

Section 804 Importation Program: Projecting Cost Savings for the American Consumer

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U.S. Department of
Health and Human Services

Enhancing the health and well-being of all Americans

Executive Order 14273



- Executive Order 14273 of April 15, 2025, on [Lowering Drug Prices by Once Again Putting Americans First](#)
- “streamline and improve the Importation Program under section 804 of the Federal Food, Drug, and Cosmetic Act to make it easier for States to obtain approval without sacrificing safety or quality.”

Outline of Talk

- Discuss principles HHS identifies as best practices for benefit-cost analysis, as they relate to the cost-savings analysis of program proposals
- Discuss the program enhancements announced this year
- However, other analytical approaches may be appropriate, as long as they are consistent with the regulation:
 - **§ 251.3 SIP proposal submission requirements:**
 - (e) The SIP Sponsor's importation plan must: [...]
 - (9) Explain how the SIP Sponsor will ensure that the SIP will result in a significant reduction in the cost to the American consumer of the eligible prescription drugs that the SIP Sponsor seeks to import. The explanation must include any assumptions and uncertainty, and it must be sufficiently detailed to allow for a meaningful evaluation.



General Analytic Principles

- The analysis should be transparent and contain enough information about the data and methods to facilitate the reproducibility of its major findings
- Clearly set out the basic assumptions, methods, and data underlying the analysis and discuss the uncertainties associated with the estimates
- Provide adequate citations of data sources used in the compiling of the underlying estimates for all quantitative elements
- Reference drug pricing data that are sufficient to project annual expenditures projections for each drug under the Plan and Baseline Scenarios



Terminology When Measuring Total Cost Savings

- **Plan Scenario:** a projection of the total expenditures the SIP Sponsor anticipates if the SIP Proposal is authorized and implemented
- **Baseline Scenario:** a projection of the total expenditures the SIP Sponsor anticipates if the SIP Proposal is not authorized and implemented
- **Cost Savings:** the difference between the total expenditures under the Plan Scenario and the Baseline Scenario

Scope of Analysis

- Plan and Baseline Scenarios should cover:
 - Annual projections of the anticipated total expenditures for each year for the two years of the SIP
 - Identify the calendar year, or specific 12-month period covered for each year of the analysis
- For example, a SIP Sponsor could identify that the projections cover 2026 and 2027

Level of Detail of Analysis

- The SIP Proposal should contain expenditure projections for each drug under the Plan and Baseline Scenarios
- These drug-expenditure projections should include quantity and per-unit price estimates
- The sum of these drug-specific expenditure projections should be consistent with the total expenditure projections for each scenario



Measuring Prices

- The SIP Sponsor should adopt an analytic approach for estimating cost savings that is appropriate in the context of the specific Proposal
- When measuring drug prices:
 - “To demonstrate expected cost savings, a SIP Sponsor could compare anticipated acquisition costs or consumer prices per unit of each eligible prescription drug that the SIP Sponsor is seeking to import. A SIP Sponsor could also compare the current retail cash price of the drugs.” (85 FR 62101)
- Critically, the SIP Proposal should assess cost savings from comparable price measures for the Baseline Scenario and Plan Scenario



Demonstrating Cost Savings

- It is generally not sufficient to identify differences in drug prices between the United States and Canada.
- The SIP Proposal should demonstrate that the SIP Sponsor will be able to leverage these drug price differences for the eligible prescription drugs identified in the SIP Proposal and that the SIP will result in cost savings for the American consumer
- The SIP Proposal should include all anticipated costs associated with implementation:
 - Importer price markups
 - Other transportation and logistical costs not captured by the importer price markup
 - Costs associated with drug samples, testing, and other requirements under Section 804 and the Importation of Prescription Drugs Final Rule
- The SIP Proposal should account for these costs when reporting the projected cost savings

Additional Best Practices

- The Plan and Baseline Scenario projections should be consistent with reasonable assumptions of potentially related trends
- The SIP Sponsor could consider providing a framework for ex-post quantitative evaluation of the SIP Proposal projections, should the SIP Sponsor seek to renew the SIP at the conclusion of two years



State Importation Program Enhancements

FDA NEWS RELEASE

FDA takes steps to enhance state importation programs to help lower prescription drug prices

For Immediate Release: May 21, 2025

The U.S. Food and Drug Administration is continuing to take steps to help state importation programs provide safe, effective and more affordable drugs for American patients, as part of its efforts to implement Executive Order [Lowering Drug Prices by Once Again Putting Americans First](#). Today, the agency is announcing enhancements to the pathway under section 804 of the Federal Food, Drug and Cosmetic Act that allows states and Indian tribes to import certain prescription drugs from Canada to significantly reduce the cost of these drugs to the American consumer, without imposing additional risk to public health and safety.

- [May 21, 2025 Press Release](#) and [State Importation Program Enhancements](#)
- Reducing the burden on states: Cost savings analysis
- Baselines and assumptions
- Future costs consideration
- Impact of tariffs on cost-savings



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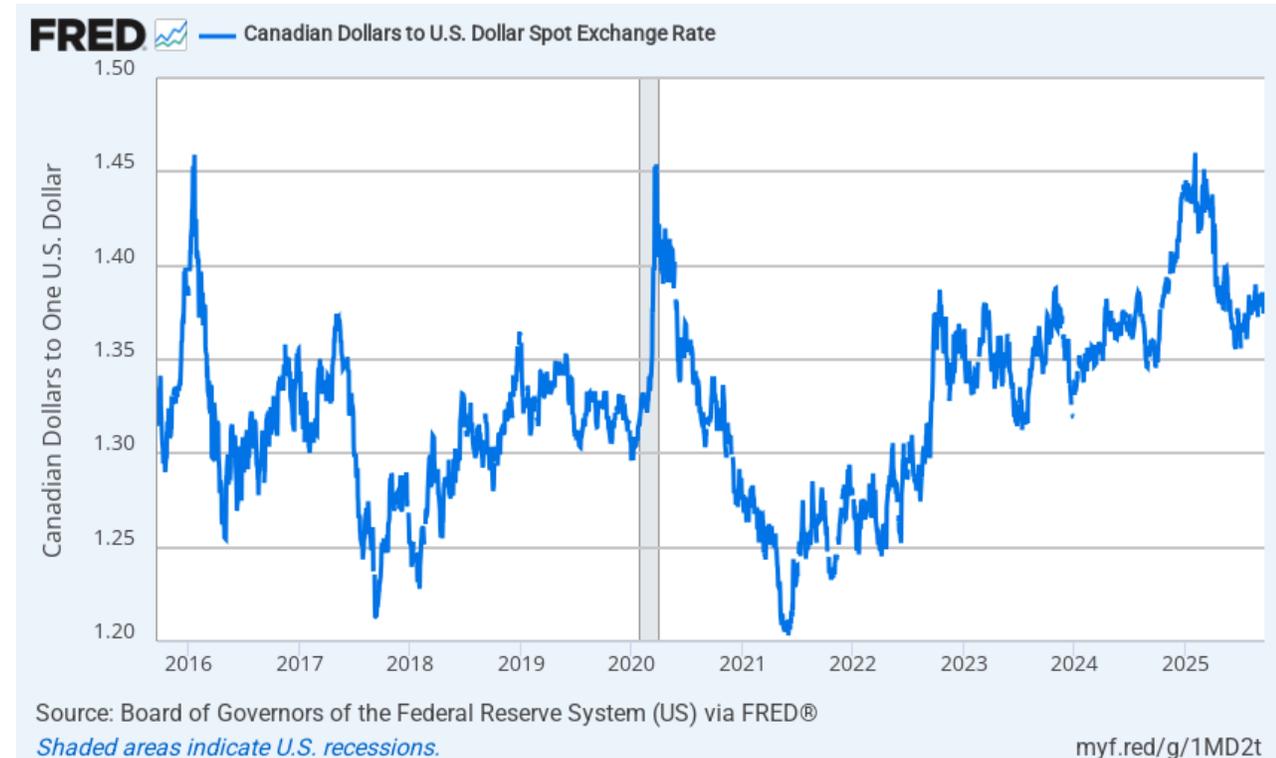
Reducing the burden on states: Cost savings analysis

- If the data support a determination that the proposal has demonstrated cost-savings, then the state or tribe will not need to update that data while the SIP proposal is under active FDA review.

State Importation Program Enhancements

Baselines and assumptions

- Option to utilize a static baseline approach for the cost-savings analysis rather than accounting for anticipated trends in markets
- This approach could include static assumptions for variable economic factors such as:
 - domestic and foreign prices
 - exchange rates
 - tariff rates



State Importation Program Enhancements

Future costs consideration

- Cost savings analyses can be impacted by a number of variables that are not always predictable.
- However, a state or tribe may seek to address this uncertainty, for example, by specifying in their SIP proposal that they intend to compare prices of eligible drugs at the time of sale and only purchase drugs that provide a particular margin of savings.
- Cost-savings analyses could reference this intention as part of a discussion of assumptions made regarding the variables considered in the analysis and explanation of cost savings to allow for a meaningful evaluation.
- This could help reduce the burden of extensive or ongoing analyses.



State Importation Program Enhancements

Impact of tariffs on cost-savings

- States may choose to generally identify tariffs as an area of uncertainty or, as appropriate, may assume that tariffs have a neutral impact for the purpose of section 804 demonstration of cost-savings.
- For example, states could either assume constant tariff rates or omit consideration of a tariff on section 804 drugs imported from Canada entirely.

