COLORADO
Department of Health Care Policy & Financing
303 E. 17th Ave. Suite 1100
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Date May 5, 2025

BY ELECTRONIC FILING (via www.regulations.gov)
Stephen Astle, Director Defense Industrial Base Division, Office of Strategic Industries and Economic Security, Bureau of Industry and Security
U.S. Department of Commerce
1401 Constitution Avenue NW
Room 3876
Washington, D.C. 20230

RE: Request for Public Comments Section 232, Docket No. d/250414-0065

Dear Director Stephen Astle,

The Colorado Department of Health Care Policy & Financing (HCPF) appreciates the opportunity to comment on the Department of Commerce's Notice of Request for public comment under Docket No. d/250414-065 regarding the use of Section 232 of the Trade Expansion Act of 1962 to impose tariffs, quotas, or other import restrictions on pharmaceuticals and pharmaceutical inputs. HCPF administers the Colorado Medicaid program, Health First Colorado, and provides prescription medicines to about 1.3 million Colorado residents each year covered by Medicaid and the Children's Health Insurance Program (CHIP). HCPF is also responsible for Colorado's Drug Importation Program; our submitted application[1] is with the FDA awaiting approval.

Colorado Medicaid, CHIP and our emerging importation program share the Administration's goal of strengthening domestic pharmaceutical supply chains. Nevertheless, we are concerned that Section 232 remedies, when broadly applied to finished drugs or to active pharmaceutical ingredients (APIs), will impair our ability to furnish clinically appropriate medications at sustainable cost and would achieve limited national-security benefits. Our comments address two areas including potential impact of API and finished-dose tariffs on the Colorado Medicaid and CHIP programs as well as specific risks to Colorado's Section 804 Canadian Drug Importation Program.

Impact on Colorado Medicaid

The United States—and by extension Colorado—relies heavily on offshore production of pharmaceuticals. FDA data indicate that 77 percent of Active Pharmaceutical Ingredient (API) manufacturers[2] and roughly 40 percent of finished-dose prescription drugs serving the U.S. market are manufactured abroad.[3] Imported products make up 68 percent of the 100

[1] Colorado Section 804 Application March 2025
[2] FDA At A Glance October 2024
[3] GAO Testimony: Drug Safety (2019)

most-dispensed Medicare Part D drugs,[4] and about 91 percent of biologic sales originate overseas.[5]

Because Colorado Medicaid reimburses pharmacies using wholesale acquisition cost (WAC) and average acquisition cost (AAC) benchmarks, any import duty will be embedded in those rates. In Fiscal Year 2023/24, CO Medicaid's prescription drug total fund expenses totaled $1.7 billion in gross costs, with an additional $16.3 million in prescription drug costs under the CO CHP+ plans. CO Medicaid covers outpatient drugs at zero cost-sharing to beneficiaries; therefore, every incremental price increase has direct cost impacts on the State General Fund and the federal match. For example, a 10 percent[6] duty on a high-volume generic could raise rates, adding more than $170 million in annual gross spend, impacting both state and federal expenditures. This pressure on the budget could mean that the State would not be able to continue to provide other critical services to members, such as adult dental, hospice, physical therapy, etc.[7]

Products most vulnerable to Section 232 tariffs are those that rely on multiple foreign APIs as well as many generics – which ordinarily lower Colorado's costs, substantially. If duties are imposed at the ingredient level, every imported API or excipient is taxed separately, so a U.S.-made combination drug containing three foreign ingredients could incur three layers of tariffs—making it more expensive than an identical finished product imported under a single tariff line. This scenario would punish domestic manufacturing without improving supply-chain security. In addition, generic manufacturers already operating on narrow margins may be unable to absorb the added costs; many would either raise prices or withdraw from the market,[8] worsening the drug-shortage problem while increasing costs for Colorado consumers, which has been shown to affect prescription compliance.[9]

Colorado negotiates annual supplemental rebates in exchange for preferred-drug-list placement. Manufacturers facing higher landed costs are likely to seek early contract termination, or decline to bid, forcing HCPF to accept higher net prices. For low-margin sterile injectables—already prone to shortage—tariffs could be the tipping point that makes continued marketing unviable, endangering hospital supply.

In summary, tariffs would inflate Medicaid and CHIP drug spend, strain the state-federal budget partnership, and undermine existing rebate arrangements, yet leave underlying dependency on foreign supply unchanged.

Impact on Colorado's Section 804 Canadian Drug Importation Program

By definition, Colorado's FDA-submitted Section 804 Canadian Drug Importation Plan[10] hinges on a Health Canada-licensed foreign seller and a U.S. importer of record performing an importation transaction for Colorado to directly reduce the costs of drugs for Coloradans. Tariffs imposed on finished-dose medicines at the border would immediately erode the program's projected 45–60 percent savings on chronic-disease therapies—savings the State

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4 Not Made In The USA (Pharmacy Checker Research)

5 FDA At A Glance October 2024

6 White House Fact Sheet 4.5.25

7 Colorado Medicaid Benefits & Services List

8 Association for Accessible Medicines Comments on New Tariffs 2.2.25

9 A Dose of Reality: Prescription Drugs in Colorado

10 *See* 21 CFR Parts 1 and 251

Legislature and public already anticipate and that FDA regulation targeted. We have a shared goal of providing cheaper, more accessible medicines to patients. The April 15, 2025, Executive Order, "Lowering Drug Prices by Once Again Putting Americans First,[11]" explicitly supports drug importation under Section 804 as a federal strategy to reduce costs. Colorado's program[12] directly aligns with this national policy objective and stands as a critical test case for its success. We caution that broad Section 232 remedies could unintentionally raise the costs for vulnerable beneficiaries and jeopardize a federally established and regulatorily supervised importation pathway.

Moreover, Health Canada regulation C.01.014.13[13] prohibits exports that could worsen a domestic shortage. If U.S. tariffs inflate Canadian drugs destined for Colorado—or if they trigger retaliatory measures—Canadian authorities could instruct wholesalers to cease participation altogether. Such an outcome would shut down Colorado's importation pathway and eliminate a federally supervised mechanism designed precisely to relieve cost pressure on U.S. patients and payers.

Thus, a Section 232 remedy, if applicable to Colorado's Section 804 Importation Program (SIP), would not only undercut the economic rationale for Colorado's program but could provoke foreign policy responses that eliminate the program entirely. We think that there is a risk that a Section 232 investigation could lose sight of other federal regulatory programs designed to reduce drug costs expressly by encouraging drug importation (from Canada, at least). Therefore, we recommend the Department provide an exclusion for State Importation Program drugs ensuring that tariffs do not undermine the intent of the drug importation program. HCPF supports efforts to strengthen pharmaceutical supply-chain resilience; however, we caution that overly broad Section 232 remedies risk undermining the very federal cost-saving strategy they aim to protect. Without a targeted exemption, such actions could impose unintended costs on vulnerable beneficiaries and dismantle the long-awaited importation pathway that Coloradans and federal regulators have worked together to establish. We urge the Department to adopt a tailored approach that safeguards national security and preserves affordable access to medicines through the SIP program.

Thank you for considering our views. We stand ready to provide additional data or technical assistance.

Sincerely,

Kim Bimestefer
Executive Director
Department of Health Care Policy & Financing

cc:
Office of Drug Security, Integrity and Response, Office of Compliance, & Center for Drug Evaluation and Research, U.S. Food and Drug Administration
Karen Meister, Senior Policy Advisor, U.S. Food and Drug Administration

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[11] Lowering Drug Prices by Once Again Putting Americans First

[12] Colorado's Drug Importation Program

[13] Guide to distributing drugs intended for the Canadian market for consumption or use outside Canada (GUI-0145)