

# Projecting Cost Savings for the American Consumer

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**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
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# § 251.3 SIP proposal submission requirements

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- (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.



# Analysis of Cost Savings

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- Discussion today draws on principles HHS identifies as best practices for benefit-cost analysis
- The [\*HHS Guidelines for Regulatory Impact Analysis\*](#) discuss this widely-used framework for collecting, organizing, and evaluating data on the anticipated consequences of regulatory actions
- Other analytical approaches may be appropriate. Note that the SIP Proposal's cost-saving "explanation must include any assumptions and uncertainty, and it must be sufficiently detailed to allow for a meaningful evaluation." The SIP Proposal's discussion of assumptions should include an explanation of the analytic approach adopted by the SIP Sponsor.



# Measuring Total Cost Savings

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- Terminology
  - **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



# Measuring Total Cost Savings

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- Plan Scenario should cover:
  - Annual projections of the anticipated total expenditures for each year for at least the first two years of the SIP
  - Identify the calendar year, or specific 12-month period covered for each year of the analysis
- For example, an SIP Sponsor could identify that the projections cover 2023 and 2024



# Measuring Total Cost Savings

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- Baseline Scenario should cover:
  - time period covered under the Plan Scenario
  - time period between the most recent year of drug pricing data the Plan Scenario projections
- For example, if the SIP covers 2023 and 2024 and the drug pricing data are from 2020, the Baseline Scenario should cover 2020-2024



# Measuring Cost Savings

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



# Measuring Prices

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- 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 price:
  - “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)



# Measuring Prices

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- 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
- Critically, the SIP Proposal should assess cost savings from comparable price measures for the Baseline Scenario and Plan Scenario



# Measuring Prices

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- The SIP Proposal should include all costs associated with implementation anticipated by the SIP Sponsor:
  - 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



# Analytic Principles

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



# Additional Considerations

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- 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

