

## SB19-005: IMPORT PRESCRIPTION DRUGS FROM CANADA Colorado Wholesale Importation of Prescription Drugs Act

### Details

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<b>Bill Sponsors:</b>	House – <i>Jaquez Lewis (D)</i> Senate – <i>Rodriguez (D) and Ginal (D)</i>
<b>Committees:</b>	Senate Health & Human Services Senate Appropriations
<b>Bill History:</b>	1/4/2019- Introduced in Senate 1/31/2019- Hearing in Senate Health & Human Services Committee
<b>Next Action:</b>	Hearing Senate Appropriations Committee
<b>Fiscal Note:</b>	<u>1/28/2019 Version</u>

### Bill Summary

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This bill directs the Department of Health Care Policy and Financing (HCPF) to design a program to import prescription drugs from Canada to be sold to Colorado residents. The program must ensure the safety of the products and cost savings for consumers. The federal government must approve the program for implementation to occur. If approved, HCPF must create and adopt a funding mechanism to cover the program's administrative costs.

### Issue Summary

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#### Prescription Drugs in the United States

Recently there has been renewed attention on the cost of prescription drugs and the increase of these prices over the past decade. There were more than 5.8 billion dispensed prescriptions in 2017.<sup>1</sup> Approximately 58 percent of Americans report that they are currently taking at least one prescription drug while 25 percent take four or more prescription drugs.<sup>2</sup> Prices of individual drugs have been high and/or increasing over the last decade and the cost of these drugs as a whole have been encompassing a greater share of health care costs and the country's gross domestic product (GDP).<sup>3</sup> From 2017 until 2026 prescription drug spending is anticipated to increase 6.3 percent per year.<sup>4</sup> According to the Centers for Medicare & Medicaid Services (CMS), \$325 billion was spent on retail prescription drugs in 2015.<sup>5</sup> Net per-capita spending was \$896 per person in 2016 and dropped to \$876 in 2017.<sup>6</sup> Out-of-pocket costs for patients was \$57.8 billion in 2017, but each patient's exposure to these costs varied dramatically. For example, only 0.2 percent of the 5.8 billion prescriptions cost more than \$250 for the patient; however, these prescriptions were 9 percent of all the out-of-pocket costs for patients. Conversely, the majority of patients only had prescriptions that cost less than \$10 to fill. However, a 2015 Consumer Reports poll found that 30 percent of people who take at least

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<sup>1</sup> IQVIA Institute (Apr. 19, 2018). *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022*. Retrieved from <https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022>

<sup>2</sup> Henry J Kaiser Family Foundation (2018). *Public opinion on prescription drugs and their prices*. Retrieved from <https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/>

<sup>3</sup> Olson, P. & Sheiner, L. (Apr. 16, 2017). The Hutchins Center Explains: Prescription Drug Pricing. *Brookings Institution*. Retrieved from <https://www.brookings.edu/blog/up-front/2017/04/26/the-hutchins-center-explains-prescription-drug-spending/>

<sup>4</sup> Cuckler, G.A. et al. (2018). National Health Expenditure Projections, 2017-26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth. *Health Affairs*, 37(3). DOI: 10.1377/hlthaff.2017.1655

<sup>5</sup> Olson, P. & Sheiner, L. The Hutchins Center Explains: Prescription Drug Pricing.

<sup>6</sup> IQVIA Institute. *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022*.

one prescription drug a month had unexpected spikes in the out-of-pocket cost of their drug(s) in the past year.<sup>7</sup>

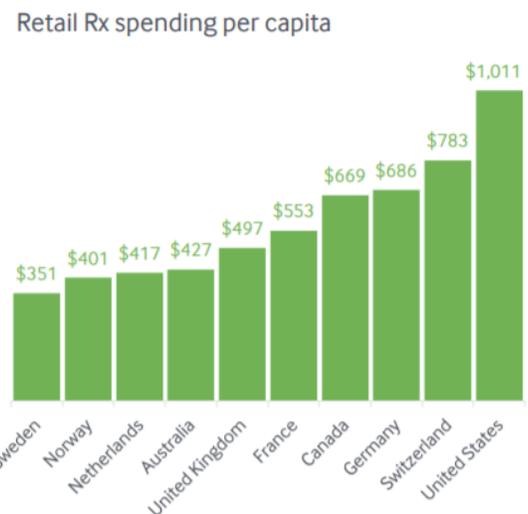
### Prescription Drugs in Colorado

In 2017, more than 45.9 million prescription drugs were filled at pharmacies in Colorado, resulting in \$6.28 billion of retail sales.<sup>8</sup> On average, there are approximately 10.8 medications dispensed per year per person in Colorado; of those, 8.7 are generic medications.<sup>9</sup> This approximation utilizes data from the Center for Improving Value in Health Care (CIVHC), which does not reflect the uninsured, some people covered by self-insured employer plans, and those covered under Federal programs like TRICARE, Indian Health Services, or Veterans Affairs (VA). According to the Colorado Health Institute's (CHI) 2017 Colorado Health Access Survey, 10.7 percent of Coloradans cited the cost of prescription drugs as reason that they did not fill the medicines they were prescribed.<sup>10</sup> Another study by CHI found that in 2015 the median out-of-pocket expenditures on prescription drugs was \$149 per year per person.<sup>11</sup> In the 2016 Community Health Survey conducted by the Health District of Northern Larimer County, 8.6 percent of adult residents within the Health District reported being unable to have a prescription filled because they could not afford it during the preceding two years.<sup>12</sup> This rate is much higher among those who reported being uninsured (28 percent).

### Prescription Drugs in Canada vs U.S.

The United States remains an outlier for prescription drug spending compared to other high-income countries. The following graph demonstrates the difference in per capita spending between the U.S., Canada, and other countries.<sup>13</sup> While Lyrica<sup>14</sup> costs \$6.04 in the United States and 63 cents in Canada, Xarelto<sup>15</sup> cost \$12.44 here compared to Canada's \$2.11 price, and Eliquis<sup>15</sup> costs \$6.21 compared to \$1.60 in Canada, per course of treatment.<sup>16</sup>

Exhibit 2. Retail Pharmaceutical Spending, 2015



### Federal Food Drug and Cosmetic Act

Under Federal Food Drug and Cosmetic Act (FDCA) Section 804, Congress permits importation and re-importation of prescription drugs from Canada by a pharmacist or wholesaler, provided the drugs meet certain minimum standards and the Secretary of the U.S. Department of Health and

<sup>7</sup> *Impact of Surging Drug Prices on Consumers: Hearings before the Democratic Steering and Policy Committee, House, 114th Congress (2015)* (Testimony of Lynn Quincy). Retrieved from

[http://www.healthcarevaluehub.org/files/3214/4969/6175/Consumers\\_Union\\_Drug\\_Prices\\_Testimony.pdf](http://www.healthcarevaluehub.org/files/3214/4969/6175/Consumers_Union_Drug_Prices_Testimony.pdf)

<sup>8</sup> Henry J Kaiser Family Foundation (2018). *Health Costs & Budgets Indicators*, Retrieved from <https://www.kff.org/state-category/health-costs-budgets/prescription-drugs/>

<sup>9</sup> Center for Improving Value in Health Care (n.d.) *Utilization*. Retrieved from <http://www.civhc.org/get-data/interactive-data/statewide-metrics/utilization/>

<sup>10</sup> Colorado Health Institute [CHI] (2017). *Colorado's New Normal: Findings from the 2017 Colorado Health Access Survey*. Retrieved from [https://www.coloradohealthinstitute.org/sites/default/files/file\\_attachments/2017%20CHAS%20DESIGN%20FINAL%20for%20Web.pdf](https://www.coloradohealthinstitute.org/sites/default/files/file_attachments/2017%20CHAS%20DESIGN%20FINAL%20for%20Web.pdf)

<sup>11</sup> CHI (2016). *Sticker Shock: Prescription Drug Affordability in Colorado*. Retrieved from <https://www.coloradohealthinstitute.org/research/sticker-shock-prescription-drug-affordability-colorado>

<sup>12</sup> With a 95% confidence interval ranging from 7.3% to 10.0%.

<sup>13</sup> Sarnak, D.O., Squires, D., Kuzmak, G., & Bishop, S. (Oct. 2017) *Paying for Prescription Drugs around the World: Why Is the U.S. an Outlier?* *Commonwealth Fund*. Retrieved from [https://www.commonwealthfund.org/sites/default/files/documents/media\\_files\\_publications\\_issue\\_brief\\_2017\\_oct\\_sarnak\\_paying\\_for\\_rx\\_ib\\_v2.pdf](https://www.commonwealthfund.org/sites/default/files/documents/media_files_publications_issue_brief_2017_oct_sarnak_paying_for_rx_ib_v2.pdf)

<sup>14</sup> Intended to treat muscle and nerve pain, such as fibromyalgia

<sup>15</sup> Acts as a blood thinner

<sup>16</sup> National Academy for State Health Policy [NASHP] (n.d.) *Is It Safe and Cost-Effective to Import Drugs from Canada?*. Retrieved from <https://nashp.org/is-it-safe-and-cost-effective-to-import-drugs-from-canada/>

Human Services (HHS) certifies to Congress that implementation of such a program will (1) pose no additional risk to the public's health and safety; and (2) result in a significant reduction in the cost of covered products to the consumer.<sup>17</sup> The Secretary may certify a program if both stipulations of safety and savings are assured. By law, prescription drugs may only be imported from Canada, laboratory testing is required, and there are prohibitions on the importation of a controlled substance, biological product, infused drug, intravenously injected drug, or a drug inhaled during surgery. Section 804 has not been used previously as no state has officially requested permission for such a program.

### Drug Supply Chain Security Act

Effective January 1, 2015, the Drug Supply Chain Security Act requires all healthcare entities that distribute, dispense, and administer prescription drugs to patients to purchase these products only from authorized "trading partners" that are licensed by or registered with the state or federal government.<sup>18</sup> These authorized "trading partners" include wholesale distributors, manufacturers, re-packagers and dispensers licensed in the United States. Due to this legislation, providers like pharmacies and physicians are required to assure that their immediate suppliers are authorized. The act is intended to create uniform national standards in regards to, among other things, product identification, verification, and tracing as well as wholesaler licensing, and the creation of an enhanced system to perform some of these tasks.<sup>19</sup> There are strict penalties for violations under this act.

### Case Study: Vermont

During 2018, wholesale drug importation legislation was introduced in eight states, but only one state, Vermont, enacted this type of legislation.<sup>20</sup> Vermont became the first state to allow such a program with the passage of S175. However, the state needs to first create the design of the program and then a proposal for federal approval from HHS. A recent report from Vermont's Agency of Human Services (VAHS) outlined the preliminary design of the state's importation program. It found that commercial insurers in the state could see savings of between \$1 and \$5 million dollars by purchasing prescription drugs imported from Canada.<sup>21</sup> However, as the report notes, the substantial administrative and other upfront costs to adhere with the conditions of the FDCA have not been calculated, so it is unknown how the costs could affect the projected savings.

### Case Study: Utah

Utah's legislature considered H.B. 163 in 2018, which would have created a program and reporting requirements for safely importing certain prescription drugs at lower costs from Canada. Despite passing the House, the bill did not get through the Senate. However, the bill did gain bipartisan interest so legislative leadership requested a study from the Utah Department of Health on how to make drug importation work for the state in advance of a future legislative session.<sup>22</sup> A brief study was recently released that noted the federal law, existing infrastructure, and issues for the program to tackle if it were to be implemented by the state's legislature during its session.<sup>23</sup>

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<sup>17</sup> 21 U.S. Code § 384

<sup>18</sup> Friedman, R. (Sept. 2018). Importing Prescription Drugs Remains Risky Business Due to FDA and DEA Regulation. *American Bar Association*, Retrieved from [https://www.americanbar.org/groups/health\\_law/publications/aba\\_health\\_esource/2017-2018/march2018/importing/](https://www.americanbar.org/groups/health_law/publications/aba_health_esource/2017-2018/march2018/importing/)

<sup>19</sup> U.S. Food and Drug Administration (2018). *Drug Supply Chain Security Act (DSCSA)*. Retrieved from <https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/>

<sup>20</sup> NASHP. (Oct. 2018). *Twenty States Passed 37 Bills to Curb Rising Rx Drug Costs in the Short 2018 Legislative Session*. Retrieved from <https://nashp.org/twenty-states-passed-37-bills-to-curb-rising-rx-drug-costs-in-the-short-2018-legislative-session/>

<sup>21</sup> Vermont Agency of Human Services (Dec. 31, 2018). *Wholesale Importation Program for Prescription Drugs Legislative Report*. Retrieved from [https://nashp.org/wp-content/uploads/2019/01/Report-to-VT-Legislature-on-Rx-Wholesale-Importation-1\\_3\\_2019.pdf](https://nashp.org/wp-content/uploads/2019/01/Report-to-VT-Legislature-on-Rx-Wholesale-Importation-1_3_2019.pdf)

<sup>22</sup> NASHP. (Oct. 2018). *Twenty States Passed 37 Bills to Curb Rising Rx Drug Costs in the Short 2018 Legislative Session*. Retrieved from <https://nashp.org/twenty-states-passed-37-bills-to-curb-rising-rx-drug-costs-in-the-short-2018-legislative-session/>

<sup>23</sup> Utah Department of Health (2018). *Feasibility of Canadian Drug Importation to lower prescriptions costs for Utahns A Report for the Utah State Legislature/Health Reform Task Force*. Retrieved from <https://le.utah.gov/interim/2018/pdf/00004242.pdf>

## This Legislation

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The bill declares the following: Consumers in the U.S. pay some of the high prescription drug prices in the world, and pay twice as much as Canadians for brand drugs and 20 percent more for generics. Federal law allows for wholesale importation of drugs from Canada and the importation is shown to be both safe and less costly for U.S. consumers. Although it is assumed to be less costly to import drugs, there may be risks to the consumer if source, quality, and purity of prescription drugs cannot be verified. Canada has a rigorous system to license drug products that is equivalent to the system in the U.S. The “Drug Supply Chain Security Act” at the federal level has improved drug security and safety through “track-and-trace” procedures. The creation of a wholesale drug importation program for the exclusive benefit of Colorado residents is meant to provide access to safe and less expensive prescription drugs.

The bill adds the wholesale importation program to the list of programs that the Department of Health Care Policy and Financing (HCPF) is to administer.

The bill defines “actual acquisition cost” as the price paid for an imported prescription pharmaceutical product by a wholesaler under the importation program. The “importation program” is meant to be a program that is administered by HCPF in accordance with the bill language that follows. The bill defines “licensed provider” as a person who is licensed to prescribe pharmaceutical products to consumers by a health care prescriber board.

On or before July 1, 2020, HCPF, in consultation with stakeholders and federal agencies, shall design an importation program to import prescription drug products from one or more licensed Canadian suppliers for distribution to participating pharmacies and other licensed providers that may then dispense the drugs to Colorado residents with a valid prescription. In its design, HCPF is to ensure that the program satisfies applicable federal law.<sup>24</sup> HCPF shall include in the program design information that indicates how the program will:

- Designate an office or division of a state agency that will become a licensed pharmaceutical wholesaler or contract with a wholesaler
- Ensure drug safety and cost savings
- Meet the requirements for wholesaler licenses set in Colorado law<sup>25</sup>
- Select qualified Canadian suppliers licensed under national or provincial laws
- Sample imported products for purity, chemical composition, and potency to the extent required by federal law
- Determine which products will be imported and ensure that all products are significantly less costly to residents than U.S.-licensed equivalent
- Ensure that the products are not distributed, dispensed, or sold outside of Colorado
- Ensure that participating pharmacies and licensed providers charge individuals, carriers, and other payers no more than the limit established by HCPF for each product
- Ensure that each payment made by a carrier for reimbursement of the product component of a claim does not exceed the limit set by HCPF
- Ensure that carriers maintain up-to-date formularies and claims payment systems that are consistent with the importation program
- Ensure that participating carriers base their plans’ coinsurance and cost-sharing on prices that are no higher than the limit established by HCPF for each imported product
- Ensure that participating carriers demonstrate to HCPF how savings in imported products are reflected in health plan premiums

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<sup>24</sup> 21 U.S.C. sec. 384

<sup>25</sup> C.R.S. 12-42.5-301-7

- Set a maximum profit margin so a participating wholesaler, distributor, pharmacy, or other licensed provider maintains a profit margin that is no greater than the margin it would have earned on the equivalent non-imported product
- Exclude generic products if the importation would violate federal patent laws that apply to brand-name products
- Comply with requirements pertaining to track-and-trace requirements<sup>26</sup>
- Determine a method for covering the administrative costs of the program, which may include a fee imposed on each product sold or any other appropriate method as long as it would not significantly decrease consumer savings

On or before July 1, 2020 HCPF is to prepare and publicly release a draft report that describes the program and any other importation options that the department may include. The draft report is to be posted on HCPF's website and the document submitted to the Joint Budget Committee, Senate Health and Human Services Committee, House Health and Insurance Committee, and the House Public Health Care and Human Services Committee. Fifteen to forty-five days after posting the draft report on its website, HCPF is to hold at least two public meetings (at least one in Denver-metro area and at least one in western Colorado) to receive comments. After the public meetings, and no later than November 15, 2020, HCPF shall prepare and publicly release a final report. As before, the final report is to be posted on the website and submitted to the designated committees of the General Assembly. This section is repealed effective December 1, 2020.

On or before January 1, 2021, HCPF is to submit a formal request for the Secretary of the U.S. Department of Health and Human Services to review and approve the program. HCPF is to provide any information requested by the Secretary. HCPF can modify the design of the program as required by the Secretary as long as the modifications are consistent with the bulleted list above.

The following sections of the bill only take effect if the federal government approves the program.

Once approved, HCPF shall approve a method of financing the administrative costs for the program. Rules are to be promulgated by HCPF as necessary to implement and administer the program.

In order to implement the program, HCPF is to complete certain tasks. The department is to develop and issue a request for proposals from one or more pharmaceutical wholesalers and is to select wholesaler(s) best suited to import the products. The wholesaler is to agree to the following stipulations:

- Develop registration system to enroll distributors, pharmacies, other licensed providers, and carriers in the program
- Establish outreach and marketing plan to foster public awareness
- Establish a telephone hotline and create an internet portal to address questions and assist pharmacies, licensed providers, and carriers in registering for the program

HCPF is to require participating providers, licensed providers, and Canadian suppliers to contract directly with the wholesaler(s) selected. Finally, HCPF is to establish and make public the initial list of imported products covered by the program and the actual acquisition cost for each product. At any time, HCPF can add or remove products from the program. The public list is to be updated at least quarterly.

On or before January 1, 2022, and each January 1 thereafter, HCPF is to submit a report to the Joint Budget Committee, Senate Health and Human Services Committee, House Health and Insurance Committee, and the House Public Health Care and Human Services Committee. The report is to include the following:

- Specific products imported through the program

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<sup>26</sup> 21 U.S.C. sec 360ee-360ee-4, as enacted in Pub.L. 113-54, "Drug Quality and Security Act"

- Number of wholesalers, distributors, pharmacies, licensed providers, and carriers that are participating
- Number of imported prescription products dispensed and sold
- Estimated savings to consumers, carriers, and employers from the program
- Information collected pursuant the monitoring of anticompetitive behavior (to be explained below)
- Any other information that HCPF deems relevant

HCPF and the Attorney General are to identify the potential for anticompetitive behavior in pharmaceutical and other health care industries that are affected by the program.

The act takes effect August 2, 2019 if no referendum petition is filed against this act.

### Reasons to Support

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Significant increases in the price of both branded and generic drugs negatively impact consumers that may already have a difficult time affording their drugs or do not expect their costs to radically change. About 25 percent of people in the U.S. have a hard time affording their prescription drugs<sup>27</sup>; for those Coloradans that are in these types of circumstances, this bill may help them afford their drug and adhere to the guidelines from their prescriber to manage their condition. The increasing costs of prescription drugs also impact health insurance coverage for all individuals, as it is a factor that insurance carriers take into consideration in determining premium rates each year. As Vermont's report was not robust, Colorado has the opportunity to develop a comprehensive proposal that takes into account the possible costs, savings, and issues that need to be addressed by the state. Since no state has ever submitted a proposal, Colorado can be the first and provide reliable information on the possible results of such a program. Furthermore, the safety of the drugs from Canada should be the same as Colorado residents are accustomed to, as a 2016 bipartisan report from the U.S. Senate Special Committee on Aging stated that pharmaceutical manufacturing in Canada is stringent and comparable to U.S. standards.<sup>28</sup>

### Supporters

- AARP
- Center for Health Progress
- Colorado Consumer Health Initiative
- Colorado Senior Lobby

### Reasons to Oppose

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Industry associations may assert that this may reduce their sales and profit, and reduce the amount of funds available for research and development, which dampens innovation for patients and the vibrancy of the sector. Opponents assert that such a program may expose patients to counterfeit, altered or unapproved drugs that lack oversight and quality control. The enforcement of the program is concerning to some, such as: how will the program ensure that the products are only sold to Colorado residents and how will the program ensure that the products do not cross state lines? Some have demonstrated there are gaps in Health Canada's (the equivalent to the Food and Drug Administration) regulatory framework as a result of a decentralized health care system, a lack of transparency, and insufficient communication.<sup>29</sup> Opponents point to this framework as a reason to be wary of the safety of the pharmaceutical products from Canada.

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<sup>27</sup> Kamal, R., Cox, C., & McDermott, D. (Dec. 10, 2018). What are the recent and forecasted trends in prescription drug spending?. *Peterson-Kaiser Health System Tracker*. Retrieved from [https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-people-taking-rx-drugs-say-can-afford-treatment-1-4-difficult-time-affording-medicine\\_2017](https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-people-taking-rx-drugs-say-can-afford-treatment-1-4-difficult-time-affording-medicine_2017)

<sup>28</sup> Senate Special Committee on Aging (Dec. 2016). *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System*. Retrieved from <https://www.aging.senate.gov/imo/media/doc/Drug%20Pricing%20Report.pdf>

<sup>29</sup> White J, and Reid G. (Jan. 2018). A suggestion for evolution of Canada's health regulatory system. *FACETS* 3: 45–60. doi: 10.1139/facets-2017-0049

## Opponents

- AstraZeneca
- Biotechnology Innovation Organization (BIO)
- Colorado BioScience Association
- Colorado Chamber of Commerce
- Colorado Competitive Council
- Healthcare Distribution Alliance
- Pharmaceutical Research and Manufacturers of America (PhRMA)

## Other Considerations

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The bill does not include an “escape hatch” for the state to opt to end the development of a proposal if it has not shown “substantial savings” or if it will cost the state a large amount of money that is untenable in a possible future state budget. Furthermore, the bill does not define what is an acceptable level of savings to be considered “substantial” and it is unknown how the federal government may define it. Medicaid’s ability to participate in such a program remains unclear. Insurance programs may, or may not, cover the cost of imported prescription drugs, and this could force retail sales pharmacies have duplicate stocks of some drugs (imported drugs and non-imported drugs), just as 340B pharmacies must separate those medications from the products available to sell to the general public.

Carriers and pharmacy benefit managers and other entities at all levels of the supply chain have the option of participating in this program. It is important to consider how rebates may make non-imported drugs more attractive as it will decrease the price for certain entities, but these rebates may not make the non-imported drug cheaper than the imported drug for the consumer. As the federal government has recently proposed regulation surrounding the issue of rebates, it will be important to note how the final regulation would impact the entities within the supply chain and their willingness to participate in an importation program.

Note that time constraints have limited the reasons to support and oppose this legislation, as well as the other considerations for such a complex topic. This analysis may be expanded in the future.

## About this Analysis

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This analysis was prepared by Health District of Northern Larimer County staff to assist the Health District Board of Directors in determining whether to take an official stand on various health-related issues. The Health District is a special district of the northern two-thirds of Larimer County, Colorado, supported by local property tax dollars and governed by a publicly elected five-member board. The Health District provides medical, mental health, dental, preventive and health planning services to the communities it serves. This analysis is accurate to staff knowledge as of date printed. For more information about this summary or the Health District, please contact Alyson Williams, Policy Coordinator, at (970) 224-5209, or e-mail at [awilliams@healthdistrict.org](mailto:awilliams@healthdistrict.org).