My concern is that the drugs be quality drugs, safe, affordable and available.

Just as long as the drugs are as safe as US drugs.

Since we live in a rural area, the choices are limited. However, we could drive which is fine now, but question is will it always be okay.

I would be willing to use mail order for a 90 day supply of my current medication, assuming the source is reliable and considers shipment time for keeping me stocked. For acute care needs, I'd like to go to the closest and cheapest location that I can purchase my prescription.

There is some value to convenience. We don't pay huge amounts, so the savings may not be worth the hassle of less convenient access.

Some medications laying in the mailbox can be frozen or become damaged

Choice of pharmacy is not my first concern. Affordability and quality are primary, area proximity to pharmacy is secondary.

Question 13: If Canadian imported drugs were only available through a mail order pharmacy, would you be willing to switch if it meant those drugs were less expensive?

	Number of Response(s)	Response Ratio
Yes	21	53.8%
No	9	23.0%
I'm not sure	8	20.5%
No Responses	1	2.5%



Total

39

100%

Question 14: Do you have anything else you would like to share with us regarding a Canadian prescription drug importation program?

Canadian drug importation should look for the most bang for the buck. Vermont made a list of the most expensive drugs to the consumer, to employers (in self-insured health plans) and to the taxpayer (for Medicaid and other public programs).

Clearly there needs to be some reason/advantage for Canadian wholesalers to sell to the U.S., in the way of expansion of their markets as well.

Drugs become more of a commodity sale, like generics are, than a branded drug.

Absolutely the ludicrousness of on TV ads from drug companies, spending huge amounts of our precious health care dollars on marketing, needs to be stopped. And let's stop it by importing from Canada.

Interestingly, the Consumer is not very influenced by brands, as they most undoubtedly will be by their premium and out of pocket costs.

Do it

thanks for all you are doing to try to bring down the cost of health care in colorado Really hope this doesn't happen.

Personally, I believe that there are far more sustainable programs Colorado could consider to alleviate the cost pressures we face v/v Rx.

I think we need to be careful to be respectful of Canada and their health system and I would like to know why their drugs are so much cheaper, maybe we need to look into some significant system changes.

While there may be a limited role for importation during shortages, I generally feel importation is a work around that is not solving the key issue which is primarily a cost and contracting problem. Canada has limited resources and interested in participating in importation programs due to the concerns with supply, cost, and logistics. I strongly suggest that government agencies pursue expansion of 340B and other discount/contracting programs to address the issue of cost. Please refer to the ASHP statement on drug importation for additional concerns related to importation.

After my mother passed, it was very hard to discontinue services from Canadian pharmacy. It seemed at though we were put on unnecessary holds on the phone, lasting for over an hour.

Hell Yes please go for this!

As a health insurance agent I listen to client express their concerns of the cost of prescription medication. This becomes more of a concern for those clients on Medicare, as doctors continue to prescribe more new expensive medication and the client is making some very interesting decisions regarding their medications.

Just get it done, please.

I have used a mail order pharmacy before. For me it was not convenient and felt less reliable than going to my corner pharmacy.

mail order pharmacies have been problematic for some of my patients due to delayed delivery and disagreement between insurance and pharmacy as to # of months supplied.



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Safety and quality are very important. If Canadian drugs are not as safe or have the same quality, I would not put safety and quality over cost.

let all pharmacies do this! don't limit it.

I would like to see transparency on costs and the process. I am concerned that politics might interfere with successful execution of the program once HHS Sec approval and regulations are achieved. I would like visible accounting of the drugs selected and the average cost savings.

Get on it!

Only allow independent pharmacies to dispense them.

How can we be sure that the medications are not going to be counterfeit?

My spouse and I have both good and bad experiences with mail-order pharmaceuticals.

The answer to question #13 would have to depend upon the mail-order pharmacy policies and procedures, and comparative local pharmacy choices.

My particular prescriptions are inexpensive. I am more concerned for my patients, and society in general.

Mail order pharmacies are problematic, as there is no real connection between the pharmacist and the customer.

Colorado's Drug Importation Program

January 10, 2023



Webinar Rules

Due to the large number of attendees, all lines will be muted for the duration of the webinar. If you have questions, please type them into the Q&A box. We'll read out loud and respond to as many questions as possible.

Agenda

- Program background
- Federal requirements
- Cost savings analysis
- Supply chain overview and partners
- Oversight and compliance
- Consumer support and education
- Next steps

Legislative & Regulatory Background

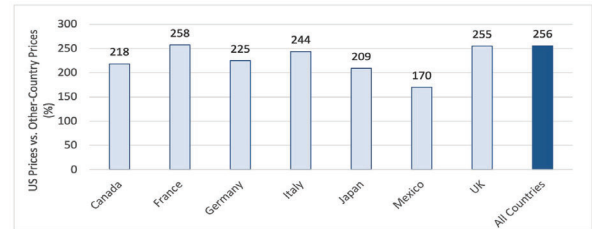
- Medicare Modernization Act of 2003
 - Amends Section 804 of the Federal Food Drug and Cosmetic Act (FDCA) to: Permit the importation and reimportation of prescription drugs from Canada by a pharmacist or wholesaler, provided the prescription drugs meet certain minimum safety and quality standards
- Colorado Senate Bill 19-005 - 2019
 - Authorizes HCPF to apply to HHS to implement an importation program
- Final Rule went into effect November 2020
 - States can begin applying to the FDA to operate state-led importation programs

Colorado's Importation Program - General Timeline



Why Importation?

Figure S.1. U.S. Prescription Drug Prices as a Percentage of Prices in Selected Other Countries, All Drugs, 2018



Source: Rand Corporation, January 2021, <https://www.rand.org/news/press/2021/01/28.html>

Why Importation?

- Increasing health care affordability, including lowering drug costs, is a top priority for Governor Polis
- Retail drug spend totals \$5 billion in Colorado and prescription drugs account for 19% of total health care spending
- Nearly one in three Coloradans do not take their prescription drugs as directed because they simply cannot afford to.

Canadian importation is one lever that can help to address high drug costs in our state

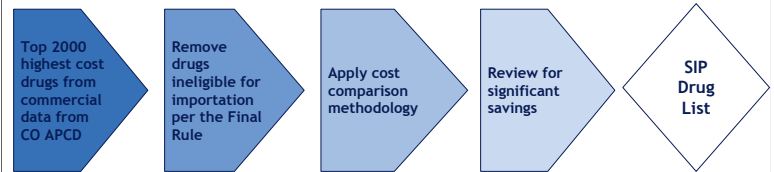
Importation is an Opportunity

- Creation of a new marketplace
- Increase transparency for drug pricing
- Partnering with manufacturers, health plans and PBMs

Program Requirements

- State Importation Plan (SIP) Sponsors must obtain federal approval to operate a Canadian prescription drug importation program.
- A SIP sponsor's detailed application to FDA must include:
 - Names/details of all partners in the supply chain,
 - List of drugs intended for importation (and related details)
 - Analysis of cost savings, and
 - Demonstration of compliance with federal safety rules/standards
- SIPs will be approved for 2 year terms, with the option to request extensions from the FDA.

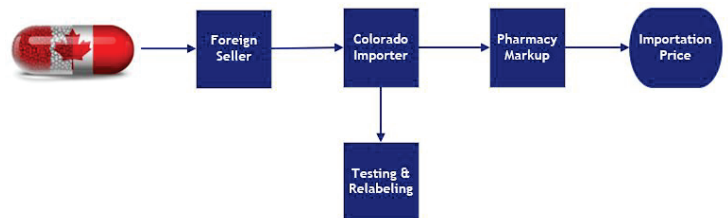
SIP Drug List Methodology



Eligible Drug Requirements

- Drugs must be:
 - Approved by Health Canada's Health Products and Food Branch
 - The same as an FDA-approved drug in the United States
- Excluded drugs include:
 - FDCA: intravenous, infusion, controlled substances, biologics, drugs inhaled for surgery
 - Importation Final Rule: REMS, intrathecal, and intraocular

Colorado Importation Price



SIP Drug List

- Wholesale importation program targeting the commercial market.
- Aspirational drug list and cost analysis for SIP includes:
 - 112 unique drugs and dosages
 - 80% brand, 20% generic

Cost Savings Summary

Drug Category	Number of Unique Drugs	% Savings
Anaphylaxis	4	24%
Antipsychotic	4	91%
Blood Thinners	6	73%
Cancer	18	56%
Dry eyes	3	59%
HIV	10	53%
Low Blood Sugar	3	54%
Multiple Sclerosis	6	64%
Respiratory	28	66%
Smoking Cessation	4	80%
Type 2 Diabetes	12	78%
Women's Health	6	62%
Miscellaneous Classes	8	69%

Colorado Department of Health Care Policy & Financing, 2022

Price Comparisons for U.S. and Canadian Brands and Generics				
Name	U.S. Brand	U.S. Generic	Imported Brand	Imported Generic
Nuvaring	\$142.71	\$92.01	\$14.11	\$14.11
Ventolin	\$54.00	\$25.97	\$6.75	\$5.63
Chantix	\$8.35	\$7.50	\$1.93	\$1.04

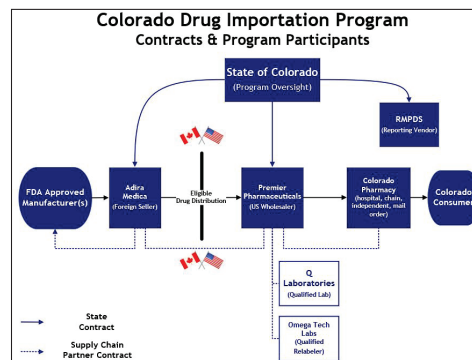
Colorado Department of Health Care Policy & Financing, 2022.

SIP Overview: Cost Savings

Colorado Drug List Savings Summary by With Market Replacement Estimates 2022 Colorado SIP Drug List (112 Unique Drugs)				
Market Replacement Percentage	Colorado Annual Drug Spend in the Commercial Market	Estimated Annual Importation Spend	Difference in Price between Colorado Drug Spend & Importation Drug Spend	% Savings
100%	\$523,072,244	\$182,641,586	\$340,430,658	65%
25%	\$130,768,061	\$45,660,397	\$85,107,664	65%
15%	\$78,460,837	\$27,396,238	\$51,064,599	65%

Colorado Department of Health Care Policy & Financing, 2022

Colorado Drug Importation Program Contracts & Program Participants



Supply Chain Partners



ROCKY MOUNTAIN
POISON & DRUG SAFETY
Saving lives with answers.™

Supply Chain Partners

Site visits to all supply chain partners to evaluate compliance with FDA Final Rule requirements including:

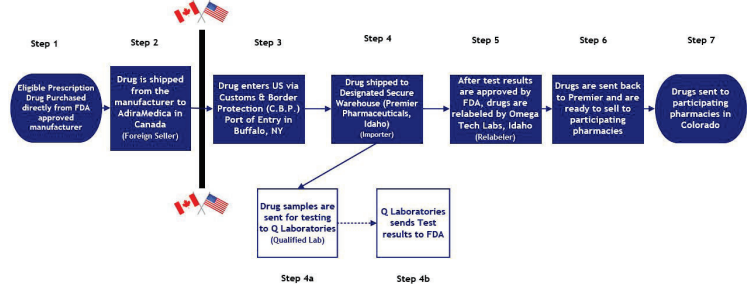
- Good Manufacturing Practice (GMP) compliance
- Robust standard operating procedures (SOPs) for their facilities, procedures, and systems
- Physical security
- Inventory management
- Employee training programs

Supply Chain Partners

In addition our primary supply chain partners, Premier Pharmaceuticals has identified a qualified laboratory and a relabeler to fulfil those roles for the program.



SIP Distribution Chain



HCPF Oversight

Compliance with federal safety requirements is operationalized through partner contracts which include compliance requirements for:

- Statutory/regulatory rules including licensure and regular reporting
- Maintenance standards for physical space & security, SOPs, staff education and training
- Track and trace monitoring
- Regular auditing and inspections

HCPF will have ongoing oversight of these terms

Testing & Relabeling

- Testing - Statistically valid sampling for authenticity and degradation
 - Test results submitted to FDA for review/approval
- Relabeling - All eligible drugs, once tested and FDA-approved will be relabeled according to the Final Rule.

DSCSA Compliance

CO's SIP includes extensive safety and security requirements supported by the Final Rule and the Drug Supply Chain Security Act (DSCSA).

Compliance by:

- Placement of product identifiers on all products
- Inclusion of transaction data to permit track/trace.
- Registration & license requirements (state and federal level)



Product Identifier Example

Supply Chain Monitoring

- Returns - Premier is required to follow standard return protocols within the original supply chain
- Recalls - All supply chain partners are required to monitor, report, and suggest drug recalls
- Adverse Events - RMPDS, our critical reporting partner, will:
 - Maintain reporting and recordkeeping requirements for adverse events and pharmacovigilance
 - Manage a consumer reporting hotline to report any safety events
 - Support on consumer level recalls

Consumer Support & Education

- Educational outreach to engage
 - Consumers
 - Pharmacists
- SIP website expansion including (upon application approval):
 - Approved imported drugs' National Drug Codes (NDCs)
 - List of participating pharmacies
 - Access to consumer support hotline, including adverse event reporting
 - Access for pharmacies to Premier's secure online portal for placing orders

QUESTIONS?

Contact us as at:

hcpf_005drugimportation@state.co.us

For more information, please visit our
website:

<https://www.colorado.gov/hcpf/drug-importation>

Next Steps

- Awaiting federal approval
- Negotiations with drug manufacturers
- Outreach to CO stakeholders
 - Pharmacy commitments to offer imported products
 - Partnership with plans for coverage
 - Others: State employee program, Department of Corrections
- Additional programmatic planning with supply chain partners