ASPE
ASSISTANT SECRETARY FOR PLANNING AND EVALUATION

ISSUE BRIEF

December 31, 2024

—Inflation Reduction Act Research Series— An Evaluation Framework for the Inflation Reduction Act's Medicare Prescription Drug Related Provisions

The Inflation Reduction Act (IRA) changes the way Medicare pays for prescription drugs. We introduce an evaluation framework to serve as a roadmap to systematically and comprehensively examine key impacts of the IRA's Medicare prescription drug-related provisions.

OVERVIEW

The Inflation Reduction Act (IRA) changes the way Medicare pays for prescription drugs. These changes will impact various stakeholders, including the federal government, Medicare enrollees, drug manufacturers, prescription benefit managers, and others. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) has carried out a series of analyses to identify projected impacts of the IRA's Medicare drug-related provisions, but it is also necessary to identify observed impacts of the provisions on various stakeholders once the provisions go into effect.[*]

In this brief, we introduce and describe "An Evaluation Framework for the Inflation Reduction Act's Medicare Prescription Drug-Related Provisions" referred to as the "Evaluation Framework Report," which presents a high-level approach for how to evaluate each IRA Medicare prescription drug-related provision. The Report includes identification of potential key research questions and outcomes that may be examined in the short, intermediate, and long-term; the potential quantitative and qualitative methods that can be used; and the various challenges that may arise. We also describe the issues that were considered in the development of the Evaluation Framework Report, including whether the evaluation should begin by examining the effects of all the IRA's drug-related provisions collectively or whether it is more appropriate to examine the impacts of each individual provision separately; how best to account for the timeline for implementation of the IRA's drug-related provisions and the changing health and policy landscape; how to address the uncertainty associated with the behavioral responses of stakeholders; and how to approach the construction of treatment subgroups and comparison groups that are required for impact analyses. The framework presented here can be used to develop and implement a comprehensive evaluation of the IRA's Medicare drug-related provisions, which is necessary to fully understand the impact of these provisions on the various stakeholders.

[*] For example, please see here and here.

BACKGROUND

The Inflation Reduction Act (IRA), which was passed in August 2022, includes provisions that change the way Medicare pays for prescription drugs with the goal of reducing costs for Medicare enrollees and taxpayers, increasing access to prescription drugs, and improving health outcomes for Medicare enrollees. These provisions are also expected to affect a broad range of stakeholders, including drug manufacturers, prescription drug plans, pharmacies, and pharmacy benefit managers (PBMs). A description of the Medicare drug-related provisions and their implementation dates are available here.

Since the passage of the IRA, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) has carried out a series of analyses to examine use and spending of prescription drugs among Part D enrollees and estimate the projected impacts of the IRA drug-related provisions. Our analyses have included estimating the impacts on enrollee out-of-pocket spending for the IRA's vaccine provision, which eliminates copays for Part D covered adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP); the $35 insulin cap provision, which limits the out-of-pocket cost of a month's supply of each Part D and Part B covered insulin to $35; and the Part D redesign, which includes a number of provisions such as the $2,000 cap on out-of-pocket spending beginning in 2025 and adjusted for inflation annually thereafter. Collectively, findings show that a subset of Medicare enrollees pay high out-of-pocket costs for their prescription drugs and the IRA is projected to reduce their spending considerably. For example, about 8.4 million enrollees who do not receive the low income subsidy (LIS) are projected to save about $759 per enrollee in out-of-pocket costs in 2025, after many of the IRA Part D provisions are in effect.[1,†‡]

Although projections are helpful in identifying the potential impacts of the IRA's Medicare drug related provisions, it is also necessary to carry out a systematic evaluation to identify observed impacts of the provisions on various stakeholders. A comprehensive evaluation includes examining the quantitative impact of the IRA's drug related provisions on key outcomes such as prescription drug utilization, total and out-of-pocket spending, and health outcomes as well as qualitative approaches to understand stakeholder perspectives. For example, it is important to examine the extent to which enrollees are aware of the IRA provisions and how they may increase access to their prescription drugs. A comprehensive evaluation also includes understanding how other stakeholders respond to the provisions. For example, under the IRA, prescription drug plans have greater costs in the catastrophic coverage phase of the Part D benefit than they did prior to the IRA. Thus, examining whether plans respond by increasing premiums and/or employing additional utilization management approaches for certain drugs is important because it will impact long-term outcomes such as utilization of drugs and spending. As many of the provisions have gone or will go into effect in the upcoming years, there will be an opportunity to analyze administrative claims data and collect additional data, both quantitative and qualitative, to monitor and evaluate the impacts of the IRA's drug-related provisions.

As an initial step towards this goal, ASPE contracted with RAND to design an evaluation framework of the IRA's Medicare drug related provisions and produce an Evaluation Framework Report to serve as a roadmap to guide analytical activities in a systematic, cohesive, and complementary way. The purpose of the Evaluation Framework Report is to:

(1) develop a logic model and associated theory of action for the IRA's Medicare Part B and Part D drug-related provisions,
(2) present the main research questions and key outcomes that should be considered,

---

† For more details, please see here: aspe-part-d-oop.pdf (hhs.gov)

‡ For eligible enrollees whose income and resources are limited, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 established Extra Help (a subsidy) for prescription drugs. Subsidies are paid by the Federal government to drug plans and provide assistance with premiums, deductibles, and co-payments. Under the IRA, beginning in 2024, the LIS program is expanded to individuals with limited financial resources and incomes up to 150 percent of the Federal Poverty Limit (FPL).

(3) outline the potential methodological approaches that may be used and the data that will be needed to carry out analyses, and
(4) explore the potential challenges that may arise and ways to address them.

The Evaluation Framework Report is not intended to provide detailed instructions on how to carry out specific analyses, but rather serve as a roadmap to guide future analyses and ensure that the evaluation of the IRA's drug related provisions is comprehensive and cohesive, and will lead to a clear understanding of the potential impacts of the IRA for Medicare, Medicare enrollees, taxpayers, and other stakeholders.

DEVELOPING THE EVALUATION FRAMEWORK

To design the evaluation framework, we developed logic models and associated research questions for the IRA provisions, separately for Medicare Part B and Medicare Part D, and identified the key short, intermediate, and long-term expected effects and outcomes that should be examined as part of the IRA evaluation. Expected outcomes were identified based on the theory of action for each provision and considered the range of potential effects for each stakeholder.

Once key research questions and outcomes were identified for each provision, a technical expert panel (TEP) was convened. The TEP consisted of subject matter experts in the areas of pharmaceutical policy and law, knowledge of the Medicare program, evaluation and statistics, and pharmaceutical innovation. During the TEP, participants were asked to share their expertise on how they would approach evaluating legislation that includes broad changes to Medicare Part D implemented over time and in the context of other health care initiatives. The TEP was asked about the key outcomes to examine, the methodological approaches that should be considered to identify and potentially isolate the impact of each provision, and the anticipated behavioral responses of stakeholders to the provisions. In addition, there was discussion on whether and to what extent there should be an overall evaluation that aims to collectively capture the impacts of all the IRA Medicare-drug related provisions and if so, the key outcomes that would be the most appropriate for such an evaluation. The final Evaluation Framework Report, which is discussed in this brief, integrates recommendations from the TEP and expertise from RAND and ASPE.

EVALUATION FRAMEWORK APPROACH

The Evaluation Framework Report presents central research questions that should be addressed in the short-term for each IRA drug-related provision, as well as key intermediate and long-term research questions.[§] It also includes guidance on how to approach each research question, the existing administrative data sources that can be used, additional data that may be collected from various stakeholders, and potential analytical approaches that may be used to evaluate impacts.[**] Because it is challenging to identify the collective effects of all IRA Medicare drug-related provisions (see next section for more details), the Report's main focus is evaluation of each provision separately through a series of analyses that capture the most salient outcome domains.

Table 1 presents the key outcome domains and research questions for each of the IRA Medicare drug-related provisions. Details on each outcome and associated measures are available in the Evaluation Framework Report.

[§] Due to potential behavioral responses of stakeholders to the IRA provisions, modifications and/or additions to long-term research questions and outcomes may be necessary, depending on the results of monitoring and findings from earlier analyses.

[**] Data collection directly from stakeholders is particularly important for understanding implementation and awareness of IRA provisions. For example, enrollees may not obtain recommended vaccines if they are not aware of the provision that eliminates cost-sharing for adult vaccines covered under Part D.

Table 1. Outcome Domains and Associated Research Questions for IRA Medicare Drug-Related Provisions

IRA Provision	Key Outcome Domain and Research Question
Biosimilars Provision (Medicare Part B)	**Implementation:** What were the major steps to implementing this provision? What were the major challenges and opportunities? **Behavioral Responses:** Did providers change prescribing behavior for originator and biosimilar products? How did prescribing patterns change and why? **Pharmaceutical Markets and Innovation:** To what extent have originator and biosimilar drug prices changed, and how have these effects varied over time? How did the biosimilars provisions affect the composition of types of products under development by the pharmaceutical industry? What are pharmaceutical industry views on any impacts on innovation?
Inflation Rebates (Medicare Parts B and D)	**Implementation:** What were the major challenges and opportunities associated with implementing inflation rebates? **Spending:** How, if at all, did the inflation rebates provisions impact Medicare Program spending, both overall and for drugs with inflation rebates owed? Did the inflation rebates provisions impact beneficiary OOP costs for drugs with coinsurance adjustments and/or rebates owed? If so, how and why? **Pharmaceutical Markets and Innovation:** How, if at all, did the inflation rebates provisions change growth in branded drug prices? Did these effects vary over time? Did the inflation rebates provisions change drug launch timing or prices? Why, why not?
Insulin Copayment Provisions (Medicare Parts B and D)	**Implementation:** Were beneficiaries aware of the $35 insulin copay provision? What were the challenges and opportunities associated with implementing $35 insulin copays? **Behavioral Responses:** Did the $35 insulin copayments provisions result in Part D formulary changes? If so, what has changed and why? **Utilization:** How did the $35 insulin copayments provisions change utilization rates or utilization patterns for beneficiaries taking insulin? Did any impacts vary by subgroups? Why? **Spending:** Did the $35 insulin copayments provisions impact Medicare enrollee drug spending? Do any impacts differ by subgroups? Why? How did the $35 insulin copayments impact Medicare Program drug spending? **Health Outcomes:** How did the $35 insulin copayments provisions affect adherence to insulins? Did the $35 insulin copayments provisions result in reduced complications for patients with diabetes?
$0 Vaccine copayment for ACIP recommended adult vaccines (Medicare Part D)	**Implementation:** What were the major challenges and opportunities associated with implementing $0 vaccine copays? Were beneficiaries aware of the $0 vaccine copayments? **Utilization:** Did the IRA increase uptake of vaccines newly covered with $0 copayments? Why, why not? **Health Outcomes:** Did the IRA reduce the incidence of vaccine-preventable conditions and associated complications among vaccine-eligible beneficiaries and those especially vulnerable to the vaccine-preventable conditions? What type of beneficiaries benefited the most?
Part D Low-Income Subsidy Expansion (Medicare Part D)	**Implementation:** What were the major challenges and opportunities associated with implementing the LIS expansion? Were beneficiaries aware of this provision? What were their experiences applying for the expanded LIS? **Utilization:** How, if at all, did the Part D LIS expansion change utilization rates for the top 20 drugs filled by LIS-eligible beneficiaries? **Spending:** Did the Part D LIS expansion affect Part D enrollment of LIS-eligible beneficiaries? If so, how? Did the Part D LIS expansion impact Medicare Part D LIS enrollee OOP drug spending and Medicare Program drug spending? If so, why and how? **Health Outcomes:** How and why did the Part D LIS expansion change adherence rates for beneficiaries newly eligible for the Part D LIS?

IRA Provision	Key Outcome Domain and Research Question
Medicare Part D Benefit Redesign	**Implementation:** What were the challenges and opportunities associated with implementing these benefit redesign changes? Which provisions were the easiest or most challenging to implement? Were beneficiaries aware of the $2,000 OOP cap? **Behavioral Response:** Did the Part D benefit redesign have any impacts on plans' formularies and utilization management tools? What stakeholder groups were most affected by these changes, if any? **Utilization:** How have the Part D benefit redesign provisions changed utilization rates or utilization patterns for prescription drugs covered under Part D? To what extent did the Part D benefit redesign provisions change utilization of non-drug related health care services? **Spending:** Did the Part D benefit redesign provisions impact Medicare enrollee OOP drug spending and Medicare Program drug spending? Why, why not? Did the Part D benefit redesign result in changes in spending for non-drug related health care services? Why or why not? **Health Outcomes:** Did the Part D benefit redesign impact beneficiary health status and incidence of complications? Why, why not? How, if at all, has the Part D benefit redesign (especially the $2,000 OOP cap) affected adherence rates for high-cost Part D drugs? Did the Part D benefit redesign affect mortality rates among Medicare beneficiaries taking high-cost drugs? Why, why not? **Pharmaceutical Markets and Innovation:** Did the Part D benefit redesign change manufacturer rebate payments for branded and biosimilar drugs? Why, why not?
Drug Price Negotiation (Medicare Parts B and D)	**Implementation:** What were the challenges and opportunities associated with implementing drug price negotiation? **Behavioral Responses:** Did the drug price negotiation provision have any impacts on plans' formularies and utilization management tools? What stakeholder groups were most affected by these changes, if any? **Utilization:** Did the drug price negotiation provision change utilization of negotiated drugs and/or their close substitutes? Why, why not? **Spending:** Did the drug price negotiation provision change beneficiary out-of-pocket costs for negotiated drugs and/or their close substitutes? Why, why not? How, if at all, has the drug price negotiation provision changed Medicare program spending for negotiated drugs? **Pharmaceutical Markets and Innovation:**[a] Did the drug price negotiation provision change drug prices for negotiated drugs and those drugs in the same therapeutic class, and did any effects vary over time? Why, why not? Did the drug price negotiation provision change manufacturer rebate payments for negotiated drugs or their close substitutes? Why, why not? To what extent has the drug price negotiation provision shifted investment related to drug development? Why?

Source: The Evaluation Framework Report for the Inflation Reduction Act's Medicare Drug Related Provisions
Notes: OOP = Out-of-Pocket
[a] Note that addressing an overall research question about the general impact of the drug price negotiation provision on pharmaceutical innovation (i.e., are there changes in pharmaceutical innovation associated with the drug price negotiation provision? If so, how has innovation changed?) will be an important part of future evaluation efforts. Innovation can be assessed in a number of different ways, and the research questions and outcomes identified in this table represent a starting point.

Given the complexity of the provisions and the magnitude of the changes under the IRA, particularly for Medicare Part D, the Report recommends a mixed methods approach that includes using existing

administrative data where feasible and collecting additional quantitative and qualitative data when necessary to answer the research questions listed in Table 1.

For an overall evaluation that aims to identify the collective impact of all the IRA's Medicare drug-related provisions, a handful of key potential research questions and cross-cutting outcomes are included in the Report. The research questions are presented below:

- Did the IRA change utilization rates for drugs covered under Part B and Part D, and if so, how?
- Did the IRA impact Medicare enrollee out-of-pocket and Medicare Program drug spending, and if so, how?
- Did the IRA impact beneficiary health outcomes, and if so, how?
- Did the IRA impact prescription drug prices, and if so, how?
- Did the IRA change drug launch timing or launch prices, and if so, how?

In addition, the Report also includes research questions to explore spillover effects of the IRA's Medicare drug related provisions, such as:

- Did the IRA provisions change the affordability of prescription drugs for other populations (e.g., those with private insurance, Medicaid, others)?
- Did the IRA provisions accelerate or contribute to policy changes related to prescription drug pricing and access for other payers (not Medicare)?

As monitoring and evaluation activities learn more about the IRA's impacts on stakeholders, the research questions may need to be modified to reflect these learnings. Wherever possible, examining the potential impacts of each IRA Medicare drug-related provision in multiple ways to understand whether the directionality of the identified effects are consistent over time and across population groups is recommended. This, coupled with a mixed methods evaluation approach, will help to generate a clear understanding of the impacts of the IRA's Medicare drug-related provisions.

CONSIDERATIONS IN DEVELOPING THE EVALUATION FRAMEWORK

Evaluating the impact of legislation as it is implemented can be complex and challenging in terms of establishing its impact on the desired outcomes. Moreover, many laws go into effect nationally, making it difficult to establish a counterfactual through choice of comparison groups. The IRA is particularly complex because its many pharmaceutical related provisions go into effect at different times and may interact with other provisions in their impact on the outcomes of interest. Decisions on design alternatives for evaluating IRA's provisions early in the process should impact research methods and priorities for the evaluation process over the next few years.

There are several considerations that shape the way the IRA evaluation strategy is designed. The most important overarching question is to what extent changes in the outcomes of interest can be detected and with what confidence these changes can be attributed to the IRA's provisions as opposed to other factors that may also affect the same outcomes. Initially, there are two broad strategies to consider for evaluating the IRA's Medicare drug-related provisions. The first strategy would evaluate the combined effects of all IRA drug-related provisions collectively on cross-cutting measures such as overall drug utilization and spending across the Medicare Part D and Part B populations. The second strategy would be to evaluate each IRA provision separately.

We recommend prioritizing the second approach. The complexity of changes made by the IRA would make it challenging to understand their collective impact through examining only a handful of cross-cutting measures.

Additionally, some of the IRA provisions have not yet gone into effect so an overall evaluation would yield limited insights in the near future. Moreover, such an approach would miss impacts that are population-specific (e.g., provisions that only impact enrollees with high out-of-pocket drug costs) or provision-specific (e.g., whether the insulin cap provision that limits the out-of-pocket cost of a month's supply of a Part D covered insulin to $35 increases enrollees' accessibility and use of insulin). Most importantly, it would be challenging to identify an appropriate comparison group with an overall approach, making it difficult to attribute any changes to the IRA. There are other health market and policy related changes that are occurring simultaneously as IRA provisions are going into effect – for example, continued growth of Medicare Advantage enrollment and shift of traditional program beneficiaries into accountable care models such as Accountable Care Organizations (ACOs). Thus, the proposed approach is to evaluate each provision separately while concurrently monitoring overall IRA Medicare drug-related impacts on key cross-cutting measures over time. As we learn more about the provision-specific impacts and monitor overall cross-cutting measures over time, we can consider how best to understand the collective effect of all the IRA provisions on key stakeholders in the future.

There are also a number of methodological considerations and challenges to address when evaluating individual provisions of IRA. First, many of the IRA drug-related provisions have gone into effect already while some are scheduled to go into effect in later years and many provisions interact with each other in affecting key outcomes. For example, several out-of-pocket provisions (e.g., insulin cap, elimination of cost-sharing for recommended adult vaccines covered under Part D, elimination of cost-sharing in the catastrophic coverage phase of the Part D benefit) will be affected by the $2,000 out-of-pocket cap. The implementation of IRA provisions over a long period of time but also within overlapping time periods will require modelling that allows isolating the effects of a specific provision and assessing the interactive effects with other provisions. A further challenge will be to examine anticipatory impacts of provisions – that is, effects that occur related to behavioral changes by key stakeholders that take place in anticipation of implementation of a specific provision. Addressing this requires monitoring and examining changes before provisions go into effect.

Another consideration is that the IRA's drug-related provisions affect multiple stakeholders, who may respond in different ways. This, in turn, may have cascading consequences for other stakeholders. These behavioral responses by various stakeholders may affect the long-term outcomes and impacts of the provisions, particularly for Medicare enrollees. For example, whether enrollees encounter changes in their plans' drug formularies due to the IRA is dependent on how plans and manufacturers respond to the IRA provisions (e.g., the drug price negotiation program), and this in turn may affect enrollees' utilization of and access to certain drugs. To appropriately account for behavioral responses, it is necessary to monitor and examine responses over time for the various stakeholders and use qualitative and quantitative findings from earlier research to develop additional long-term research questions as more information becomes available.

Additionally, as with the overall evaluation approach, provision specific evaluations must consider non-IRA changes that can affect key outcomes. Baseline trends may be changing due to policy changes, market shifts, technological changes, and other factors. Collectively, these factors make it challenging to attribute any observed effects solely to the IRA provisions. For example, there is concern that the IRA's inflation rebate provision, which requires manufacturers to pay rebates if the price of a drug increases faster than inflation, may have an impact on the launch prices of new drugs. However, the trend even before the inflation rebate provisions went into effect has been for manufacturers to launch drugs at higher prices.[23] Identifying baseline trends over time, accounting for existing initiatives that are implemented during IRA implementation, and appropriately controlling for other contextual factors will be critical to ensure that the evaluation of the IRA is able to detect the observed effects for each provision. Moreover, any effects that are identified will need to be appropriately contextualized to account for the changing health and policy landscape.

For the quantitative impact analyses for each provision, one challenge that may arise is how best to identify effects for enrollees that are more directly impacted by the IRA provisions among a large group of applicable enrollees. It is important to examine how a provision affects the entire population of applicable enrollees (e.g., the entire Part D population). However, when examining the entire population of enrollees, certain effects may be difficult to detect because not all enrollees may benefit from a given provision during a specified time period. As a result, the treatment effect may be diluted across the entire population of Part D enrollees. Therefore, it is necessary to construct subgroups of enrollees that may be more directly affected for each provision. For example, the Part D $2,000 out-of-pocket cap provision applies to all Medicare Part D enrollees, however, enrollees who have historically had the highest prescription drug out-of-pocket spending are likely to be the most impacted by this provision and the magnitude of the effect may be different for these enrollees vis a vis the entire population of Medicare Part D enrollees, many of whom do not have more than $2,000 in out-of-pocket spending in a year. Enrollees who have historically low adherence to prescription medications may be another subgroup to consider when evaluating whether the Part D $2,000 out-of-pocket cap improves adherence to prescription drugs. Constructing appropriate subgroups will be necessary to fully understand the effects of the IRA's provisions.

Another key consideration related to carrying out impact analyses is identifying an appropriate comparison group that is as similar as possible to the treatment group but is not subject to the IRA's drug related provisions. As noted above, this is difficult for the overall evaluation, and we expect that it will be challenging for certain provisions in the provision-specific evaluation as well. However, an appropriate comparison group is critical for understanding whether an IRA provision is responsible for changes in outcomes. Therefore, it is worthwhile to explore constructing comparison groups where feasible for each IRA drug-related provision, though there may be limitations and in certain cases, other methods will need to be used (e.g., pre-post or single series time-series analyses).[††] The Evaluation Framework Report considers whether comparison groups can be constructed for each IRA Medicare drug-related provision and presents options for comparison groups where feasible.

Finally, another key aspect considered in the design of the evaluation is the role of qualitative methods in identifying the effects of each drug-related provision. Administrative claims data provide crucial information on use and spending on health care services, however, this data cannot be used to understand implementation processes and stakeholder perspectives. Thus, relying on quantitative data alone will limit the evaluation considerably. To gain a more complete understanding of the effects of the IRA's Medicare drug-related provisions, qualitative approaches to collect detailed information from the various stakeholders are required -- particularly to gain greater insight into the "how" and "why" evaluation questions. Qualitative studies can be especially valuable for understanding the mechanisms driving any observed effects. The Evaluation Framework Report includes research questions that are best examined through various qualitative methods (e.g., interviews and focus groups). Findings from qualitative analyses may help to generate additional impact-oriented research questions and hypotheses that can be tested empirically using quantitative approaches such as regression discontinuity designs and difference-in-difference techniques.

In developing the Evaluation Framework Report, we considered the points listed above to ensure that the evaluation approach can fully and systematically examine what happens under the IRA's drug related provisions, how it happens, and why it happens.

[††] Comparison group-based analyses will require a rigorous assessment of the differences between the treatment and comparison groups and will need to employ methodologically sound ways to address these differences. For example, the $35 insulin provision can be evaluated by comparing the outcomes for enrollees in the low-income subsidy program who use insulin with enrollees who are not in LIS who use insulin. Because LIS enrollees do not have significant out-of-pocket costs for insulin, the changes in outcomes for these enrollees can be compared over time with changes in outcomes for those who do not have LIS.

DISCUSSION

A systematic evaluation that aims to comprehensively capture the effects of the IRA's Medicare prescription drug-related provisions is necessary to fully understand impacts, including impacts on the various stakeholders such as Medicare enrollees, the Medicare program, prescription drug plans, pharmaceutical manufacturers, and others. This Report provides the foundation for beginning this evaluation in a systematic way using a variety of data sources and robust quantitative and qualitative methods. Evaluation of the impacts of the IRA will help to inform future policymakers seeking to improve the affordability and accessibility of prescription drugs for Medicare enrollees.

APPENDIX

Outcome Domains in the Evaluation Framework Report

Implementation Questions:

- Implementation: How do the different stakeholders implement the IRA and what barriers or challenges to implementation, if any, do they face?
- Context: What is the landscape or context within which the IRA's drug-related provisions are being implemented, in terms of other federal or state prescription drug pricing or coverage policies enacted at similar times?
- Behavioral Responses: To what extent are stakeholders aware of relevant provisions? How do stakeholders respond to the IRA drug-related provisions?

Impact Evaluation:

- Utilization and Access: How do the IRA's drug-related provisions affect enrollee use of and access to prescription drugs and other services in the Medicare Program?
- Spending: How have the IRA's drug-related provisions impacted spending by different stakeholders, especially the government and beneficiaries, on prescription drugs and other services under the Medicare Part D and Part B Programs?
- Health Outcomes: Did the IRA drug-related provisions impact health outcomes for Part D enrollees?
- Pharmaceutical Markets/Innovation: What are the impacts of the IRA's drug-related provisions on pharmaceutical markets, drug development, and pharmaceutical innovation?
- Unintended Consequences and Spillover Effects: Did the IRA's drug-related provisions have any unintended or unexpected consequences? Did the IRA provisions have any spillover effects for Medicare beneficiaries not directly impacted by the provision?
- External Spillovers: Did the IRA provisions have any impacts on other parts of the health care system—for example, on commercial insurance coverage or Medicaid Programs?

REFERENCES

[1] Sayed, BA, Finegold, K, Olsen, TA, Ashok, K, Schutz, S, Sheingold, S, De Lew, N, Sommers, BD. Inflation Reduction Act Research Series: Medicare Part D Enrollee Out-Of-Pocket Spending: Recent Trends and Projected Impacts of the Inflation Reduction Act. (Issue Brief No. HP-2023-19). Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. July 2023 (Revised January 2024).

[2] Kesselheim, Aaron S, Jerry Avorn, and Ameet Sarpatwari. "The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform." *JAMA : the journal of the American Medical Association 316.8 (2016): 858–871. Web.*

[3] IQVIA Institute for Human Data Science. The Use of Medicines in the U.S. 2024: Usage and Spending Trends and Outlook to 2028. April 2024. Available from www.iqviainstitute.org

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Planning and Evaluation

200 Independence Avenue SW, Mailstop 447D
Washington, D.C. 20201

For more ASPE briefs and other publications, visit:
aspe.hhs.gov/reports

SUGGESTED CITATION
Inflation Reduction Act Research Series: An Evaluation Framework for the Inflation Reduction Act's Medicare Prescription Drug Related Provisions. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. December 2024.

Subscribe to ASPE mailing list to receive email updates on new publications:
https://list.nih.gov/cgi-bin/wa.exe?SUBED1=ASPE-HEALTH-POLICY&A=1

For general questions or general information about ASPE:
aspe.hhs.gov/about