An Evaluation Framework for the Inflation Reduction Act's Medicare Prescription Drug-Related Provisions

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About This Project Report

The Inflation Reduction Act (IRA) of 2022 enacted a range of provisions designed to reduce prescription drug costs for Medicare beneficiaries and for the Medicare Program. This project designed a framework for a future evaluation of the impact of these provisions on stakeholders for a set of outcome domains, including utilization and access, spending, and pharmaceutical markets and innovation. In this report, we present the evaluation framework, focusing on how to conduct an implementation evaluation, provision-specific evaluations, and an evaluation of the IRA Medicare prescription drug-related provisions as a whole.

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Abbreviations

ACIP	Advisory Committee on Immunization Practices
AMP	Average manufacturer price
APCD	All-payer claims database
ASP	Average sales price
ASPE	Office of the Assistant Secretary for Planning and Evaluation
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
DiD	Difference-in-differences
DIR	Direct and indirect remuneration
FDA	Food & Drug Administration
FFS	Fee-for-service
GLP-1	Glucagon-like peptide 1
HEDIS	Healthcare Effectiveness Data and Information Set
HOS	Health Outcomes Survey
HPSA	Health Professional Shortage Area
HRSA	Health Resources and Services Administration
IDR	Integrated Data Repository
IRA	Inflation Reduction Act
ITS	Interrupted time series
MA	Medicare Advantage
MA-PD	Medicare Advantage Prescription Drug plan
MBISG	Medicare Bayesian Improved Surname Geocoding
MCBS	Medicare Current Beneficiary Survey
MEPS	Medical Expenditure Panel Survey
MFP	Maximum fair price
LIS	Low-Income Subsidy
NASHP	National Academy for State Health Policy
NCSL	National Council of State Legislatures
NDI	National Death Index
NPPES	National Plan & Provider Enumeration System
OOP	Out-of-pocket
PBM	Pharmacy benefit manager
PBP	Plan benefit package
PDAB	Public Prescription Drug Affordability Board
PDC	Proportion of Days Covered

PDE	Prescription drug event
PDP	Prescription Drug Plan
PDSS	Part D Senior Savings
PhRMA	Pharmaceutical Research and Manufacturers of America
PQA	Pharmacy Quality Alliance
RDD	Regression discontinuity design
RQ	Research question
RSV	Respiratory syncytial virus
SHIP	State Health Insurance Assistance Program
TEP	Technical Expert Panel
VA	Veterans Affairs

Summary

The Inflation Reduction Act (IRA) of 2022 (117th Congress, 2022) enacted a broad set of changes to coverage of and payment for prescription drugs dispensed to Medicare beneficiaries. The prescription drug provisions of the IRA aimed to lower prescription drug prices for Medicare beneficiaries enrolled in Medicare Part B, which covers physician-administered medications, and Medicare Part D, which covers outpatient prescription drugs generally dispensed at retail or via mail-order pharmacies. These provisions were also intended to lower Medicare Program spending on pharmaceuticals. The Medicare drug-related provisions in the IRA go into effect over time (Centers for Medicare & Medicaid Services, Undated). The law is projected to reduce government spending in the Medicare Program (Congressional Budget Office, 2022b).

Issue

Evaluating the implementation and outcomes of the IRA Medicare drug-related provisions on key stakeholders will provide important information to policymakers about whether the provisions resulted in the expected outcomes and whether they led to unanticipated effects.

Approach

This report is the result of a series of tasks RAND researchers conducted with the goal of designing a framework for an evaluation of the IRA Medicare drug-related provisions. We first identified the main IRA provisions to be included in the evaluation framework and created logic models explaining the provisions, activities to implement the provisions, the outputs of those activities, and the expected outcomes of the provisions. We then identified key data sources that could be used to construct the outcome measures of interest, as well as potential statistical approaches to identify effects and primary data collection opportunities to provide additional context around findings. We finally convened a Technical Expert Panel (TEP) to elicit feedback on key aspects of the evaluation framework.

How to Use This Report

This report describes an evaluation framework for provision-specific studies and an overall approach to evaluating the IRA, focusing on analyses that are feasible to conduct with existing datasets and are likely to result in meaningful findings based on data availability and methodological rigor. This report is not a set of "step-by-step" instructions on how to evaluate the IRA Medicare drug-related provisions; rather, it is intended to provide the reader with an

overall understanding of the potential research questions to consider, the methods that may be employed, and the considerations and high-level challenges that they may encounter in formulating a more detailed evaluation design for each IRA provision and for the overall IRA evaluation.

The intent behind this report is to provide a menu of options for future evaluators to use when conducting mixed-methods evaluations of the implementation and impacts of IRA Medicare drug-related provisions. Readers should be able to select pieces from different chapters to inform a more in-depth analytic plan after selecting specific provision(s) of interest for an evaluation. The chapters in the report are as follows:

- Chapter 1 provides information about the different IRA Medicare drug-related provisions included in this report, along with implementation timing.
- Chapter 2 presents the logic models to facilitate the understanding of the process by which the provisions may lead to potential outcomes.
- Chapter 3 provides specific discussion of research questions, outcome measures, treatment and comparison groups, statistical methods, and primary data collection activities that would apply to analyses of specific IRA drug-related provisions.
- Chapter 4 provides information on how future evaluators might conduct an overall evaluation of all IRA drug-related provisions.
- Chapter 5 describes a set of additional considerations for future evaluators.
- Appendices: There are also a series of appendices that provide additional details on the data sources and availability, statistical methods, primary data collection and analysis approaches, and a brief description of a possible approach to evaluating spillover effects on other parts of the health care system (non-Medicare).

As an example of how to use this report, evaluators interested in measuring the outcomes of the provisions related to biosimilars should use the information presented in the biosimilars section in Chapter 3 to learn about potential options and pair that information with the more data sources and statistical methods appendices to design their own analytic plan that would guide their work to estimate the impact of the provisions.

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Chapter 1. Provisions and Implementation Timeline

The Inflation Reduction Act (IRA) of 2022 (117th Congress, 2022) enacted a range of provisions to lower prices and out-of-pocket spending for prescription drugs covered by Medicare Parts B and D, and to lower Medicare Program spending. The prescription drug provisions of the IRA aimed to lower prescription drug prices on which cost sharing is based for Medicare beneficiaries enrolled in Medicare Part B, which covers physician-administered medications, and Medicare Part D, which covers outpatient prescription drugs generally dispensed at retail or via mail-order pharmacies, as well as reduce spending by the Medicare Program. Table 1 summarizes these provisions, separately by Medicare Parts B and D. For each provision, we include a shorthand name, a longer description, the drugs covered, and the patient populations impacted by it. Some provisions (e.g., the inflation rebates and drug price negotiations) apply to both Medicare Parts B and D, but others are focused specifically on a given Part (e.g., the biosimilars payment changes applied within Part B). The prescription drugs covered under Part B versus Part D are different, and some beneficiaries are enrolled in Part B but not Part D (Assistant Secretary for Planning and Evaluation, 2022); therefore, the patient populations impacted by the IRA provisions for each Part might be very different. To reflect these differences and to illustrate the types of patient populations impacted, we organized the table by the Part of Medicare to which the provision applies and repeated the provisions under each Part (repeated provisions across both Parts indicated with a *).

Table 1.1. Inflation Reduction Act Provisions, Drugs Covered, and Patient Populations Impacted

Provision	Description	Prescription Drugs Covered	Patient Population Impacted
Medicare Part B			
Biosimilars add-on fee (2022)	Temporary increase in reimbursement to providers for qualifying biosimilars from Average Sales Price (ASP) + 6% to ASP + 8%.	Qualifying biosimilars	Prescribed specific drugs
Inflation rebates* (2023)	Requires manufacturers to pay a rebate to Medicare if their prices increase faster than inflation in a given quarter.	Certain single-source drugs and biologic products[a]	Prescribed specific drugs
Coinsurance inflation-based reductions (April 2023)	Beneficiaries may pay lower coinsurance if their medication's price increased faster than inflation in a given quarter.	Certain single-source drugs and biologic products[a]	Prescribed specific drugs
$35 insulin copays* (July 2023)	Imposes a $35 maximum out-of-pocket (OOP) monthly cost share for each insulin product covered by Part B (pump insulins). Also waives the deductible for these medications.	Insulins paid for under Part B	Prescribed insulins under Durable Medical Equipment Benefit
Payment cap for new biosimilars (July 2024)	Imposes a cap on the reimbursement amount for new biosimilars when average sales price data are not available.	Biosimilars	Prescribed specific drugs

Provision	Description	Prescription Drugs Covered	Patient Population Impacted
Drug price negotiation* (2028)	Allows the Medicare Program to enter into negotiations to establish the Maximum Fair Price for a selected group of drugs.	Certain single source drugs with high expenditures[b]	Prescribed specific drugs
Medicare Part D			
Inflation rebates* (2022)	Requires manufacturers to pay a rebate to Medicare if their prices increase faster than inflation over a 12-month period.	Certain single-source drugs and biologic products[a]	All Part D enrollees
$35 insulin copays* (2023)	Imposes a $35 maximum OOP cost share per month's supply for beneficiaries using insulins covered by their Part D plan (non-pump insulins). Waives the Part D deductible for covered insulins as well.	Insulins covered by Part D plans	Prescribed insulins covered by Part D
$0 copay vaccines (2023)	Waives the cost sharing for adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP).	Vaccines	Eligible for ACIP-recommended vaccines covered by Part D
$0 catastrophic cost sharing (2024)	Reduces to $0 the amount beneficiaries pay after they hit the catastrophic threshold in Part D.	All	Part D enrollees with high drug OOP costs
Low-Income Subsidy (LIS) expansion (2024)	Expands eligibility to allow for full LIS eligibility to some beneficiaries making less than 150 percent of the federal poverty level.	All	Lower income Part D enrollees
Premium stabilization (2024)	Provides for Part D premium stabilization by capping base beneficiary premium increases per year to 6 percent.	All	All Part D enrollees
OOP cap of $2,000 (2025)	Imposes a limit of $2,000 in beneficiary OOP costs per year. Also allows certain third-party payments to count toward the cap.	All	Part D enrollees with high drug OOP costs
Medicare Prescription Payment Plan (2025)	Provides an option for beneficiaries to spread their payments over the course of the year instead of spending the full amount at the beginning of the year.	All	All Part D enrollees, but especially those with high drug OOP costs early in calendar year
Changes to financial liabilities (2025)	Shifts how much the plans, Centers for Medicare & Medicaid Services (CMS), and manufacturers pay for Part D benefits due to the changes to the overall benefit design and cost-sharing structures.	All	All Part D enrollees
Drug price negotiation* (2026)	Allows the Medicare Program to enter into negotiations to establish the Maximum Fair Price (MFP) for a selected group of drugs.	Certain single-source drugs with high expenditures[b]	Prescribed specific drugs

SOURCE: Summarized from CMS guidance and rulemaking, fact sheets, and timeline documents related to IRA implementation.

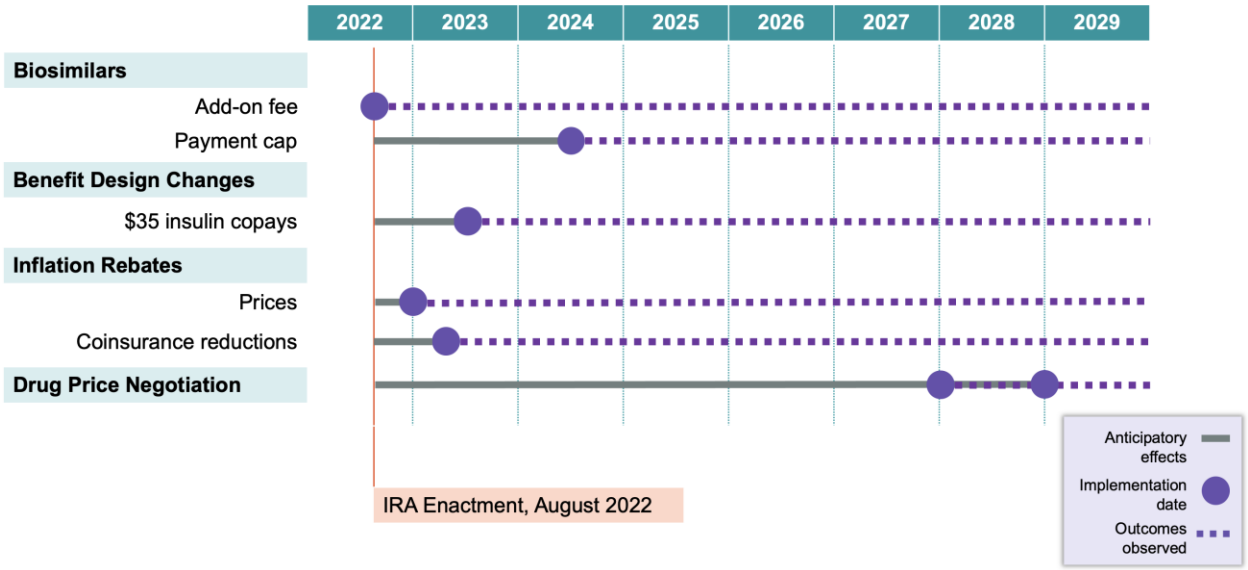
[a] See CMS, "Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Revised Guidance, Implementation of Section 1847A(i) of the Social Security Act." December 14, 2023. Please reference the CMS Fact Sheet: Medicare Prescription Drug Inflation Rebate Program Policies in the Calendar 2025 Physician Fee Schedule Final Rule from November 2024. Please click this link to access the list of drugs subject to this provision on a quarterly basis.

[b] Please reference the CMS Fact Sheet: Medicare Drug Price Negotiation Program Revised Guidance from June 2023. Please click this link to access the list of drugs selected for the first round of drug price negotiations. Please click this link to access the MFPs for the first cycle of negotiations.

Medicare Part B Provisions

The Medicare Part B provisions are specific to physician-administered drugs—largely biosimilars, single-source drugs, or biologic products—that can generally be characterized as having high costs or expenditures. Beneficiaries affected by these provisions will be those taking the drugs targeted by the provision, though we note there may be further downstream effects for all Part B enrollees if changes to drug spending and utilization impact Part B premiums. Figure 1.1 shows the timeline for implementation of the different provisions, described in more detail below. In this figure, we have plotted the implementation date when each provision comes into effect, as well as the period after implementation where we expect to observe outcomes, and the period between enactment of the IRA and the implementation date where stakeholders will likely take actions in anticipation of the implementation of the provision.

Figure 1.1. Medicare Part B IRA Provisions Timeline



SOURCE: Summarized from CMS guidance and rulemaking, fact sheets, and timeline documents related to IRA implementation.

The IRA made minimal changes to the Part B benefit. The major change is a **limit on OOP costs for covered insulins taken by pump** to no more than $35 for a one-month supply, starting in July 2023. The provision also waived the Part B deductible for these insulins. Beneficiaries directly impacted by this provision will be those who take insulin that is administered via a pump.

Two provisions will apply when drug prices increase faster than the rate of inflation. The first, **inflation rebates for certain drugs covered under Part B,** was implemented in 2023 as the beginning of the time periods for which manufacturers could be subject to rebates. Per this

provision, manufacturers pay rebates to Medicare if their drug prices rise faster than inflation. The other related provision is **coinsurance reductions** for beneficiaries in traditional Medicare or Medicare Advantage (MA) who were administered medications covered by Part B where the prices increase faster than inflation.

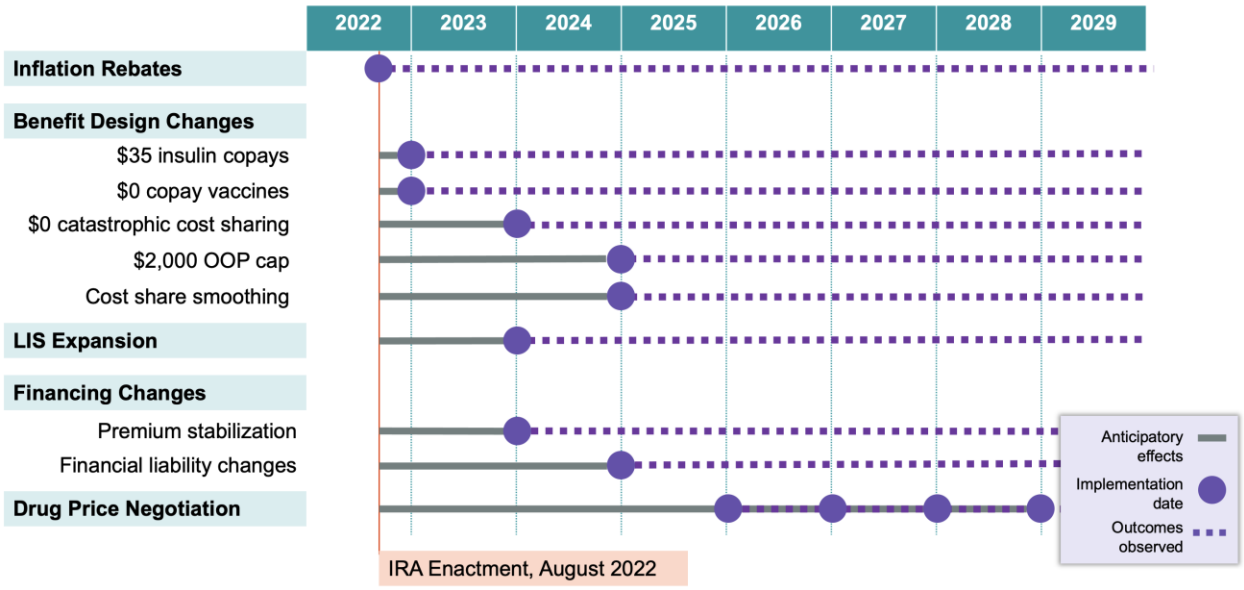
Two provisions of the IRA relate to biosimilars—biologic products that are "highly similar" to Food & Drug Administration (FDA)–approved biologics (U.S. Food & Drug Administration, 2024). Historically under Part B, biosimilars prescribed in certain settings, such as hospital outpatient departments and ambulatory surgical centers, were typically reimbursed at a rate calculated by taking the ASP and adding a 6 percent fee. Starting in 2022, the IRA temporarily **increased the biosimilar add-on fee** to 8 percent for qualifying biosimilars, increasing the incentive for providers to prescribe lower-cost biosimilars instead of higher-cost originator biologics (Centers for Medicare & Medicaid Services, 2024). Starting in July 2024, the IRA also **capped payment for new biosimilars** in the event that there is no ASP available (Centers for Medicare & Medicaid Services, Undated). This cap is based on either the ASP of the reference biologic or the wholesale acquisition cost of the biosimilar and is meant to limit spending in cases where there is only a single biosimilar approved for an originator biologic.

Finally, though the IRA's **drug price negotiation** starts with drugs covered under Part D, drugs covered under Part B will become eligible for selection starting in 2026, with negotiated prices taking effect in 2028 and 2029 if additional drugs covered under Part B are selected for negotiation.

Medicare Part D Provisions

Some of the Part D provisions of the IRA are analogues of similar provisions in Part B. For example, **inflation rebates in Part D** were implemented in 2022 as the first time period for which manufacturers could be subjected to rebates. Similar to Part B, manufacturers pay rebates to Medicare if their average manufacturer prices (AMPs) rise faster than inflation. Though there are no reductions to cost sharing applied via the inflation rebate provisions for Part D, this provision may affect all Part D enrollees by, for example, deterring price increases above inflation, which may impact Part D premiums and overall Medicare spending. Figure 1.2 shows the implementation year, timing of any anticipatory effects, and timing for outcomes for the Part D provisions.

Figure 1.2. Medicare Part D IRA Provisions Timeline



SOURCE: Summarized from CMS guidance and rulemaking, fact sheets, and timeline documents related to IRA implementation.

There are several provisions that impact benefit design in Part D. These include limiting **copays for a one-month supply of covered insulins to $35** starting in 2023 (this includes all Part D–covered insulins), **eliminating copays for adult vaccines recommended by the ACIP,** starting in 2023, and **eliminating copays for all Part D–covered drugs when the beneficiary is in the catastrophic phase** starting in 2024. Other benefit design changes include **capping OOP drug costs to no more than $2,000** starting in 2025; the $2,000 cap is adjusted based on inflation in subsequent years. In addition, in order to reach the $2,000 OOP cap, certain third-party payments may be counted as OOP payments beginning in 2025. Another benefit design change included in the IRA is the option for enrollees of **smoothing OOP costs** starting in 2025. This provision is also known as the Medicare Prescription Payment Plan.

The Medicare Part D provisions will likely impact those taking the specific drugs targeted for a benefit change—that is, insulins and vaccines covered by Part D—as well as beneficiaries with OOP drug costs that exceed $2,000 per year. Both groups will pay lower OOP drug costs as part of the benefit redesign enacted via the IRA.

One other provision applicable to Part D enrollees is the **expansion of the full LIS in Part D,** an existing program providing premium and copay support for those with low incomes and limited assets. Before the IRA, people with incomes below 135 percent of the federal poverty level who met resource limits were eligible for a full subsidy covering all OOP costs for drugs covered under Part D, and those with slightly higher incomes (below 150 percent of the federal poverty level) who met resource limits were eligible for a partial subsidy (Feyman et al., 2024).

Under the IRA, those with incomes below 150 percent of the federal poverty line who meet resource limits are eligible for the full subsidy. This provision will affect beneficiaries newly eligible for the full subsidy, who will receive additional subsidies that will lower their premiums and OOP drug costs.

There are also two provisions affecting stakeholder financial liabilities for the Part D benefit. The first of these is **premium stabilization,** which limits the increase of the Part D base beneficiary premium to no more than 6 percent per year through 2029. This upper limit on base beneficiary premium increases will help limit average basic Part D premium increases for beneficiaries by requiring the federal government to pay a greater proportion of the costs of basic Part D coverage.[1] The IRA also includes substantial **changes to benefit liabilities,** whereby beneficiaries still pay 100 percent of the cost of their medications in the deductible phase, but plans, manufacturers, and CMS pay different amounts in the initial coverage and catastrophic phases. Beneficiaries will still pay, on average, 25 percent of their drug costs in the initial coverage phase, but once they hit the $2,000 OOP cap, they will pay $0. Part D plans will pay 75 percent in the initial coverage phase for generic medications and 65 percent for brand drugs. The Coverage Gap Discount Program, through which manufacturers paid 25 percent of the cost of brand drugs for beneficiaries in the coverage gap, was replaced by the Manufacturer Discount Program, through which manufacturers will pay 10 percent for brand drugs in the initial coverage phase and 20 percent for brand drugs in the catastrophic phase. The coverage gap was eliminated as part of the IRA provisions; therefore, once beneficiaries exit the initial coverage phase, they enter the catastrophic phase. Once beneficiaries enter the catastrophic phase, Part D plans will pay 60 percent for both brands and generics, and manufacturers will pay 20 percent for brand drugs. CMS will pay reinsurance costs of 40 percent for generic drugs and drugs selected for negotiation, and 20 percent for brand drugs, which is a large reduction from the 80 percent of costs CMS paid in the catastrophic phase pre-IRA (Sayed et al., 2023).[2] All Part D enrollees will be impacted by the changes to the Part D financing mechanisms, though those with spending that exceeds the new lower OOP cap will likely be most affected. The shifts in financing for Part D among plans, CMS, and manufacturers may lead to changes in incentives for Part D plans in designing formularies and cost-sharing structures and negotiating with manufacturers for rebates. They may also impact manufacturers by changing incentives related to drug development.

The IRA also gave CMS the authority to **negotiate drug prices** directly with manufacturers for certain drugs covered under Part D, with drugs first eligible for negotiation selected in 2023

[1] In addition, CMS has implemented the Part D Premium Stabilization Demonstration, a voluntary demonstration program for stand-alone prescription drug plans (PDPs) to test whether additional policy changes stabilize year-over-year changes in premiums during the transition to the new Part D benefit design. See CMS announcement for more information.

[2] Note that CMS will also pay the manufacturer's 10 percent in the initial coverage and 20 percent in the catastrophic phase for drugs selected for price negotiation and for which an MFP is negotiated, during the time frame for which the MFP applies. See the CMS IRA timeline for more information.

and negotiated prices taking effect in 2026. These negotiations may impact beneficiaries taking the drugs selected for negotiation, as lower prices may translate to lower OOP costs for those medications (Office of the Assistant Secretary for Planning and Evaluation, 2023a).

Stakeholders Directly Impacted by the IRA Medicare Drug-Related Provisions

The above-described drug-related provisions are likely to impact a wide range of stakeholders. Table 1.2 lists the key stakeholders likely to be directly impacted by each provision; the table does not include the full range of stakeholders that may be impacted by each of the IRA Medicare drug-related provisions. While some impacts of the IRA provisions may in turn impact certain stakeholders as third-order effects, we focus this table and the evaluation framework on those impacts that are expected to directly affect specific stakeholders. We describe specific analyses focused on different stakeholders for each provision grouping in Chapter 3.

Table 1.2. Inflation Reduction Act Provisions and Stakeholders Directly Impacted

Provision	Stakeholders						
	Beneficiaries	Plans	Federal Government	Pharmaceutical Industry[a]	Providers	PBMs	Pharmacies
Medicare Part B							
Biosimilars	✓	–	✓	✓	✓	–	–
Inflation rebates	✓	✓	✓	✓	✓	–	–
$35 insulin copays	✓	✓	✓	–	–	–	–
Drug price negotiation	✓	✓	✓	✓	✓	–	–
Medicare Part D							
Inflation rebates	–	–	✓	✓	–	–	–
$35 insulin copays	✓	✓	✓	–	–	✓	–
$0 copay vaccines	✓	✓	✓	–	–	✓	✓
LIS expansion	✓	✓	✓	–	–	–	✓
Part D benefit redesign							
$0 catastrophic cost sharing	✓	✓	–	–	–	✓	–
Premium stabilization	✓	–	✓	–	–	–	–
OOP cap of $2,000	✓	✓	✓	✓	–	✓	–

	Stakeholders						
Medicare Prescription Payment Plan	✓	✓	✓	–	–	✓	✓
Third-party payments	✓	✓	✓	–	–	✓	–
Changes to financial liabilities	✓	✓	✓	✓	–	✓	–
Drug price negotiation	✓	✓	✓	✓	–	✓	✓

SOURCE: Summarized from CMS guidance, fact sheet, and timeline documents related to IRA implementation.
[a] We use the term “pharmaceutical industry” here instead of “manufacturers” to capture the broader impacts of the IRA in the industry.
PBM = Pharmacy benefit manager

Chapter 2. Logic Models

A rigorous evaluation of the IRA's drug-related provisions should be informed by logic models. In this chapter, we present two such logic models, one for Part B provisions and one for Part D provisions. We created both logic models based on the review of summary materials describing the IRA's Medicare prescription drug-related provisions produced by federal agencies, including reports from CMS (Centers for Medicare & Medicaid Services, Undated), the Congressional Research Service (Congressional Research Service, 2022), and the Congressional Budget Office (Congressional Budget Office, 2022a). We included only the major provisions of the IRA that are likely to have a substantial impact on beneficiaries, plans, or manufacturers.[3] For many provisions, we conducted additional targeted searches for reports or articles describing their potential impact. For example, we found additional information about Medicare Part B inflation rebates in an Assistant Secretary for Planning and Evaluation (ASPE) report that addressed which drugs would be subject to those rebates (Office of the Assistant Secretary for Planning and Evaluation, 2023b). When necessary to add context and details regarding a specific provision, we reviewed the legislative text of the IRA. All additional sources are cited in the text.

For each major IRA provision we included in our logic models (e.g., biosimilars add-on fee), we show a short description (e.g., temporarily increasing the add-on fee for biosimilars from 6 percent to 8 percent of the ASP of the reference product), initial implementation year (e.g., 2022), what high-level activities would be required to implement the provision (e.g., identifying drugs, calculating the ASP and increased fee), and the outputs of the enacted provision (e.g., a list of drugs with the increased add-on fee). We also assessed the mechanism by which the provision works (e.g., promoting the use of lower-cost biosimilars); the drugs affected by the provision (e.g., biosimilars); the patient populations affected (e.g., those prescribed specific drugs); which outcomes were likely affected (e.g., utilization and access, spending, etc.); whether those outcomes would likely be seen in the short, medium, or long term; which stakeholders were responsible for implementing; and which stakeholders were directly affected by the provision.

Each logic model includes each identified major provision for the relevant part of Medicare as inputs. Each input provision is grouped with similar provisions and appears in the order of implementation timing. For each input grouping, we also include high-level descriptions of the major activities needed to implement those provisions and the outputs resulting from

[3] We focused on these specific stakeholders as most outcomes directly impact them in some way. While providers and pharmacies play a role and evaluations into the impact of the IRA on them will provide important insights, we focused on the stakeholders listed here as the core group. We do note that providers and pharmacies are referenced in the evaluation framework where appropriate (for specific provisions).

implementation of those provisions. We also include potential outcomes for each grouping, splitting the outcomes into implementation outcomes and impact outcomes. We include four types of impact outcomes (utilization and access, spending, health outcomes, and pharmaceutical markets/innovation) and note whether we would expect to see these outcomes in the short, medium, or long term. Short-term outcomes are seen immediately after implementation of the provision. Medium-term outcomes follow short-term outcomes and are likely a result of the changes observed in short-term outcomes. Long-term outcomes are more distal and require more time to develop, often resulting from strategic changes made by the pharmaceutical industry or health outcomes resulting from cumulative years of increased access to drugs. Exact timelines vary by drug and intervention, so we do not define the exact time frames for these three categories. For each model, we also include contextual factors around the provisions, as the broader context in which the provisions are implemented will likely affect both the implementation and impact outcomes observed.

We note that the activities undertaken to implement the IRA provisions mentioned in this chapter and throughout the report are described at a high level, drawn from publicly available sources, and **do not represent the full scope of activities required to implement and effectuate the IRA provisions.** Implementation research questions are included in this report because a comprehensive evaluation framework of the IRA's drug-related provisions and their outcomes requires an inclusion of research questions and potential approaches to assess how different provisions have been implemented. However, the implementation evaluation approach described in this report only includes a limited number of implementation outcomes, such as stakeholder awareness of provisions and experiences with implementation, and, by design, does not focus on the nuances of the implementation process itself. Researchers who seek to conduct more detailed implementation analyses will have to develop an approach that is more detailed than the high-level descriptions provided as a framework in this report.

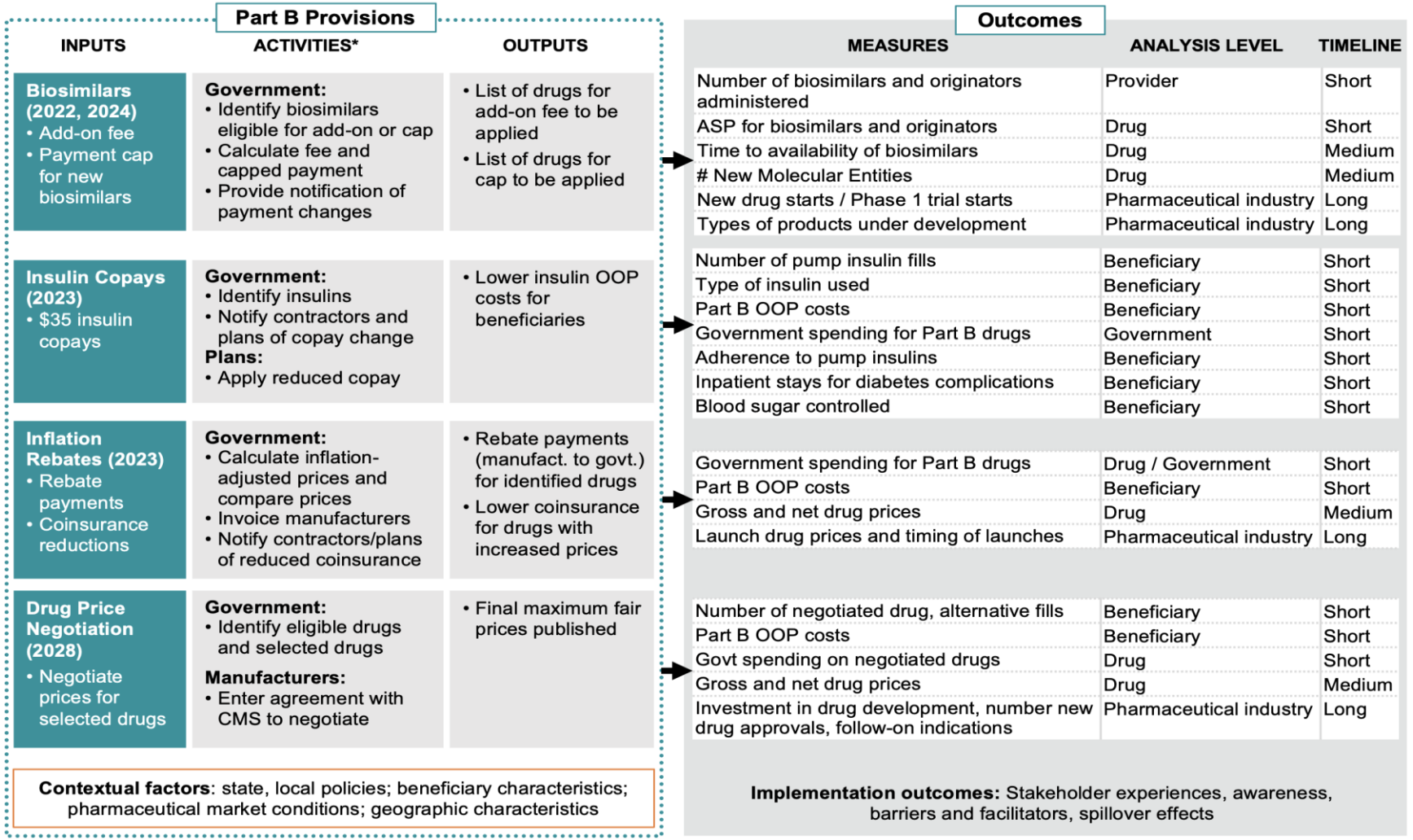
Medicare Part B Logic Model

Figure 2.1 shows the logic model for the Medicare Part B provisions of the IRA.

Inputs

The Medicare Part B provisions (inputs) can be grouped into four categories: biosimilars, benefit changes, inflation rebates, and drug price negotiation.

Figure 2.1. Logic Model for IRA Medicare Part B Provisions



* There are many activities required to implement these provisions, which are not reflected in this high-level logic model.

Activities

An important part of an evaluation is to understand how a provision or set of provisions was implemented, which in turn can help shed light on findings from the impact evaluation. For each provision, a range of implementation activities have occurred and will continue to occur, with different stakeholders required to participate in different activities. The logic model describes activities at a high level and does not capture the full range of activities that may occur to effectuate a provision. The key stakeholder at this stage and for each grouping is the federal government ("Government" in the figure), which in most cases is CMS. For the biosimilar provisions, the government identifies those biosimilars eligible for the add-on payment or for the payment cap. The government also calculates the amount of the increased fee and the amount of the capped payment. Finally, the government provides notification of the payment changes. For the insulin copay provision, the government must identify the insulins for which the $35 maximum copayment provision applies and notify the Medicare Administrative Contractors (MACs) and MA plans of the copay change. Suppliers and plans in turn apply the updated copay in their systems to ensure that beneficiaries are charged the correct amount.

For the inflation rebates provisions, government activities include calculating prices from manufacturer-submitted data, comparing them to an inflation-adjusted price, and sending invoices to manufacturers whose drugs were subject to this provision. The government also notifies the MACs who operationalize the cost sharing of the reduced coinsurance for medications with prices that increased faster than inflation.

For the drug price negotiation provision, at a high level, the government identifies eligible drugs and selects the drugs based on statutory criteria. Manufacturers in turn may voluntarily enter into agreements with the government to negotiate prices. The government will publish the final MFPs for those drugs for which an agreement is reached. We note that a range of additional activities are involved in implementing the final MFPs if negotiated, which are not described here.

As noted above, the activities described in this section are at a high level, drawn from various public sources, and do not represent the full range of activities that are required to implement each provision.

Outputs

The outputs of the biosimilar provisions are the lists of biosimilars that qualify for the temporary add-on fee or are subject to the payment limit. The primary output for the $35 maximum OOP cost for insulins is lower insulin OOP costs for beneficiaries taking insulins covered by Part B. The outputs of the inflation rebates provisions are rebate payments from manufacturers of these drugs to the government and lower coinsurance rates for beneficiaries taking these drugs. The output for the drug price negotiation provisions will be the publication of

the list of MFPs for each drug in which Medicare and participating manufacturers agreed to a negotiated price during the negotiation period.

Impact Outcomes

Figure 2.1 also shows the key outcome domains for each provision grouping for which we anticipate seeing impacts. We anticipate that most specific outcomes will begin to appear in the short, medium, or long term and to continue to appear going forward. For example, outcomes that appear in the short term are expected to continue into the medium and long terms, with cumulative effects over time. Some outcomes, however, may be seen in the short term only, especially those related to implementation and behavior change. We discuss the outcome measures in more detail in the provision-specific evaluation framework chapter.

Contextual Factors

In the Part B logic model, we also noted several contextual factors that affect all Part B provisions. These include state and local policies (e.g., existing state-level OOP price caps for some drugs), beneficiary characteristics (e.g., demographics, income, health status), pharmaceutical market conditions (e.g., patent expirations, entry of new products, entry of new biosimilars), and geographic characteristics (e.g., market structure, MA plans available in an area, whether an area is a health provider shortage area).

Implementation Outcomes

At the bottom right of the logic model, we noted potential implementation outcomes that could be assessed. These include stakeholder experiences with implementation, beneficiary and provider knowledge of IRA provisions, barriers and facilitators with regard to implementing the different provisions, and spillover effects that might have occurred, such as the adoption of negotiated MFPs by other payers (e.g., employer-sponsored plans).

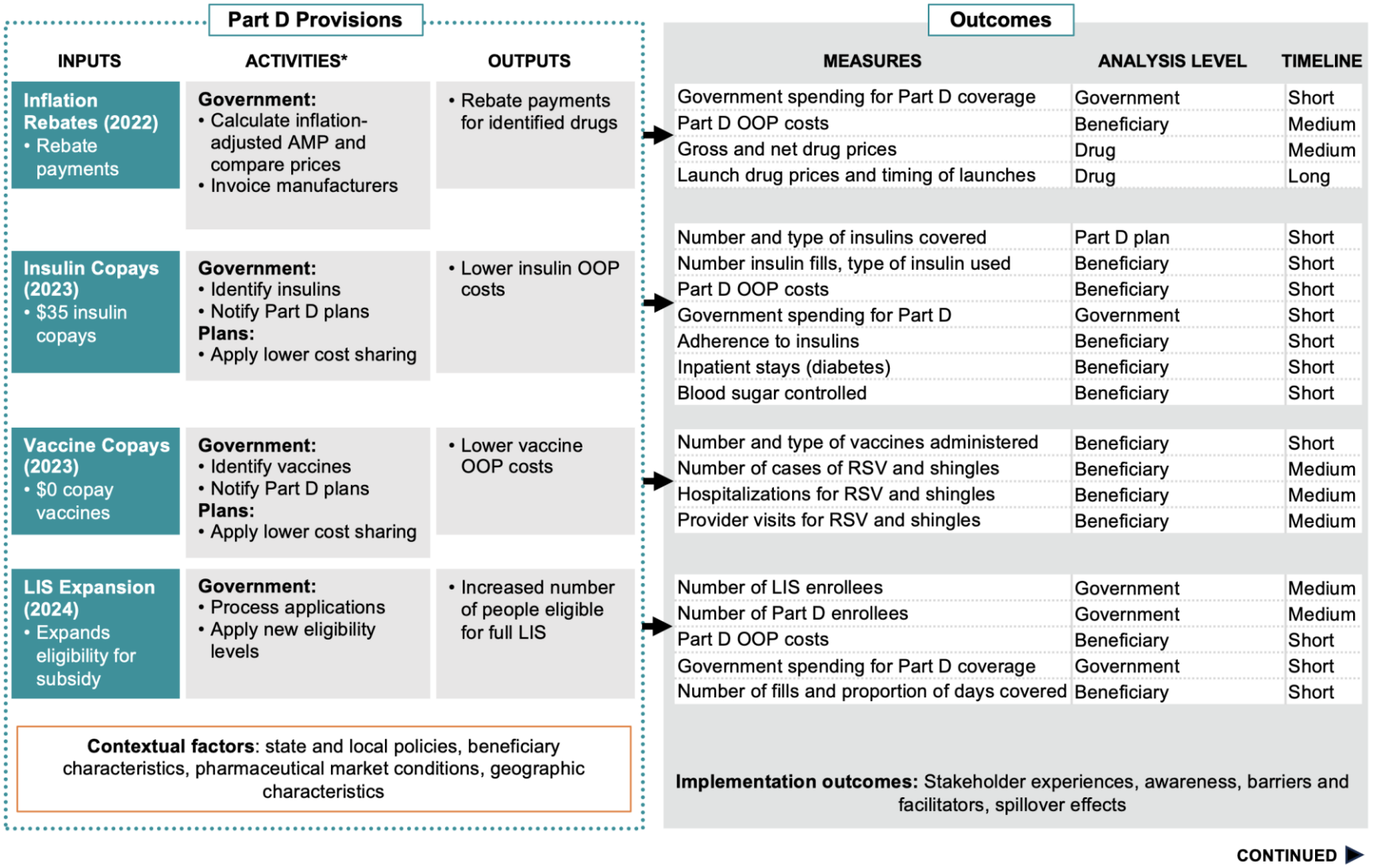
Medicare Part D Logic Model

Figure 2.2 depicts the logic model for the Medicare Part D provisions of the IRA.

Inputs

There are six groupings of provisions within the Medicare Part D logic model. These groupings are inflation rebates, insulin copays, vaccine copays, benefit design changes, Part D LIS expansion, and drug price negotiation.

Figure 2.2. Logic Model for IRA Medicare Part D Provisions



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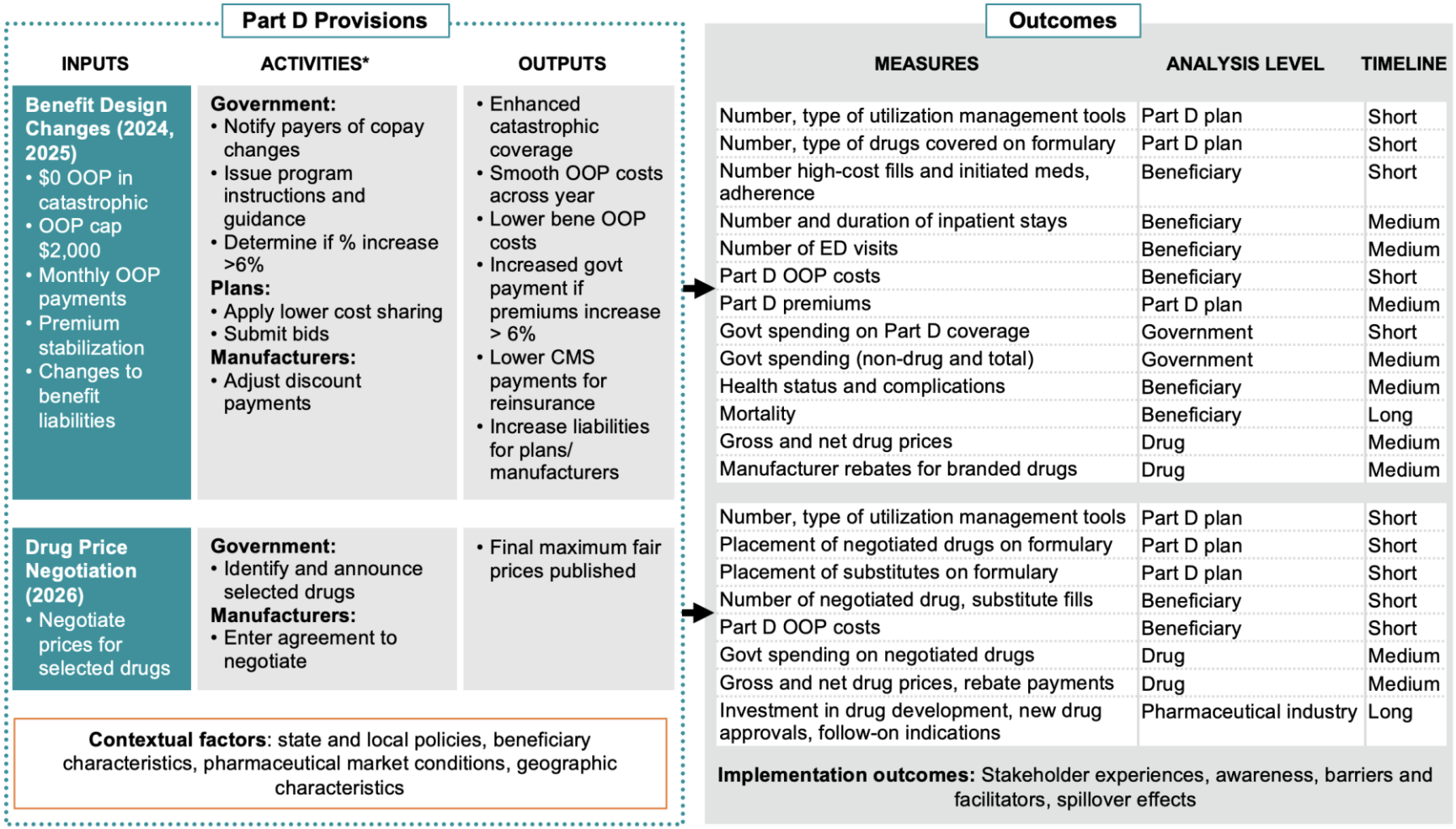

* There are many activities required to implement these provisions, which are not reflected in this high-level logic model.

Activities

The logic model describes activities at a high level and does not capture the full range of activities that may occur to effectuate a provision. The government issued program instructions in order to implement many of the Part D provisions described in this section. In parallel with the Part B inflation rebate provisions, for the Part D provisions the government must also calculate the inflation-adjusted price (based on the AMP as submitted by manufacturers) and compare this to the AMP for covered Part D drugs. For those drugs for which rebates apply, the government will determine how much manufacturers must pay in rebates.

For the changes to the copay structure (e.g., $35 maximum monthly cost sharing for covered insulin products and $0 cost sharing for recommended adult vaccines), the government identified the products for which the provision applies and how to apply it and notifies Part D plans. Plans must then apply these changes within their systems to ensure that beneficiaries are charged the appropriate copays when enrollees obtain covered insulins or receive a vaccine. (For the purposes of the logic model figure, we group PBMs with Part D plans in showing the activities and potential impacts.)

For the Part D LIS expansion, the government (Social Security Administration) must process applications and issue determinations to beneficiaries regarding their eligibility for the LIS and the new subsidy level.

The government issued guidance to the Part D plans regarding how to submit bids for the new benefit structure. Part D plans must implement changes to their payment systems to ensure they are able to appropriately track beneficiary OOP drug costs and identify when the beneficiary enters the catastrophic phase where $0 cost sharing begins. The Part D financial liability changes, as part of the benefit design changes, require updates to the federal regulations governing the Part D benefits. The government also needs to calculate the increase in premiums year to year and ensure that the increase in the base beneficiary premium is no greater than the 6 percent threshold. As noted above, Part D plans will need to update their systems and submit bids that reflect the new benefit design. The government generates invoices for the amount of the manufacturer discount, which Part D plans in turn submit to manufacturers for payment.

For the drug price negotiation provisions, the government will identify and announce the drugs selected for negotiation and manufacturers will decide whether to enter into agreements to negotiate prices with the government. The government will announce the final MFPs if an agreement on price is reached. Pharmacies also play a role in implementing cost sharing for those drugs where an MFP has been negotiated. We note that a range of additional activities are involved in the negotiation process and in implementing the final MFPs if negotiated, which are not described here.

As noted above, the activities described in this section are at a high level, drawn from various public sources, and do not represent the full range of activities that are required to implement each provision.

Outputs

The outputs for the inflation rebates provision are rebate payments made by manufacturers to the government for the identified drugs. The outputs for the insulin and vaccine copayment changes are lower insulin and vaccine OOP costs. The expanded Part D LIS eligibility provision will increase the number of people eligible for the full LIS benefit and therefore increase the number of enrollees paying lower premiums and OOP costs as part of their Part D coverage. The benefit design changes will result in increased catastrophic coverage offering protection from very high costs, the ability to smooth high OOP drug costs over the course of a year, and a lower threshold of beneficiary OOP drug costs to reach the catastrophic phase. Increased government contributions will be made if the base beneficiary premium increases by more than 6 percent. In addition, the government will pay less for reinsurance in the catastrophic phase, while plans and manufacturers will increase their share due to the changed contribution amounts. Finally, the output for the drug price negotiations will be the publication of the MFPs.

Impact Outcomes

Figure 2.2 also shows the impact outcomes that we anticipate will occur as a result of the Part D IRA provisions and the direction of their effect. We discuss the outcome measures in more detail in Chapter 3 as part of the provision-specific evaluation framework.

Contextual Factors

In the Part D logic model, we included contextual factors affecting all Part D provisions. As with the Part B model, these include state and local policies, beneficiary characteristics, pharmaceutical market conditions, and geographic characteristics. We note that the figure does not provide detail on this logic model component, though work conducted in parallel with the development of this report has started to collect this information for future use in evaluation efforts.

Implementation Outcomes

In parallel with the Part B provisions, there are a series of implementation outcomes of interest to the evaluation. These include stakeholder experiences, patient and provider knowledge of IRA provisions, barriers and facilitators to implementation, and spillover effects.

Chapter 3. Provision-Specific Impact Evaluations

The different IRA provisions will likely lead to a range of impact outcomes that affect different stakeholders. In this chapter, we describe how different provisions, which we grouped into seven categories based on their primary mechanism of action, could be evaluated using a mixed-methods approach. (Appendices B and C provide detailed descriptions of potential methodological approaches for impact and implementation evaluations, respectively.) For each grouping, we selected a set of research questions (RQs) that could be answered as part of an implementation evaluation and would require primary data collection, as well as RQs that could be answered as part of an impact evaluation focusing on anticipated direct impacts of the provision(s). We have also mapped these questions to the key stakeholders impacted. Finally, for each grouping, we present:

- A set of outcome measures that could be developed using secondary data sources
- Potential treatment group and comparison group options, if applicable
- Anticipated timing for observing any impacts (e.g., in the short, medium, or long term)
- Statistical methods appropriate for the available secondary data
- Primary data collection approaches for gathering information from the key stakeholders.

The intent of the evaluation framework presented here is to provide future evaluators with a road map for where to begin fleshing out detailed analytic plans for provisions selected for evaluation. Additional information on data sources that could be used to construct the outcome measures and to identify subgroups and comparison groups as described in this chapter is presented in Appendix A.

We also note that future evaluators will need to carefully consider issues of attribution and causality, as well as other challenges that are briefly described later in this report, but which were beyond the scope of this report to fully address. For example, it will be difficult to disentangle effects of a specific IRA provision from the other provisions that are implemented within a similar time frame (e.g., the Part D redesign and expansion of LIS eligibility provisions). Future evaluators will need to consider how best to address these issues and identify limitations of findings as a result of these and other challenges.

Research Questions

We have identified nine outcome domains for the purposes of organizing the key RQs that could be addressed as part of an evaluation of the IRA drug-related provisions. Each of these outcome domains is associated with an overarching framework question. The first three domains are key for an implementation evaluation, whereas the remaining six are core components of the impact evaluation.

RQs for Implementation Evaluation:

1. **Implementation:** How did the different stakeholders operationalize the changes from the IRA and what implementation challenges, if any, did they face? What implementation successes or opportunities, if any, did they encounter?
2. **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?
3. **Behavioral Responses:** To what extent are stakeholders aware of relevant provisions? How do stakeholders respond to the IRA drug-related provisions?

RQs for Impact Evaluation:

4. **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?
5. **Spending:** How have the IRA's drug-related provisions impacted spending (prescription drug spending, total spending, premiums, and out-of-pocket costs) by different stakeholders, especially the government and beneficiaries, on prescription drugs and other services under the Medicare Part D and Part B Programs?
6. **Health Outcomes:** Did the IRA drug-related provisions impact health outcomes for Part D enrollees or those beneficiaries who received drugs covered by Part B?
7. **Pharmaceutical Markets/Innovation:** What are the impacts of the IRA's drug-related provisions on pharmaceutical markets, drug development, and pharmaceutical innovation?
8. **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?
9. **External Spillovers:** Did the IRA provisions have any impacts on other parts of the health care system—for example, on commercial insurance coverage, the Veterans Health Administration, or Medicaid Programs?

Within each of these framework questions are multiple possible subquestions focusing on specific outcomes and stakeholders, each of which might apply differently to different IRA provisions. Later sections in this chapter present the provision-specific evaluation framework approaches, each of which has a selected set of research questions.

Summary of Methodological Approaches

Statistical Method Options

The provision-specific evaluation approaches described below include causal inference approaches that may be considered for each RQ being addressed. We considered three designs in causal inference that may be appropriate: interrupted time series (ITS), difference-in-differences (DiD), and regression discontinuity designs (RDD). Table 3.1 provides a high-level overview of these approaches. Additional details are available in Appendix B.

Table 3.1. Summary of Causal Inference Approaches

Approach	Summary	Key Assumption	Data	Use Case
Interrupted time series	Estimates effects of interventions affecting all units simultaneously	Pretreatment trends in the treatment group would continue absent the intervention	Requires longitudinal data (units observed over time)	When no comparison group is available
Difference-in-differences	Estimates causal effects of interventions using changes in outcomes among a comparison group	Absent the intervention, the average trends in the treatment group would equal the trends in the comparison group ("parallel trends")	Requires longitudinal data	When a comparison group is available and the parallel trends assumption is plausible
Regression discontinuity design	Estimates causal effects near the threshold of some variable that separates an intervention from a control group (e.g., age determines Medicare eligibility)	Individuals near the threshold that determines treatment eligibility are similar across observable and unobservable characteristics	Requires data containing a variable that separates a control and an intervention group (called a "running variable")	When a running variable exists and generalizability is not a concern

Qualitative Method Options

Evaluators should also consider using a wide range of qualitative methods to collect and analyze new data and to analyze already available data. Surveys, interviews, and focus groups with stakeholders are likely to be sufficient to collect the primary data needed to evaluate both the implementation and impacts of various IRA drug-related provisions. The analysis of implementation context is likely to require secondary analysis of already available data, such as data on existing state and federal policies that might affect drug costs and access, such as state-level biosimilar substitution policies or the presence of state prescription drug affordability boards. Creating a database of such policies can help not only to establish a pre-IRA baseline but also to interpret the outcomes of the IRA's impact. Moreover, evaluators should also use existing data to identify potential control variables for quantitative analyses, including demographic, health status, and health system factors.

The following sections present provision-specific evaluation framework, with detailed information for each provision or group of provisions on approaches to an evaluation, including the RQs, methods, outcome measures, level(s) of analysis, potential subgroups of interest and comparison groups, and groups from which primary data could be collected. We note that the set of RQs presented for each provision-specific evaluation is by design limited and focused on those RQs determined to be feasible and important for initial evaluations of these provisions. As such, this document is not intended to be an exhaustive list of all RQs and potential outcomes that could be measured and how they would be measured, but instead a road map to provide guidance to future evaluators conducting the detailed evaluations.

Biosimilars (Part B)

The two biosimilars provisions included in the IRA both apply to Medicare Part B. The first provision applied a temporary increase to the biosimilar add-on fee, to 8 percent, and was implemented in 2022 (Centers for Medicare & Medicaid Services, 2024). The second provision caps payment for biosimilars if no ASP is available and was implemented beginning in July 2024 (Centers for Medicare & Medicaid Services, Undated).

Providers that administer drugs covered under Part B and the pharmaceutical industry are the two key stakeholders likely directly impacted by these provisions. An evaluation of the impact of these provisions on provider behavior could offer insights into whether the add-on fee provision's increased incentive to prescribe lower-cost biosimilars instead of higher-cost originator biologics was sufficient to alter their prescribing behavior. Addressing questions about the impact of the provisions on the pharmaceutical industry will shed light on how the industry responded to these payment changes in terms of drug prices and the composition of products under development. One possible outcome of these provisions is that the pharmaceutical industry will increase focus on development of biosimilars to fill existing gaps in the market, though the complex dynamics of the pharmaceutical supply chain for originator biologics and biosimilars may limit the incentive provided by the add-on payment to do so (Von Eisenburg et al., 2023).

Table 3.2 lists main components of the potential evaluation approach, including the RQs, quantitative methods and outcome measures, level(s) of analysis, subgroups of interest, comparison groups that could be identified to isolate causal impacts of the provisions, and stakeholders whose perspectives should be solicited.

Implementation Evaluation

To address questions about the implementation of the biosimilars provisions of the IRA, evaluators should solicit the perspectives of the major stakeholders involved (pharmaceutical companies and providers). Pharmaceutical company representatives and providers may also be able to speak about any communications with the federal government about the implementation of this provision and the identification of drugs affected, including provider awareness of this provision when making prescribing decisions.

Table 3.2. Potential Biosimilars Provisions Evaluation Approach

Research Question	Quantitative Methods, Outcome Measure(s)	Quantitative Level(s) of Analysis	Quantitative Subgroups of Interest	Quantitative Potential Comparison Group(s)	Qualitative Primary Data Collected From
Implementation					
What were the major steps to implementing this provision? What were the major challenges and opportunities?	NA	NA	NA	NA	Federal government, Drug manufacturers Providers
Behavioral Responses					
Did providers change prescribing behavior for originator and biosimilar products? How did prescribing patterns change and why?	ITS • # biosimilars administered • # originator biologics administered	Provider	NA	NA	Providers
Pharmaceutical Markets/Innovation					
To what extent have originator and biosimilar drug prices changed, and how have these effects varied over time?	ITS • ASP per quarter for biosimilars • ASP per quarter for originator biologics	Drug	NA	NA	Drug manufacturers
How did the biosimilars provisions affect the composition of types of products under development by the pharmaceutical industry?	ITS • Time to availability of biosimilars • Number of new molecular entities • New drug starts/Phase 1 trial starts • Types of products under development by the pharmaceutical industry	Drug/Drug manufacturers	NA	NA	Drug manufacturers
What are pharmaceutical industry views on any impacts on innovation?	NA	NA	NA	NA	Drug manufacturers

NA = Not applicable. For subgroups, NA means that no subgroups were identified as specifically relevant to the RQ.

Impact Outcome Measures

To address the behavioral response question, two measures could be constructed: the number of biosimilars administered and the number of originator biologics administered. These measures could be constructed at the individual provider level. We anticipate these effects would appear in the short term as providers consider the financial incentives associated with shifting prescribing behavior due to the add-on fee.

We recommend a set of measures designed to assess the impact of these provisions on the pharmaceutical industry. First, tracking changes to the ASP for biosimilars and their originator biologics over time via the publicly available ASP files would provide insights into how drug prices change in response to the provisions. These changes may occur in the short term as providers shift utilization in response to payment incentives. Second, we recommend a set of measures focused on the timing of availability of biosimilars (constructed as the amount of time between an originator biologic approval and the approval of the biosimilar), as well as the registration of new drugs and the start of new drug trials, to track whether there are any changes to the composition of pharmaceutical industry development efforts in response to these provisions. We anticipate that any changes to the pharmaceutical industry would occur over the long term, especially as relatively few new drugs are launched each year. We note that other outcomes beyond those listed here may be identified as part of future work.

Statistical Approach to Impact Evaluation

We do not expect that future evaluators will be able to identify a comparison group for a DiD analysis given that prescribers may change behavior for all patients in response, and because drug manufacturer responses will impact all originator biologics and biosimilars. As a result, we recommend using an ITS design to examine this research question. However, the results based on this design should be interpreted with caution, as effect estimates from these designs cannot disentangle effects due to the biosimilar provisions from those due to other changing factors during the time of implementation.

Primary Data Collection for Impact Evaluation

To comprehensively assess the impact of the biosimilar-focused provisions on key outcomes of interest, the evaluators should collect primary data from the following stakeholders:

Providers: Interviews or focus groups with providers will be important for explaining how and why their prescribing behavior changed because of these provisions. These interviews can start right away because these provisions have already been implemented. Several waves of provider interviews may need to be conducted if prescribing behavior does not change right away. Interview or focus group questions may focus on providers' and their patients' attitudes toward biosimilars, the extent to which manufacturers changed their communication related to biosimilars, and whether their willingness to prescribe biosimilars changed, among others.

Drug Manufacturers: Interviews with the manufacturers of originator and biosimilar products will be particularly important for explaining the impact on the pharmaceutical industry and describing the strategies manufacturers may implement to reduce possible negative impacts on their revenues, as well as their thoughts on pharmaceutical innovation moving forward. Engaging with trade associations and other membership/trade organizations might be useful for capturing the industry perspective on whether and how these provisions have already affected drug prices or might do so in the future. They are likely to articulate their members' perspectives on the types of products under development by the pharmaceutical industry. We note, however, that drug manufacturers, trade associations, and other membership organizations may be hard to engage with due to ongoing litigation related to some of the IRA provisions. Evaluators should also be conscious about the need to engage with a wide range of stakeholders and ensuring objectivity of their findings.

Inflation Rebates (Parts B and D)

Broadly, these provisions require manufacturers of certain drugs to pay rebates to Medicare if their prices rise faster than inflation. Prescription drugs covered by Part D could be subjected to rebates beginning in 2022; drugs covered by Part B could be subjected beginning in 2023. In addition, beneficiaries taking drugs covered under Part B may pay lower coinsurance for medications whose prices increased faster than inflation, though their final OOP drug costs are dependent on any supplemental coverage they may have. This provision was implemented in 2023.

The government may see reduced total spending as a result of these provisions due to the rebates paid by drug manufacturers that increase prices faster than inflation or because drug manufacturers may not increase drug prices faster than inflation in response to the incentive to keep increases low. Manufacturers may also respond by increasing their launch prices for new medications, thereby increasing government spending above what it would otherwise have been.

In Table 3.3, we have identified five key RQs for these provisions, shown with the associated quantitative methods and outcome measures, level(s) of analysis, subgroups of interest, potential comparison groups, and stakeholders whose perspectives should be solicited. The RQs focus on implementation experiences, impacts on spending by the Medicare Program on Part B and D drugs, and impacts on the pharmaceutical industry.

Table 3.3. Potential Inflation Rebates Provisions Evaluation Approach

Research Question	Quantitative Methods, Outcome Measure(s)	Quantitative Level(s) of Analysis	Quantitative Subgroups of Interest	Quantitative Potential Comparison Group(s)	Qualitative Primary Data Collected From
Implementation					
What were the major challenges and opportunities associated with implementing inflation rebates?	NA	NA	NA	NA	Federal government, Drug manufacturers
Spending					
How, if at all, did the inflation rebates provisions impact Medicare Program spending, both overall and for drugs with inflation rebates owed?	DiD • Government spending for drugs covered under Part B (total and for drugs with inflation rebate payments owed) • Government spending on Part D coverage (total and for drugs with inflation rebate payments owed)	Drug/ Government	Drugs with inflation rebates owed	Other rebatable drugs (with no rebates owed)	Federal government
Did the inflation rebates provisions impact beneficiary OOP costs for drugs with coinsurance adjustments and/or rebates owed? If so, how and why?	DiD • Part B OOP drug costs • Part D OOP drug costs	Beneficiary	Beneficiaries taking drugs with coinsurance adjustments and/or inflation rebates owed	Beneficiaries taking other rebatable drugs (no coinsurance adjustments and/or rebates owed)	Insurers
Pharmaceutical Markets/ Innovation					
How, if at all, did the inflation rebates provisions change growth in branded drug prices? Did these effects vary over time?	DiD • Gross prescription drug prices • Net prescription drug prices	Drug	Drugs with inflation rebates owed	Other rebatable drugs (with no rebates owed)	Drug manufacturers
Did the inflation rebates provisions change drug	ITS	Drug	NA	A	Drug manufacturers

Research Question	Quantitative Methods, Outcome Measure(s)	Quantitative Level(s) of Analysis	Quantitative Subgroups of Interest	Quantitative Potential Comparison Group(s)	Qualitative Primary Data Collected From
launch timing or prices? Why, why not?	• Launch prices for new drugs • Timing of drug launch				

NA = Not applicable. For subgroups, NA means that no subgroups were identified as specifically relevant to the RQ.

Implementation Evaluation

The key stakeholders whose input is needed to assess the success of the implementation of inflation rebates are the federal government and the pharmaceutical industry. Key questions for the federal government include whether there were challenges in identifying which drugs were subject to these rebates and communicating that with both the manufacturers and the beneficiaries impacted by these rebates, in particular those beneficiaries taking drugs covered by Part B for which their coinsurance was lowered.

Impact Outcome Measures

A set of spending measures would need to be constructed at the government level and represent the amount of government spending for drugs covered by Parts B and D for which inflation rebate payments were owed and those eligible for rebates but for which payments were not owed due to their price increases falling below inflation, accounting for any inflation rebate payments. These measures could also be subset to focus on drugs covered by Parts B and D for which inflation rebates were applied. Changes to these outcomes are likely to be observed in the short term after drugs may be subjected to the inflation rebate provisions. We note that data on inflation rebate payments may not be publicly available, and therefore evaluators could consider estimating likely payments based on publicly available data.

Future evaluators could also construct measures of beneficiary OOP drug costs to assess the extent to which beneficiary OOP drug costs changed over time as a result of the inflation rebate provisions. These measures could be constructed separately for beneficiaries in Parts B and D and also could be stratified by whether or not beneficiaries filled prescriptions for any drugs where inflation rebate payments were made.

Prescription drug pricing outcome measures should also be measured and tracked over time. Pharmaceutical markets may see changes in gross and net prescription drug prices for branded drugs that were rebatable given potential changes to rebates negotiated and paid by drug manufacturers to Part D plans. In addition, launch prices may change and drug manufacturers might alter the timing of launch so as to limit the potential impact of any inflation rebates. Changes to the pharmaceutical market are likely to occur in the medium to long term, as

manufacturers develop a response and implement it across existing drugs (prices) and new drugs coming to market (future launches).

We note that other outcomes beyond those listed here may be identified as part of future work to understand the impact of the IRA's inflation rebate provisions.

Statistical Approach to Impact Evaluation

The subgroups of interest for these RQs include the drugs for which inflation rebates are applied and beneficiaries taking these drugs. Potential comparison groups could include those rebatable drugs for which inflation rebates were not applied, and beneficiaries taking rebatable drugs for which inflation rebates were not applied. However, tracking launch prices and the timing of launch will result in very small sample sizes, and establishing what would have been expected to occur in the absence of the inflation rebates provisions will be difficult with so few observations. We recommend constructing all outcome measures at the annual level and using a DiD design to examine the effects for the RQs where comparison group options may exist and using an ITS study design to examine the effects for drug launch timing and pricing.

Primary Data Collection for Impact Evaluation

To comprehensively assess the impact of inflation rebates and explain how and why they affected key outcomes of interest, evaluators should collect primary data from the following stakeholders:

Drug Manufacturers: Inflation rebates are likely to affect drug manufacturers, including their approaches to launching new drugs and change prices of existing drugs—in other words, how they set launch prices, their strategies around launch times, and how they change prices after drugs are launched. To better understand the impact of these rebates on these activities, evaluators should conduct interviews with drug manufacturers and the organizations that represent their interests, including manufacturers launching new drugs after the implementation of this IRA provision.

Federal Government: Since a major impact of the inflation rebates provision will be on federal spending, interviews with officials from CMS will be useful for describing their experiences identifying manufacturers who need to pay rebates, which will help evaluators explain the impact of this provision. Officials from the FDA might also provide important information about launch timings of new drugs through interviews.

Insurers: Part D insurers will have real-time access to data on beneficiary OOP costs for drugs with rebates and therefore could help provide early insights into the impact of inflation rebate provisions on beneficiary OOP drug costs.

Maximum $35 Insulin Copayments (Parts B and D)

These provisions imposed maximum $35 copayments for a one-month supply of covered insulin administered and paid for under Part B and insulins dispensed and covered under Part D. The Part D copayment cap was implemented in January 2023, while the Part B provision was implemented in July 2023.

Beneficiaries with diabetes who previously took insulin, or who were prescribed insulin but avoided taking it due to cost, might increase their insulin fills or change the type of insulin used when faced with lower monthly copayments. However, beneficiaries might also face different formulary designs with fewer covered insulins if a Part D plan alters its benefit design, for example by removing a more expensive insulin to keep plan costs down. The government may have experienced short-term increases in spending for insulins given the subsidies paid to plans for 2023 to fill the gap between the $35 maximum copayment and the plan's intended cost-sharing amount (McWright, 2022). However, beginning in 2024, the impacts of these provisions on government spending are unclear and will be difficult to disentangle from the impacts of the Part D benefit redesign provisions that are implemented on a similar timeline (described below).

In Table 3.4, we have identified seven key RQs for these provisions, shown with the associated quantitative methods and outcome measures, level(s) of analysis, subgroups of interest, potential comparison groups, and stakeholders whose perspectives should be solicited. These research questions focus on implementation experiences; the impact of imposing maximum insulin copayments on utilization, spending, and health outcomes for beneficiaries with diabetes; and the impact on Medicare spending as a whole.

Table 3.4. Potential Insulin Copayments Provisions Evaluation Approach

Research Question	Quantitative Methods, Outcome Measure(s)	Quantitative Level(s) of Analysis	Quantitative Subgroups of Interest	Quantitative Potential Comparison Group(s)	Qualitative Primary Data Collected From
Implementation					
Were beneficiaries aware of the $35 insulin copay provision?	NA	NA	NA	NA	Beneficiaries
What were the challenges and opportunities associated with implementing $35 insulin copays?	NA	NA	NA	NA	Federal government Insurers PBMs
Behavioral Response					
Did the $35 insulin copayments	ITS • # covered insulins	Part D plan	NA	NA	Insurers PBMs

Research Question	Quantitative Methods, Outcome Measure(s)	Quantitative Level(s) of Analysis	Quantitative Subgroups of Interest	Quantitative Potential Comparison Group(s)	Qualitative Primary Data Collected From
provisions result in Part D formulary changes? If so, what has changed and why?	• Type of insulins covered (e.g., short-, long-, rapid-acting, mix)				
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?	DiD • # beneficiaries with new insulin fills • # insulin pump fills (Part B) • # insulin fills (Part D) • Type of insulin used (e.g., short-, long-, rapid-acting, or pump)	Beneficiary	• Beneficiaries with diabetes • Insulin pump users • Insulin users in Part D plans	• Beneficiaries with diabetes, insulin users in: ○ PDSS-participating plans ○ Part D LIS ○ Commercial insurance	Beneficiaries Insurers
Spending					
Did the $35 insulin copayments provisions impact Medicare enrollee drug spending? Do any impacts differ by subgroups? Why?	DiD • Part B drug OOP costs • Part D drug OOP costs	Beneficiary	• Insulin pump users • Insulin users in Part D plans • Beneficiaries eligible for LIS level 4	• Insulin users in: ○ PDSS-participating plans ○ Part D LIS ○ Commercial insurance	Beneficiaries Insurers
How did the $35 insulin copayments impact Medicare Program drug spending?	DiD • Spending on drugs covered under Part B • Spending on Part D drug coverage	Beneficiary	• Insulin pump users • Insulin users in Part D plans	• Insulin users in: ○ PDSS-participating plans ○ Part D LIS ○ Commercial insurance	Federal government
Health Outcomes					
How did the $35 insulin copayments provisions affect adherence to insulins?	DiD • Adherence to insulins by type	Beneficiary	Beneficiaries diagnosed with diabetes	• Patients diagnosed with diabetes in: ○ PDSS-participating plans ○ Part D LIS ○ Commercial insurance	Beneficiaries Insurers
Did the $35 insulin copayments provisions result in reduced complications for patients with diabetes?	DiD • Inpatient stays for short-term diabetes complications • Diabetes care - blood sugar controlled (HbA1c)	Beneficiary	• Insulin pump users • Insulin users in Part D plans • Beneficiaries meeting criteria for	• Insulin users in: ○ PDSS-participating plans ○ Part D LIS ○ Commercial insurance	Beneficiaries Insurers

Research Question	Quantitative Methods, Outcome Measure(s)	Quantitative Level(s) of Analysis	Quantitative Subgroups of Interest	Quantitative Potential Comparison Group(s)	Qualitative Primary Data Collected From
			inclusion in blood sugar–controlled measure		

NA = Not applicable. For subgroups, NA means that no subgroups were identified as specifically relevant to the RQ. PDSS = Part D Senior Savings.

Implementation Evaluation

Insulin copay reductions are implemented primarily by the federal government and insurers/PBMs. To determine whether implementation of these changes was successful, evaluators should talk with government employees about the process of communicating this policy change to insurers. Insurers/PBMs could provide their perspective on the process of implementing these provisions, specifically in lowering copayments for beneficiaries and communicating this change; they may also be able to provide their perspective on the impact of this provision on manufacturer rebate negotiations with insulin manufacturers. Finally, beneficiary awareness of this provision may increase utilization of insulins due to the lower OOP costs; conducting surveys or asking beneficiaries in interviews or focus groups about their awareness of this provision could provide important insights into quantitative impact findings.

Impact Outcome Measures

The utilization measures focus on the number of new insulin fills for beneficiaries with diabetes, as well as the total number of fills for insulins covered by both Part B and Part D. The evaluation should also track the type of insulin used by a beneficiary to observe whether there are any changes over time. The spending measures focus on beneficiary OOP costs for their drugs covered under Part B (e.g., insulin covered by the Part B Durable Medical Equipment benefit) and drugs covered under Part D (including insulin), while government spending measures will capture the costs to the government for drugs covered by Parts B and D separately so as to determine any impacts on overall spending of the insulin provisions. Finally, assessing adherence to insulin, accounting for the type of insulin taken, will provide important information regarding whether the provisions increased use over time of these medications. We recommend constructing Proportion of Days Covered (PDC) measures (Pharmacy Quality Alliance, 2022) for all insulin types except for the long-acting insulins, for which the Pharmacy Quality Alliance (PQA) measure for persistence to basal insulin is likely most appropriate (Oueini, 2022). Two measures will help address questions about the existence of complications for diabetes, which are generally due to low insulin adherence: inpatient stays for short-term diabetes complications, which is a PQA measure (Agency for Healthcare Research and Quality, 2013), and a Healthcare Effectiveness Data and Information Set (HEDIS) measure (National Committee for Quality

Assurance, 2024) that indicates whether a patient with diabetes had their blood sugar controlled. We note that other outcomes beyond those listed here may be identified as part of future work to understand the impact of the $35 monthly cap on covered insulin products under Part B and Part D.

Statistical Approach to Impact Evaluation

Comparison groups may exist for the insulin copay provisions. One potential group are enrollees in a model test which CMS began testing two years before implementation of these provisions. The PDSS Model test applied $35 maximum copays in Part D plans that chose to participate in the Model; participating plans selected which insulins to include for the maximum $35 copay. Beneficiaries enrolled in PDSS-participating plans in the years prior to implementation of the 2023 $35 maximum copay cap created by the IRA could be a potential comparison group for these analyses. In addition, beneficiaries eligible for the Part D LIS could be considered as a comparison group, given their low, fixed copayments for insulins; however, this population might be very different along many demographic and health characteristics from the general Medicare population; therefore, careful consideration should be used when selecting them as comparators. Finally, commercial insurance enrollees could be a third comparison group, as they were unaffected by both the PDSS Model and the $35 copayment provisions in the IRA.

Given the availability of these possible comparison groups, we recommend considering a DiD design for this analysis. To make this decision, however, the evaluators should carefully consider whether the parallel-trends assumption that underlies the DiD design is likely to hold with respect to this group. If not, one might consider possible extensions to the basic DiD design (adding covariates, for example) that rely on more plausible assumptions. If the comparison group is deemed entirely uninformative about the counterfactual trends absent the insulin copayment provisions, an ITS design may be preferable, despite the limitations of these analyses.

Primary Data Collection for Impact Evaluation

To comprehensively answer the above RQs and better explain the impact of lowering insulin copays to beneficiaries on key outcomes of interest, the evaluators should collect primary data from the following stakeholders:

Federal Government: Interviews with the federal government officials involved in the implementation of this provision could help contextualize the outcomes and explore the reasons why limiting insulin copays to no more than $35 per month may or may not have met their expectations, including how experiences with the IRA compare to experiences with the PDSS Model, which was implemented prior to the IRA. Federal officials could also discuss their interactions with other groups of stakeholders, including feedback they have received on the provision from Part D plans, manufacturers, and beneficiaries. These interviews could shed light on how other policy changes related to insulin at the state level as well as changes in clinical

guidelines for diabetes management might have affected the outcomes. Finally, interviews with federal government officials may be helpful in identifying any spillover effects of this provision on federal government spending on other prescription drugs.

Beneficiaries: Beneficiaries could provide valuable information on their perceived impacts of lower and more predictable insulin copays on utilization, spending, and health outcomes. Beneficiary surveys could enable the collection of a wide range of responses but ensuring that the sample is representative of insulin users may be challenging. Interviews with insulin users may provide more useful information about the perceived impact of these provisions. Interviewing beneficiaries enrolled in plans that participated in the PDSS Model before 2023 and those that were in plans that lowered insulin copays to no more than $35 per month only in 2023 would provide insights into whether the length of exposure to lower copays may be important for detecting changes in Part D insulin utilization rates. Evaluators should account for the fact that there are different types of insulins and different modes of insulin administration when designing the sample. Evaluators should also interview beneficiaries from both MA plans that offer Part D coverage and stand-alone Part D plans that operate alongside fee-for-service (FFS) Medicare because of the difference in drug benefit designs between these two plan types. Interview questions should focus on changes in insulin use and adherence, changes in the types of insulins used (including potential probes about switching to biosimilar insulins), and use of other medications, including non-insulin diabetes medications, such as glucagon-like peptide 1 (GLP-1) agonists. Asking questions about perceived impacts on blood sugar levels may help collect information on short-term health outcomes, which may be difficult to obtain from administrative data.

Insurers and PBMs: These stakeholders will have a unique perspective on insulin utilization, adherence, spending, and health outcomes. Engaging with insurers and PBMs will help explain how lower insulin copays affected insulin utilization and identify beneficiary subgroups that may have benefited from this change the most. The insurer sample should include PDSS Model participants and nonparticipants, including plan types that were not eligible to participate in the Model test. Interviews with PBMs will provide a unique perspective on manufacturer rebates as they negotiate them on behalf of insurers. Reaching out to trade organizations like the Pharmaceutical Care Management Association may help with recruiting PBMs, who may be unwilling to participate in a voluntary interview. We note that this approach to sampling may bias the sample but also feel that given the relatively small number of large PBMs in the United States, any efforts to help make contact and recruit them for interviews would benefit a future evaluation.

Drug Manufacturers: Interviews with insulin manufacturers will be useful for exploring any changes in their perspectives on insulin cost-sharing caps and how other policy changes may have affected them. Interviewing representatives of MannKind, the only inhaled insulin manufacturer, would be particularly interesting because the PDSS Model did not require participating plans to cover inhaled insulins. Similarly, speaking with companies that

manufacture only biosimilar insulins, such as Biocon Biologics, and startups that are working on new biosimilar insulins, such as Civica Rx, may be particularly informative to answer questions about the perceived impacts of maximum $35 monthly insulin copays, as well as about other biosimilar provisions.

$0 Recommended Adult Vaccine Copayments

This provision eliminates Medicare Part D cost sharing for adult vaccines recommended by the ACIP. This provision was implemented in January 2023. The elimination of cost sharing for beneficiaries is expected to increase their incentive to receive a vaccine by eliminating any cost-related concerns preventing them from receiving it.

In Table 3.5, we have identified three key RQs for these provisions, shown with the associated quantitative methods and outcome measures, level(s) of analysis, subgroups of interest, potential comparison groups, and stakeholders whose perspectives should be solicited. These RQs focus on whether the elimination of copayments for vaccines increased uptake of the vaccines by beneficiaries, and whether vaccine-preventable complications were reduced.

Table 3.5. Potential $0 Vaccine Copayments Provision Evaluation Approach

Research Question	Quantitative Methods, Outcome Measure(s)	Quantitative Level(s) of Analysis	Quantitative Subgroups of Interest	Quantitative Potential Comparison Group(s)	Qualitative Primary Data Collected From
Implementation					
What were the major challenges and opportunities associated with implementing $0 vaccine copays?	NA	NA	NA	NA	Federal government Insurers Pharmacists
Were beneficiaries aware of the $0 vaccine copayments?	NA	NA	NA	NA	Beneficiaries
Utilization					
Did the IRA increase uptake of vaccines newly covered with $0 copayments? Why, why not?	RDD • # vaccines administered • # vaccines administered by type	Beneficiary	• Part D enrollees who are vaccine-eligible per ACIP guidelines	• Commercial insurance enrollees who are vaccine-eligible per guidelines • Part D LIS-eligible beneficiaries who are vaccine-	Beneficiaries Insurers Providers Pharmacists

	Quantitative	Quantitative	Quantitative	Quantitative	Qualitative
				eligible per guidelines	
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?	RDD • # cases of shingles • # cases of Respiratory syncytial virus (RSV) • # hospitalizations for shingles • # provider visits for RSV • # hospitalizations for RSV	Beneficiary	• Part D enrollees who are vaccine-eligible per guidelines • Part D enrollees with conditions where vaccine-preventable complications would be more severe (e.g., those for whom the guidelines recommend receipt)	• Commercial insurance enrollees who are vaccine-eligible per guidelines • Commercial insurance enrollees with conditions where complications would be more severe	Beneficiaries Insurers Providers

NA = Not applicable. For subgroups, NA means that no subgroups were identified as specifically relevant to the RQ.

Implementation Evaluation

Vaccine copay reductions are implemented primarily by the federal government and insurers. Insurers could provide their perspective on the process of implementing this provision and communicating it to beneficiaries. PBMs could also discuss their perspectives on the process of including vaccines on formularies for the $0 copayment. Pharmacist perspectives on implementation should also be sought as pharmacists play an important role in administering vaccines to beneficiaries. Beneficiary awareness of this provision could also be assessed; for beneficiaries to increase their vaccination rates, they need to be aware of the $0 copayments for adult vaccines recommended by ACIP. Finally, beneficiary awareness of the availability of vaccines for $0 cost sharing will likely impact the extent to which beneficiaries choose to receive vaccines; surveys or interviews to understand whether or not beneficiaries were aware of the provision will help inform findings from the impact evaluation.

Impact Outcome Measures

The first set of outcome measures focuses on addressing questions about vaccine uptake, both overall and by type of vaccine. The health outcome measures will track the number of diagnosed shingles and RSV cases in the Medicare population and the number of hospitalizations and provider visits for these conditions. All of these measures can be constructed at the beneficiary level. Utilization measures are likely to manifest in the short term, as beneficiaries receive information about the $0 copayments and potentially increase their use of vaccines. The

health outcome measures, however, are likely to occur in the medium to long term, as it will take time for vaccines to become effective and for any shifts in receipt of vaccines to translate to fewer cases and complications from the conditions. We note that other outcomes beyond those listed here may be identified as part of future work to understand the impacts of the $0 copayment for ACIP-recommended adult vaccines provision.

Statistical Approach to Impact Evaluation

The guidelines issued by the Centers for Disease Control and Prevention (CDC) for populations where these vaccines are recommended provide an opportunity to identify subgroups where the $0 vaccine copayment provision might have the most impact. Specifically, the CDC guidelines recommend the RSV vaccine for all adults 75 years of age and older, and for adults 60 and over who are at increased risk of complications (U.S. Centers for Disease Control and Prevention, 2024). We therefore recommend analyses focusing on the populations eligible for the vaccines and comparing their outcomes to those of commercial insurance enrollees not yet eligible for Medicare due to age. These analyses might best be suited to an RDD design, though an ITS study design may be more appropriate for the Medicare subgroup ages 75 and older as all beneficiaries in this group are vaccine-eligible due to age and not due to comorbid conditions placing them at higher risk.

Primary Data Collection for Impact Evaluation

To comprehensively explain how and why $0 vaccine copayments affected key outcomes of interest, the evaluators should collect primary data from the following stakeholders:

Beneficiaries: Because this provision affects all Medicare beneficiaries, adding questions about vaccination and the impact $0 copays may have had on their willingness to receive and the actual receipt of recommended vaccines would be useful. Evaluators may also consider adding some open-ended questions about other barriers that beneficiaries face that may prevent them from receiving recommended vaccines.

Providers and Pharmacists: Interviewing or conducting focus groups with primary care physicians and pharmacists may be important for providing a more detailed explanation of how this provision affected vaccination rates among Medicare beneficiaries and identifying potential reasons why vaccination rates may not have changed as much as one might have expected. Pharmacists can also be included since many pharmacists administer vaccines. Providers can also help generate hypotheses about the time frame needed for seeing impacts of this provision on the incidence of vaccine-preventable conditions and associated complications.

Insurers: Answering RQs about the impact of this provision on utilization and health outcomes could benefit from soliciting the perspective of insurance providers. These interviews could also help generate hypotheses about the types of beneficiaries who might have benefited from this provision the most and provide the reasons why this provision may or may not have been as effective in achieving the desired impact.

Part D Low-Income Subsidy Expansion

The expansion of the Part D LIS provided a greater number of Medicare beneficiaries with eligibility for the full LIS subsidy. It was implemented in 2024. Beneficiaries who newly receive the full subsidy might increase their utilization of Part D–covered drugs due to reduced OOP costs for their medications. Therefore, the research questions focus on the impact of the LIS expansion on changes to utilization of Part D–covered drugs by beneficiaries eligible for the LIS, changes in the number of beneficiaries eligible for the LIS enrolled in Part D, and whether the expansion led to changes in LIS-eligible beneficiary OOP drug costs and Medicare Program spending on Part D. Finally, in addition to changes to utilization rates, newly eligible LIS beneficiaries might become more adherent to their medications due to the lower cost sharing provided by the full LIS.

We consider three distinct groups as part of these analyses: (1) beneficiaries previously receiving the partial LIS who are newly transitioned to receiving the full LIS; (2) beneficiaries who newly apply for and receive the full LIS after the expansion of the LIS; and (3) beneficiaries eligible for the LIS but who never apply to determine eligibility. The first two of these groups can be identified using administrative data as both will be enrolled in Part D due to having applied for and being deemed eligible for the subsidy; the third group will be very difficult to identify. As a result, the analyses described in this section focus on the first two groups, which we refer to as "beneficiaries newly eligible for the full LIS" in this section.

We have identified six key RQs for these provisions. They are listed in Table 3.6, along with the potential quantitative methods needed to answer them, associated outcome measures, level(s) of analysis, subgroups of interest, potential comparison groups, and stakeholders whose input should be collected to comprehensively answer these RQs.

Implementation Evaluation

The Part D LIS expansion will be implemented primarily by the federal government. The facilitators and challenges associated with this effort can be identified by talking with CMS, Social Security Administration, and Administration for Community Living staff about their experiences. Beneficiary awareness about this provision, especially among those newly eligible, will also play an important role in implementation, as lack of awareness among those who are not already receiving the partial LIS would mean that beneficiaries would not apply for the LIS and therefore would not benefit from it. Data collection from beneficiaries (surveys or interviews) could include questions about each beneficiary's experiences before and after enrolling in LIS, as well as their experience with the enrollment process, including how they became aware of the provision and any difficulty they faced while enrolling.

Table 3.6. Potential Part D LIS Expansion Provision Evaluation Approach

Research Question	Quantitative Methods, Outcome Measure(s)	Quantitative Level(s) of Analysis	Quantitative Subgroups of Interest	Quantitative Potential Comparison Group(s)	Qualitative Primary Data Collected From
Implementation					
What were the major challenges and opportunities associated with implementing the LIS expansion?	NA	NA	NA	NA	Federal government
Were beneficiaries aware of this provision? What were their experiences applying for the expanded LIS?	NA	NA	NA	NA	Beneficiaries
Utilization					
How, if at all, did the Part D LIS expansion change utilization rates for the top 20 drugs filled by LIS-eligible beneficiaries?	DiD • # fills of top 20 drugs by spending among all LIS-eligible enrollees	Beneficiary	• Beneficiaries newly eligible for full LIS	• Beneficiaries previously eligible for full LIS	Beneficiaries Insurers
Spending					
Did the Part D LIS expansion affect Part D enrollment of LIS-eligible beneficiaries? If so, how?	ITS • # LIS eligible beneficiaries • # Part D enrollees	Beneficiary	NA	NA	Beneficiaries Insurers
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?	DiD • Part D OOP costs • Government spending on Part D coverage (total and for newly eligible for full LIS)	Beneficiary Government	• Beneficiaries newly eligible for full LIS	• Beneficiaries previously eligible for full LIS	Federal government Beneficiaries Insurers
Health Outcomes					
How and why did the Part D LIS expansion change adherence rates for beneficiaries newly eligible for the Part D LIS?	DiD • PDC for top 20 drugs	Beneficiary	• Beneficiaries newly eligible for full LIS	• Beneficiaries previously eligible for full LIS	Beneficiaries Insurers

NA = Not applicable. For subgroups, NA means that no subgroups were identified as specifically relevant to the RQ.

Impact Outcome Measures

The Part D LIS expansion might increase the overall number of beneficiaries with the full LIS subsidy, as those with a partial subsidy are converted to full subsidy status and those who may not have applied before now do so as they become aware of the availability of a more generous subsidy. The measure for this will track the overall number of LIS enrollees over time.

LIS beneficiaries newly eligible for the full subsidy may also experience changes to their OOP drug costs as a result of the expansion, which could be assessed via an annual measure of total Part D OOP drug costs for this population. Government subsidies will increase to pay for the lower copays for newly eligible LIS enrollees; this could be tracked with both total government spending on Medicare Part D and spending by the government on the subgroup of beneficiaries newly eligible for the full LIS.

A final measure would track the number of prescription drug fills for the top 20 drugs taken by beneficiaries eligible for the LIS, as measured by total spending. Newly eligible LIS beneficiaries may begin taking new medications or increase fills of preexisting medications; therefore, tracking individual beneficiary utilization patterns over time will provide insights into the extent to which beneficiaries responded to the lower cost sharing. By extension, increased fills overall may translate to better adherence to individual medications, which could be addressed via construction of measures of adherence (operationalized as the proportion of days covered) for the top 20 drugs taken by LIS-eligible beneficiaries. We note that other outcomes beyond those listed here may be identified as part of future work to understand the impacts of the Part D LIS expansion.

Statistical Approach to Impact Evaluation

Beneficiaries newly eligible for the full LIS are likely similar in demographic and health characteristics to beneficiaries previously eligible for the full LIS. Moreover, beneficiaries previously eligible for the full LIS would not experience any changes to their cost sharing because of this provision. Therefore, these beneficiaries could represent a meaningful comparison group for the analyses focused on beneficiary-level outcomes. Future evaluators may wish to consider a DiD analysis to isolate the impacts of the LIS expansion on those newly eligible for the full subsidy, using those previously eligible as the comparison group. Alternatively, evaluators could consider using an RDD to analyze effects at the eligibility thresholds in cases where income and resource data are available (using, for example, information in the Medicare Current Beneficiary Survey (MCBS), Medical Expenditure Panel Survey (MEPS), and Health and Retirement Survey).

For the analysis of enrollment, no comparison group may be available. In this case, an ITS study design may be preferable using annual outcome measurements. These effect estimates should be interpreted with caution, however, as other provisions were implemented at the same

time and may therefore limit the ability to attribute the government spending outcome specifically to the LIS expansion.

Primary Data Collection for Impact Evaluation

To comprehensively assess the impact of expanding eligibility for Part D LIS on key outcomes of interest, evaluators should collect primary data from the following stakeholders:

Beneficiaries: Because beneficiaries must take the steps to apply for the LIS program, surveys or interviews with newly enrolled beneficiaries would yield important information about the impact of this provision on spending, utilization, and adherence.

Insurers: Part D insurers are likely to be affected by the LIS expansion. Therefore, interviewing them would be important for answering a number of RQs, including those focused on drug utilization, spending, and health outcomes.

Federal Government: Interviews with officials from CMS who oversee the LIS expansion and officials from the Social Security Administration responsible for enrolling new beneficiaries in the LIS program can help evaluators understand the impacts of this provision on enrollment and government spending.

Other Stakeholders: It is feasible that some insurers may try to help their members with the enrollment process. Moreover, State Health Insurance Assistance Program (SHIP) counselors are actively trying to connect Medicare beneficiaries with other benefits for which they might be eligible. Therefore, interviewing both insurers and SHIP counselors might be useful for evaluating the impact of this provision as they might offer unique perspectives not only on the implementation but also the impact of LIS expansion.

Part D Benefit Redesign

The Part D benefit redesign provisions include a range of measures that work together to change the structure and financing of Part D. The first of these provisions went into effect at the beginning of 2024 and eliminated copayments for all drugs when a beneficiary enters the catastrophic phase. This is followed by a cap on beneficiary OOP drug costs at $2,000 per year beginning in 2025 (with the amount of the cap increasing each year (Cubanski, Neuman, and Freed, 2023)), coupled with the ability to count certain third-party payments as OOP payments. In addition, beneficiaries have the option to smooth their OOP drug costs over the course of the year beginning in 2025.

These changes to beneficiary OOP drug costs are implemented via changes to the benefit liabilities for Part D plans, drug manufacturers, and the government, as described in Chapter 1. In addition, to help reduce the immediate impact of these changes on beneficiary premiums, a premium stabilization provision was implemented in January 2024 to limit the increase of the base beneficiary premium for beneficiaries in Part D to no more than 6 percent per year.

Part D plans may alter their formulary benefit designs to account for the changing financial structure and increase in the proportion of costs they pay in the catastrophic phase. Some stakeholders have expressed concern that this may result in fewer drugs included on formularies and increased cost sharing for different medications, though the government does review formularies to ensure that all Part D plans meet established formulary requirements (U.S. Department of Health and Human Services, 2010). Beneficiaries, especially those who previously had OOP drug costs above $2,000, may experience a range of impacts on utilization, spending, and health outcomes. The government will likely experience changes in total spending for Part D due to the shift in financial liabilities away from the government and toward Part D plans and manufacturers. And finally, manufacturers may alter their approach to negotiating rebates with Part D plans and their PBMs as a result of their increased liabilities in the initial coverage and catastrophic phases of the benefit. Given that these behavioral responses are difficult to predict, the RQs and associated outcome measures shown below will help to shed light on the direction taken.

In Table 3.7, we have identified ten key RQs for these provisions, shown with the associated quantitative methods, outcome measures, level(s) of analysis, subgroups of interest, potential comparison groups, and stakeholders whose perspective should be solicited using qualitative approaches.

Table 3.7. Potential Part D Benefit Redesign Provisions Evaluation Approach

Research Questions	Quantitative Methods, Outcome Measure(s)	Quantitative Level(s) of Analysis	Quantitative Subgroups of Interest	Quantitative Potential Comparison Group(s)	Qualitative Primary Data Collected From
Implementation					
What were the challenges and opportunities associated with implementing these benefit redesign changes?	NA	NA	NA	NA	Federal government, Insurers, PBMs
Were beneficiaries aware of the $2,000 OOP cap?	NA	NA	NA	NA	Beneficiaries
Behavioral Response					
Did the Part D benefit redesign have any impacts on plans' formularies and	ITS • # and type of utilization management tools	Part D plan	NA	NA	Insurers, PBMs, Beneficiaries

	Quantitative	Quantitative	Quantitative	Quantitative	Qualitative
utilization management tools? What stakeholder groups were most affected by these changes, if any?	• # drugs covered on formulary • Type of drugs on formulary (brand, generic, specialty)				
Utilization					
How have the Part D benefit redesign provisions changed utilization rates or utilization patterns for prescription drugs covered under Part D?	DiD • # fills of high-cost medications • # newly initiated medications	Beneficiary	• Part D enrollees with pre-period annual drug costs >$2,000	• Part D LIS enrollees • Commercial insurance enrollees ages 60–64	Beneficiaries, Insurers, Providers, Pharmacists
To what extent did the Part D benefit redesign provisions change utilization of non-drug-related health care services?	DiD • # inpatient stays • Duration of inpatient stays • # emergency department visits	Beneficiary	• Part D enrollees with pre-period annual drug costs >$2,000	• Part D LIS enrollees • Commercial insurance enrollees ages 60–64	Beneficiaries, Insurers, Providers, Pharmacists
Spending					
Did the Part D benefit redesign provisions impact Medicare enrollee OOP drug spending and Medicare Program drug spending? Why, why not?	DiD • Part D OOP costs • Part D premiums • Government spending on Part D coverage	Beneficiary Government	• Part D enrollees with pre-period annual drug costs >$2,000	• Part D LIS enrollees • Commercial insurance enrollees ages 60–64	Federal government, Beneficiaries, Insurers
Did the Part D benefit redesign result in changes in spending for non-drug-related health care services? Why, why not?	DiD • Government spending on non-drug health care services • Total government spending (drugs and non-drug health care services)	Government	• Part D enrollees with pre-period annual drug costs >$2,000	• Part D LIS enrollees • Commercial insurance enrollees ages 60–64	Federal government, Beneficiaries, Insurers
Health Outcomes					
Did the Part D benefit redesign	DiD • Health status	Beneficiary	• Part D enrollees with	• Part D LIS enrollees	Beneficiaries, Insurers,

	Quantitative	Quantitative	Quantitative	Quantitative	Qualitative
impact beneficiary health status and incidence of complications? Why, why not?	• Condition-specific complications		pre-period annual drug costs >$2,000	• Commercial insurance enrollees ages 60–64	Providers, Pharmacists
How, if at all, has the Part D benefit redesign (especially the $2,000 OOP cap) affected adherence rates for high-cost drugs covered under Part D?	DiD • Adherence to high-cost medications	Beneficiary	• Part D enrollees with pre-period annual drug costs >$2,000	• Part D LIS enrollees • Commercial insurance enrollees ages 60–64	Beneficiaries, Insurers, Providers, Pharmacists
Did the Part D benefit redesign affect mortality rates among Medicare beneficiaries taking high-cost drugs? Why, why not?	ITS • Mortality	Beneficiary	• Part D enrollees with pre-period annual drug costs >$2,000	• Part D LIS enrollees • Commercial insurance enrollees ages 60–64	Insurers, Providers, Pharmacists
Pharmaceutical Markets/Innovation					
Did the Part D benefit redesign change manufacturer rebate agreements for branded and biosimilar drugs? Why, why not?	ITS • Gross prescription drug prices • Net prescription drug prices • Manufacturer rebate payments for branded and biosimilar drugs	Drug	NA	NA	Insurers, PBMs, Manufacturers

NA = Not applicable. For subgroups, NA means that no subgroups were identified as specifically relevant to the RQ.

Implementation Evaluation

The federal government and insurers/PBMs are the major stakeholders responsible for implementing the Part D benefit redesign provisions, though we note that the pharmaceutical industry and pharmacies will be involved in the implementation of some provisions. The government will be responsible for issuing guidance and regulations, making determinations about price increases, and notifying insurers about the guidance and regulations. Insurers will need to work with PBMs to implement changes to their formularies, and manufacturers will need to adjust their discount payments. The implementation of the Medicare Prescription Payment Plan provision that smooths monthly out-of-pocket payments will be of particular interest, as its

implementation will be complex and involve increasing beneficiary awareness. Finally, beneficiary awareness of the $2,000 OOP cap may play an important role in utilization of Part D benefits; surveys and interviews with beneficiaries could gather information about awareness to better understand the extent to which beneficiaries understand the changes to the Part D benefit design.

Impact Outcome Measures

To assess the behavioral response of Part D plans to these provisions, the evaluators may consider constructing a series of measures focused on formulary benefits and the types of drugs covered. Beneficiary drug utilization, in particular the number of fills of high-cost medications (e.g., those likely to result in a beneficiary hitting the $2,000 cap before the year ends) and the number of newly initiated medications, may change as a result of the lower OOP cap and the elimination of OOP drug costs in the catastrophic phase. By extension, beneficiaries who increase use of medications may experience reductions in other types of health care utilization. Therefore, we recommend assessing the impact of the Part D benefit redesign on the number of inpatient stays, duration of any inpatient stays, and the number of emergency department visits.

A set of spending measures are focused on beneficiary OOP spending changes and changes to government spending, both for Part D coverage and for overall medical and drug costs. Increased utilization of medications might also lead to improved health outcomes, measured as beneficiary-reported health status via existing survey instruments, the incidence of complications associated with conditions where high-cost drugs are needed, and even mortality. Finally, three measures of drug costs could help to assess any impacts on prescription drug prices: gross prices, net prices, and the amount of manufacturer rebates paid for branded drugs. We note that other outcomes beyond those listed here may be identified as part of future work.

Statistical Approach to Impact Evaluation

The beneficiaries most likely to be impacted by these provisions are those who previously took or might benefit from taking high-cost medications, specifically medications with monthly or annual costs that will result in beneficiaries exceeding the $2,000 OOP cap. One way to identify beneficiaries in this group is to identify those with OOP drug costs exceeding $2,000 before implementation of the $2,000 cap in 2025. Future evaluators could also consider identifying beneficiaries based on the presence of multiple comorbid conditions requiring medication treatment.

Identifying potential comparison groups for a DiD analysis might be challenging; however, there are a couple of possibilities. For example, beneficiaries previously eligible for the Part D LIS may serve as a comparison group, as they have low, fixed copayments for their medications and paid $0 copayments once they reached the catastrophic threshold. Alternatively, a hybrid of the DiD and RDD (a “difference in discontinuities” design) might be worth exploring for this evaluation using commercial claims data for those with employer insurance coverage.

Specifically, one could run a DiD analysis that compares patients just under age 65 (for example, ages 60 to 64) as a potential comparison group for patients just over 65 (for example, ages 65 to 69) with respect to utilization, spending, and health outcomes measures before and after the implementation of the Part D benefit redesign. While further exploration of data availability and the appropriateness of these designs will be needed, if deemed credible and feasible they should be worth strongly considering.

If the above analyses are not deemed to be credible or feasible, an ITS design may be most appropriate. In addition to the standard limitations of the ITS design, it will be especially difficult to isolate the impact of individual provisions in this group, as many provisions were implemented at the same time (2025), although the elimination of catastrophic cost sharing in 2024 does offer some ability to assess impacts in 2024 as the transition year.

Primary Data Collection for Impact Evaluation

To comprehensively assess the impact of the Part D benefit redesign on key outcomes of interest, the evaluators should collect primary data from the following stakeholders:

Beneficiaries: Because these provisions affect all Medicare enrollees, adding questions to an existing beneficiary survey or fielding a separate survey may be the best approach to measuring and explaining the perceived impact of these provisions on different outcomes, including drug utilization, adherence, spending, and health outcomes, and on different groups of beneficiaries, such as LIS-eligible beneficiaries and those who take few or multiple prescription drugs. Fielding these surveys annually to a representative sample of beneficiaries would help track whether and how these outcomes change over time. Evaluators should consider using survey results to identify beneficiary subgroups to be interviewed to obtain more detailed information. For example, interviewing those reporting no impact on adherence to prescribed medications might be useful for explaining barriers that might negatively affect their adherence, which could help identify additional policy changes that should be considered. As an alternative to sampling based on survey results, evaluators might want to interview beneficiaries who did not report taking many prescription drugs to explore how and why the Part D redesign affected them. Although surveys are a great way to collect attitudinal data, asking more complex questions, such as about the impact of the Medicare Prescription Payment Plan, might be more challenging because there is no interviewer who can explain the nuances of different provisions.

Insurers and PBMs: Engaging with insurers will be particularly important for explaining the impact of these provisions because they design health care benefits, including prescription drug formularies and pharmacy networks. A combination of annual survey and interviews to elicit insurer perspectives would be most helpful to help track how their perspectives change over time. Given the relatively small number of PBMs, conducting interviews with their representatives might be most effective. Working with professional societies to facilitate health plan participation might be needed. Survey and interview questions should focus on the impact of various provisions on formularies, drug utilization and adherence among different beneficiary

groups, Part D spending, and a range of health outcomes. For broader policy questions that do not assume sharing any trade secrets, convening focus groups might be appropriate.

Drug Manufacturers: Redesign of prescription drug formularies, including tier placements and utilization management requirements, are likely to affect drug manufacturers, including their market share and bottom line. Conducting interviews with drug manufacturers and the organizations that represent their interests will be very important.

Providers and Pharmacists: Engaging with providers and pharmacists using surveys, focus groups, or interviews would be helpful for explaining the effects of Part D redesign on drug adherence and health outcomes, including mortality rates. Providers will be able to comment on the use of non-drug health care services, as well as perceived patient well-being. We would recommend adding a series of close-ended questions to existing surveys and then conducting a series of interviews or focus groups with both primary care physicians and specialists to get more nuanced perspectives on the mechanisms through which Part D benefit redesign might have affected their patients. Partnering with the National Community Pharmacists Association, the American Pharmacists Association, and the National Association of Chain Drug Stores might help with primary data collection from pharmacists. Pharmacist interviews could cover their negotiated agreements with Part D plan sponsors, whether and how their payments changed, and the extent to which their inclusion in plan networks changed after implementation of these IRA provisions.

Federal Government: CMS staff may be able to provide input through interviews about the impact of the Part D redesign on spending and utilization among Medicare beneficiaries, though evaluators should be mindful of the difficulty in separating the impact of these provisions from other provisions impacting spending and utilization.

Drug Price Negotiation (Parts B and D)

The drug price negotiation provisions give the government the authority to negotiate drug prices directly with drug manufacturers for drugs covered under Part B and Part D. Negotiated prices for the first set of drugs covered under Part D will go into effect starting in 2026 and for any selected drugs covered under Part B for which CMS and manufacturers agree to an MFP starting in 2028.

Part D plans are required to cover the drugs selected for negotiation and for which an MFP was negotiated on their formularies beginning in 2026 and therefore might respond to the negotiated prices by altering their formulary benefit designs. For example, depending on how the negotiated prices compare to the prices for therapeutic alternatives, Part D plans might place therapeutic alternatives on different cost-sharing tiers to either encourage or discourage their use. Plans might also make changes to their utilization management requirements for the drugs selected for negotiation and for which an MFP was negotiated. Beneficiaries may respond to the negotiated prices by changing their utilization patterns for the selected drugs. For example, if

their cost sharing is reduced as a result of the negotiated prices, they may be more likely to fill the medications or to initiate treatment. Finally, the pharmaceutical industry may respond to these provisions in a variety of ways. The outcome of the negotiations will result in publicly available pricing information for the selected medications, whereby the prices may represent substantial differences from previously publicly available prices. Drug manufacturers might alter their approach to negotiating rebates with Part D plans and might do so differentially for the drugs for which an MFP was negotiated versus their close substitutes. They might also anticipate future selection of drugs for negotiation and alter these behaviors well in advance of selection for or participation in the negotiation process. Finally, the pharmaceutical industry may shift their investment in drug development in response to the drug price negotiation provisions—for example, by focusing on the development of medications that would be exempt from selection for negotiation or that target populations other than Medicare beneficiaries (Shah et al., 2023).

We have identified eight key RQs for these provisions, shown in Table 3.8. This table also lists potential quantitative methods to be used for impact evaluation, outcome measures, level(s) of analysis, subgroups of interest, potential comparison groups, and stakeholders whose perspectives should be solicited as part of a comprehensive evaluation.

Table 3.8. Potential Drug Price Negotiation Provisions Evaluation Approach

Research Questions	Quantitative Methods, Outcome Measure(s)	Quantitative Level(s) of Analysis	Quantitative Subgroups of Interest	Quantitative Potential Comparison Group(s)	Qualitative Primary Data Collected From
Implementation					
What were the challenges and opportunities associated with implementing drug price negotiation?	NA	NA	NA	NA	Federal government Drug manufacturers Pharmacists
Behavioral Response					
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?	ITS • # and type of utilization management tools • Placement of negotiated drugs on formulary • Placement of close substitutes on formulary	Part D plan	NA	NA	Insurers
Utilization					
Did the drug price negotiation provision	DiD	Beneficiary	• Beneficiaries taking drugs	• Commercial insurance	Beneficiaries Insurers

	Quantitative	Quantitative	Quantitative	Quantitative	Qualitative
change utilization of negotiated drugs and/or their close substitutes? Why, why not?	• # negotiated drug fills • # close substitute fills		in therapeutic class	enrollees ages 60–64 taking drugs in therapeutic class	
Spending					
Did the drug price negotiation provision change beneficiary out-of-pocket costs for negotiated drugs and/or their close substitutes? Why, why not?	DiD • Part D OOP costs for negotiated drugs and close substitutes • Part B OOP costs for negotiated drugs and close substitutes	Beneficiary	• Beneficiaries taking drugs in therapeutic class	• Commercial insurance enrollees ages 60–64 taking drugs in therapeutic class	Beneficiaries
How, if at all, has the drug price negotiation provision changed Medicare program spending for negotiated drugs?	ITS • Medicare Program spending on Part D negotiated drugs • Medicare Program spending on Part B negotiated drugs	Drug	NA	NA	Federal government
Pharmaceutical Markets/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 • Gross prescription drug prices • Net prescription drug prices	Beneficiary	• Beneficiaries taking drugs in therapeutic class	• Commercial insurance enrollees ages 60–64	Beneficiaries
Did the drug price negotiation provision change manufacturer rebate agreements for negotiated drugs or their close substitutes? Why, why not?	ITS • Manufacturer rebate payments for branded drugs	Drug	NA	NA	Insurers PBMs Drug manufacturers
To what extent has the drug price negotiation provision shifted investment related to drug development? Why?	ITS • Investment in drug development • # new drug approvals	Drug manufacturers	NA	NA	Drug manufacturers

	Quantitative	Quantitative	Quantitative	Quantitative	Qualitative
	• # follow-on indications for existing drugs				

NA = Not applicable. For subgroups, NA means that no subgroups were identified as specifically relevant to the RQ.
[a] Note that addressing an overall RQ about the general impact of the drug price negotiation provision on pharmaceutical innovation will be an important part of future evaluation efforts. Innovation can be assessed in a number of different ways, and the RQs and outcomes identified in this table are a starting point.

Implementation Evaluation

Drug price negotiation will be primarily implemented by the federal government and the pharmaceutical industry. To assess the challenges of this implementation, the perspectives of those on both sides of these negotiations will be important. Additionally, Part D plans will implement lower prices for these drugs and may change their approaches to utilization management for these drugs, so their perspectives on the challenges to implementation will need to be assessed as well. Finally, pharmacists will play a role in applying lower cost-sharing amounts due to the negotiated MFP and could weigh in on their experiences with the implementation of this part of the provisions.

Impact Outcome Measures

The first set of outcome measures track changes to Part D plan formularies, while a set of utilization measures will provide insights into changes in the use of the negotiated drugs and their close substitutes by beneficiaries. Two spending measures focused on whether beneficiary OOP drug costs changed for those taking negotiated drugs and/or their close substitutes will help address whether beneficiaries received any benefit from the negotiations. Government spending on drugs selected for negotiation could be constructed for both Part B and Part D. Measures of gross and net drug prices, as well as manufacturer rebates, will help address the extent to which drug prices changed. Finally, the amount of investment in drug development can be tracked over time, along with the number of new drug approvals and the number of additional indications approved for existing drugs. We note that other outcomes beyond those listed here may be identified as part of future work and the outcomes presented here do not represent a comprehensive list of outcomes that may be examined to understand the impacts of drug price negotiation.

Statistical Approach to Impact Evaluation

For beneficiary utilization and spending measures, it might be feasible to identify comparison groups from among those beneficiaries previously taking close substitutes, though drug classes within which it is relatively easy to switch among substitutes may not be feasible comparison groups given beneficiaries might change to lower-cost substitutes as a result of negotiation. Patients enrolled in commercial insurance coverage who are under age 65, and who were taking the drugs selected for price negotiation may be another comparison group, as they will

potentially be unaffected by the new prices. If either or both of these comparison group options prove feasible, DiD designs could be used for these analyses.

For the remaining measures, we have not identified any possible comparison groups. If future evaluators are unable to identify one, we recommend using an ITS study design. In addition to the standard challenges with ITS designs, for this particular analysis anticipatory effects may be especially strong. For example, the drugs selected for negotiation, and the negotiation process itself, occurs well before implementation of the MFP in each year beginning in 2026. Therefore, these analyses should account for possible behavioral responses by Part D plans in terms of formulary coverage and benefit design before 2026, which also may occur in response to other provisions and contextual factors. We also note that future evaluators will need to carefully consider issues of attribution and causality, as well as other challenges that are briefly described later in this report, but which were beyond the scope of this report to fully address. For example, it will be difficult to disentangle effects of a specific IRA provision, including drug price negotiation, from the other provisions that are implemented within a similar time frame (e.g., the Part D redesign). Future evaluators and researchers will need to consider how best to address these issues and identify limitations of findings as a result of these and other challenges.

Primary Data Collection for Impact Evaluation

To comprehensively answer the above impact evaluation RQs and explain how and why drug price negotiation affected key outcomes of interest, the evaluators should collect primary data from the following stakeholders:

Manufacturers: Manufacturers play a major role in the drug price negotiations, and evaluators could learn a lot about that process and outcomes through in-depth interviews. These interviews could cover topics such as the impact of negotiations on innovation and investments in drug development. While conducting these interviews, evaluators should encourage respondents to provide real examples of changes brought about as a direct result of price negotiations.

Federal Government: Public officials have been actively involved in negotiating the drug prices and are analyzing the impact of this provision on Medicare Program spending. Interviews with officials from CMS could help evaluators understand the impacts of this provision on spending and other outcomes.

Beneficiaries: Because beneficiaries are not involved in drug price negotiations directly, information about the impact of the negotiations would likely be best collected using a survey. The survey could be targeted only to those beneficiaries who filled a prescription for one of the negotiated drugs and contain questions about any recent changes in utilization or OOP costs for these drugs.

Insurers and PBMs: While insurers are not directly involved with drug price negotiations, the downstream effects of these negotiations are likely to impact the formularies and utilization management approaches used by health plans. Insurer interviews or surveys could explore topics

including the impact of newly negotiated prices on formulary design and drug utilization and adherence, as well as the application of utilization management tools like prior authorization or step therapy among Part D plans. Furthermore, interviews could explore the impact of drug price negotiations on manufacturer rebate payments, though past evaluations suggest that insurer representatives are sometimes reluctant to share information about these negotiations. PBM representatives might be good to include in these conversations, as they typically are more involved in negotiations with manufacturers, but they also might be unwilling to talk to evaluators about these topics.

Chapter 4. Considerations for an Overall IRA Evaluation

The government might be interested in conducting an overall evaluation across all IRA drug-related provisions to understand the collective impact of these provisions on a selected number of outcomes. While difficult to isolate the impacts of these provisions given the numerous external factors occurring at similar times, collecting these data and tracking specific outcomes over time might help policymakers, researchers, and other relevant stakeholders answer some fundamental questions about the impact of the IRA on Medicare beneficiaries and on the availability and pricing for new medications.

An overall IRA evaluation should focus on five research questions, as follows:

- 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?

These research questions capture five key outcomes the IRA was likely targeting: access to medications, drug spending, health outcomes, pricing for existing drugs, and availability of new treatments. In answering these RQs, researchers should rely on a mixed-methods evaluation approach and conduct quantitative impact assessments coupled with the analysis of primary data they collect from relevant stakeholders, including beneficiaries, insurers, drug manufacturers, providers, and government officials, using an approach similar to the one described in Chapter 3 and Appendix B.

Cross-Cutting Outcome Measures

Table 4.1 presents a set of cross-cutting outcome measures that could be constructed as part of an overall evaluation of the IRA. The first set of measures focuses on beneficiary utilization of drugs covered by Parts B and D (separately). For Part D, measures would count the number of medication fills and distinguishing those fills between brand, biosimilar, and generic. For Part B, a set of measures would count the total number of drugs administered and the number of biosimilar and originator biologic products.

Table 4.1. Cross-Cutting Outcome Measures, Data Source(s), Level of Analysis, and Anticipated Impact Timeline

Measure	Data Source(s)	Level of Analysis	Anticipated Impact Timeline
Utilization			
# prescription drugs filled (Part D), by brand, biosimilar, and generic	Prescription Drug Event (PDE)	Government	Short
# medications administered (Part B), by biosimilar versus originator	FFS Carrier claims, MA encounter	Government	Short
Health Outcomes			
Mortality	Medicare enrollment files, National Death Index (NDI) files	Government	Long
Spending			
Part B OOP costs	FFS Carrier claims	Beneficiary	Short
Part D OOP costs	PDE	Beneficiary	Short
Part B premiums	Public Medicare announcements	Government	Medium
Part D premiums	Part D landscape files	Part D plan	Short
Government spending for drugs covered under Part B	FFS Carrier claims, manufacturer inflation rebate payments	Government	Short
Government spending on Part D coverage	PDE, Part D bid data, Part D payment reconciliation data, Medicare enrollment files, manufacturer inflation rebate payments	Government	Short
Pharmaceutical Markets/Innovation			
Gross prescription drug prices	IQVIA or Symphony prescription drug data, AnalySource data	Drug	Medium
Net prescription drug prices	SSR Health data	Drug	Medium
Launch prices for new drugs	IQVIA prescription drug data, Symphony	Pharmaceutical industry	Long
Timing of drug approval and launch	FDA approval and IQVIA/Symphony drug sales data	Pharmaceutical industry	Long

The second set of measures focus on health outcomes. We note that it may be difficult to isolate impacts of the IRA overall on health outcomes, but tracking trends may provide insights into whether anything changed over time at a high level. One important health outcome is mortality, noted in the table, but other measures could be identified by future evaluators after considering the likelihood of observing impacts overall.

A set of four spending measures, four of which track OOP costs and premiums for beneficiaries for medications and two of which track government spending for each of Medicare Parts B and D, would provide insights into the extent to which spending changed after the implementation of the IRA provisions for two key stakeholders. We expect both utilization and spending measures to reflect any impacts of the IRA shortly after the different provisions are implemented.

Finally, outcomes focused on changes to prescription drug prices, both gross and net, as well as the launch prices and timing of launch for new medications, would provide information about the extent to which the IRA had an impact on drug pricing and the availability of new treatments. We expect these outcomes to develop in the medium to long term, but data could be collected soon to facilitate meaningful analyses when sufficient post-IRA data are available.

Statistical Approach

Because an overall evaluation of the IRA includes provisions that affected all Medicare beneficiaries simultaneously, we do not anticipate having a suitable comparison group for this evaluation. As a result, tracking the outcomes over time and modeling them using an ITS design is likely the most reasonable option to estimate the causal effects. However, these estimates will have to be interpreted with caution due to the dynamic and changing policy landscape. Specifically, it will be challenging to rule out that estimated effects were due to the IRA provisions alone and not to the broader changing economic and policy landscapes. These analyses might also need to account for possible anticipatory effects and the implementation of multiple sets of policies across multiple time points.

Conclusions

Despite these limitations, the results of these analyses will likely provide stakeholders with important information about the evolution of key outcomes over the course of the implementation years of the IRA and may inform future policies designed to build upon the provisions included in the IRA.

Chapter 5. Additional Considerations

This report presents a set of approaches to evaluating the IRA Medicare drug-related provisions. Future evaluators could use this report to identify key research questions of interest for a specified set of provisions and could use the information in this report to design in-depth analytic plans and carry out the evaluations.

This chapter presents a set of additional considerations for evaluators beginning the next phases of this work, as follows:

- **Accounting for anticipatory effects.** Some of the provisions in the IRA have a long implementation timeline, which means that stakeholders will be able to anticipate coming changes and alter their behavior in advance of the implementation date. For example, the drug price negotiation provisions will result in MFPs first going into effect in 2026, but the initial 10 drugs selected for negotiation were announced about two and a half years before. The likelihood of anticipatory effects might result in outcomes manifesting earlier than the implementation date for the provision, and future evaluators therefore might mistakenly conclude that there was no impact if they only consider outcomes after the implementation date and not before. Primary data collection activities could gather information on likely anticipatory effects, and quantitative analyses could either change the effective implementation dates or assess whether trends change before implementation but after key announcements have been made. Either way, future evaluators will need to incorporate the likelihood of anticipatory effects into the detailed analytic plans for specific evaluations.
- **Timing of primary data collection.** Given that a number of IRA provisions have already been implemented and a number of additional provisions will be implemented at the beginning of 2025, there is some urgency to collecting primary data from key stakeholder groups regarding their implementation responses, awareness of, and initial experiences with these provisions. Experience evaluating other efforts to increase access to prescription drugs (such as the evaluation of the PDSS Model) has revealed turnover among staff responsible for implementing new policies and programs; many of the staff responsible for implementing provisions in 2022 and 2023 may have left those positions by 2025 or 2026. Evaluators should be mindful of and account for potential Office of Management and Budget requirements related to primary data collection, which may affect the data collection timelines or its scope.
- **Recruitment of stakeholders for primary data collection may be a challenge** especially for insurers, PBMs, and manufacturers. Creative approaches will be needed to establish the value of the evaluation and the role respondents can play in helping to better understand all of the impacts of the IRA, both positive and negative.
- **Ensuring objectivity of primary data collection results** may be challenging because of the highly sensitive nature of this evaluation. Many of the stakeholders have a financial stake in the implementation of the IRA and the results of the evaluation and may bias their interview responses to best serve their interests (e.g., overstating the negative impacts of the IRA on pharmaceutical innovation, understating the extent to which

rebates and negotiations with manufacturers drive formulary design). Triangulation of results and comparative analysis of stakeholder perspectives are key strategies for overcoming this challenge. For example, evaluators should ask plans about their use of utilization management techniques but also ask patients and providers about their experiences navigating these potential barriers to drug access to gain perspectives on both sides of the issue. However, it is important to acknowledge that this will be a challenge throughout the evaluation.

- **Capturing unintended consequences and spillover effects** that may take time to emerge. Therefore, the evaluation should be longitudinal and look at both long-term and short-term impacts using the mixed-methods approach to ensure that feedback from stakeholders can be used to update the evaluation approach and potentially add new research questions and hypotheses as new consequences emerge.
- **Difficulties accessing some of the data sources** included in this report due to proprietary data restrictions. For example, data that enable researchers to identify individual Medicare beneficiaries are housed within the Integrated Data Repository (IDR) at CMS, where access is generally restricted to CMS contractors. Lack of access to these data may limit the ability of researchers to sample beneficiaries for surveys, interview, or focus groups, though we do note that other data exist that could help with this task. In addition, some data—for example, the MA and Part D bid data, Part D payment reconciliation data, and Part D direct and indirect remuneration (DIR) data—are highly protected by CMS, and access for research or evaluation purposes is highly restricted. Future evaluators would need to work with ASPE and CMS to determine the feasibility of these data being released for the purposes of the evaluation.
- **Lags in data availability.** We have noted the time frame for updates to the data sources in this report in Table A.2, which reflects the fact that some evaluation analyses will need to wait until the data are complete and final before they can be conducted. This is especially the case with Medicare claims, MA encounter, and Part D data. Lags in data availability can limit the ability of evaluators to obtain quick-turnaround results. However, we note that the mixed-methods approach described in this report can help mitigate these concerns as the primary data collection activities could provide early insights into impacts.
- **Difficulty in identifying appropriate comparison groups** that could enable a DiD study design, combined with the difficulty in disentangling the effects of multiple policies implemented simultaneously. We have attempted in this report to identify opportunities to isolate estimates of the impact of single provisions or groups of similar provisions, as some outcomes may be more likely to be the result of a specific policy implemented among many at the same time (e.g., certain vaccine-associated complications may be associated with the $0 vaccine copayment provision). However, designing an evaluation that seeks to attribute a specific outcome or set of outcomes to a specific provision might be difficult in this policy environment.

Finally, we note that it may be difficult to attribute outcomes to the IRA, because many other things may be happening at the same time. Our experience with stakeholder interviews has suggested that respondents can vary in their attribution of a change to a given policy. However, the methods described here can nonetheless provide researchers and policymakers with findings that will, at a minimum, be suggestive of potential effects.

Appendix A. Detailed Data Sources Descriptions

This appendix provides a table with additional details regarding potential evaluation data sources and their release timing, as well as which data sources could be used to construct the different outcome measures. A range of secondary data sources could be used to address the research questions described in this report. These data sources fall into different categories, as follows:

- **Trade publications and policy databases:** This category of data sources provides insight into the prescription drug policy landscape, including the information about both implementation of the IRA provisions themselves and other non-federal, state, or local policies that may have been enacted around the same time as the IRA. These data can be used to provide more context for the evaluation as it progresses.
- **Beneficiary- and patient-level data:** These data sources provide information on individual patient (both Medicare beneficiaries and those with other types of coverage) utilization, costs, and health outcomes. These data also include beneficiary characteristics, including race/ethnicity, age, Part D LIS status, geographic location, and gender, which could be used to identify beneficiaries likely to be impacted by a given provision. These data could also be used to sample beneficiaries for interviews, surveys, or focus groups (described in more detail in Appendix B).
- **Plan-level data:** These data provide detailed information on Part D plan benefit design, including cost sharing, formulary coverage, and any utilization management tools applied. Other plan-level data provide information on the number of enrollees in a plan, information on the plan's bid (reflecting the cost of coverage for Part D), premiums, payments made by manufacturers and pharmacies to the plan, and the final payments made by CMS to the plan for the government's share of the cost of coverage.
- **Prescription drug or industry-level data:** These data provide information on prescription drug pricing and changes in pricing over time. A separate set of data sources in this category also provide information on pharmaceutical industry innovation in terms of new drug applications submitted to the FDA, indications for which manufacturers are seeking approval, etc.
- **Provider-level data:** Data in this category provide information on prescribers and providers that administer drugs covered under Part B to beneficiaries, including information on location and specialty. These data could be merged with claims data to identify providers that have administered drugs or written prescriptions for drugs targeted by the IRA provisions.
- **Additional data for covariates:** Additional data sources could be used to ensure that regression models designed to isolate the impacts of the IRA control for other variables that could also impact the outcome being assessed.

Table A.1 presents information on the specific data sources within each of the above categories, including the data source, brief descriptions of each source, and the release timing.

Table A.1. Secondary Data Sources and Release Timing

Data Source	Brief Description	Release Timing
Trade Publications and Policy Databases		
Business Source Complete database	Relevant information covered in Pharma Times, Modern Healthcare, and similar trade publications indexed in this database	Continuous updates
National Council of State Legislatures (NCSL) Prescription Drug Legislation Database	Information on introduced and enacted state legislation on prescription drug access and affordability	Continuous updates (biweekly)
National Academy for State Health Policy (NASHP) Center for State Rx Drug Pricing – Legislative Tracker	Information on introduced and enacted state legislation to lower prescription drug costs	Continuous updates
Official position statements from professional societies	Public statements released by professional societies outlining their positions on certain issues	Ongoing
Public Prescription Drug Affordability Board (PDAB) announcements	Public statements released by PDABs stating their approaches to limiting drug costs	Ongoing
CMS public announcements regarding IRA provisions	Information on the drugs selected for negotiation or for which rebates will be paid	Regular updates
Beneficiary- and Patient-Level Data		
Medicare FFS claims	Utilization, costs, and diagnosis codes for Medicare-covered services	One year after close of year
MA encounter	Utilization and diagnosis codes for MA-covered services	Two years after contract year end
PDE	Part D prescription drug fills and costs	Fall after close of contract year
MEPS	Survey data on medical utilization and expenditures (including prescription drugs)	Two years after survey fielding
MCBS	Continuous longitudinal survey of Medicare beneficiaries about expenditures, health status, and satisfaction with care	Annual survey (summer)
Medicare enrollment files	Data on beneficiary plan enrollment, reason for Medicare entitlement, and demographics	Continuous updates
NDI	Data from the CDC that includes cause of death	Continuous updates
Health Outcomes Survey (HOS)	Beneficiary survey that captures patient-reported health status	Fall after second-round survey
Health and Retirement Survey	Patient survey capturing patient-reported data on health care and prescription drug utilization and costs	Two years after survey fielding

Data Source	Brief Description	Release Timing
Medicare Bayesian Improved Surname Geocoding (MBISG)	Imputed race/ethnicity for all Medicare beneficiaries	Annual updates in fall
State All-Payer Claims Databases (APCDs)	Claims data submitted by payers operating in a given state	Varies by state
Private commercial claims data (e.g., Truven, MarketScan)	Claims data for commercial insurance enrollees	Varies by source
Plan-Level Data		
Plan benefit package (PBP) data	Detailed information on MA and Part D benefit structures, including copayments, coinsurance, benefits offered	Fall prior to contract year start
MA and Part D bid data	Estimated costs of coverage data submitted by MA and Part D plans	Fall prior to contract year start
Part D formulary files	List of Part D covered drugs, cost sharing, and utilization management tools	Fall prior to contract year start
Part D payment reconciliation data	Final payments between Part D plans and CMS to close out coverage year	Fall after contract year close
CMS DIR data for Part D	Rebate and other payments made by manufacturers to Part D plans, pharmacy remuneration payments	Fall after contract year close
Prescription Drug or Industry-Level Data (Examples)		
IQVIA prescription drug data	Private claims data aggregator	Annual
Symphony prescription drug claims data	Private claims data aggregator	Annual
FDA approval data	List of FDA-approved drugs and indications	Ongoing
FDA drug shortage reports	Information on drug shortages	Ongoing
AnalySource data	Prescription drug information and pricing	Ongoing
SSR Health data	Net prescription drug price data	Quarterly
clinicaltrials.gov + Citeline	Information on clinical trials	Ongoing
Citeline + FDA	Information on drugs in development	Ongoing
Clarivate	Information on drugs in development	Ongoing
PitchBook	Data on mergers and acquisitions	Ongoing
LSEG Data & Analytics	Data on mergers and acquisitions	Ongoing
Pharmaceutical pricing announcements	Manufacturer announcements regarding launch prices, changes in pricing	Ongoing
Medispan	Identify prescription drug codes, information on manufacturer	Ongoing
Provider-Level Data		
National Plan & Provider Enumeration System (NPPES)	Clinician data, including National Provider Identifier, specialty codes, location	Ongoing

Data Source	Brief Description	Release Timing
Additional Data Sources for Covariates		
Health Resources and Services Administration Health Professional Shortage Area designations	County-level information on provider shortage areas	Ongoing
Area Health Resources File	County-level data on a range of characteristics, including demographics (population age, poverty levels, race/ethnicity, etc.) and provider characteristics	Annual
American Community Survey	County-level data, similar to Area Health Resources File	Annual

Table A.2 presents the different outcome measures discussed in the report, the likely data sources that could be used to construct them for the subgroups of interest, and the anticipated impact timing for each.

Table A.2. Outcome Measures, Data Sources, and Anticipated Impact Timing

Measure	Data Source(s)	Anticipated Impact Timeline
Behavioral Response		
# biosimilars administered	FFS Carrier claims, MA encounter, NPPES	Short
# originator biologics administered	FFS Carrier claims, MA encounter, NPPES)	Short
# and type of utilization management tools	Part D formulary files	Short
Placement of negotiated drugs and close substitutes on formulary	Part D formulary files	Short
# covered insulins	Part D formulary files, Medi-Span	Short
Type of insulins covered (e.g., short-, long-, rapid-acting, mix)	Part D formulary files, Medi-Span	Short
Utilization		
# beneficiaries with new insulin fills	PDE	Short
# pump insulin fills (Part B)	FFS Carrier claims, MA encounter	Short
# insulin fills (Part D)	PDE	Short
Type of insulin used (e.g., short-, long-, rapid-acting, or pump)	PDE, FFS Carrier claims, MA encounter	Short
# vaccines administered	PDE	Short
# vaccines administered by type	PDE	Short
# fills of top 20 drugs by spending	PDE	Short
# fills of high-cost medications	PDE	Short
# newly initiated medications	PDE	Short
# inpatient stays	FFS Inpatient claims, MA encounter	Medium
Duration of inpatient stays	FFS Inpatient claims, MA encounter	Medium

Measure	Data Source(s)	Anticipated Impact Timeline
# emergency department visits	FFS Carrier claims, MA encounter	Medium
# negotiated drug fills	PDE, FFS Carrier claims, MA encounter	Short
# close substitute fills	PDE, FFS Carrier claims, MA encounter	Short
Spending		
# LIS enrollees	Medicare enrollment data	Medium
# beneficiaries enrolled in Part D	Medicare enrollment data	Medium
Part B drug OOP costs	FFS Carrier claims	Short
Part D drug OOP costs	PDE	Short
Part D premiums	Part D landscape files	Short
Government spending for drugs covered under Part B • Total • For drugs with inflation rebate payments applied • Part B negotiated drugs	FFS Carrier claims, Manufacturer inflation rebate payments	Short
Government spending on Part D coverage • Total • For drugs with inflation rebate payments applied • For those newly eligible for LIS • Part D negotiated drugs	PDE, Part D bid data, Part D payment reconciliation data, Medicare enrollment files Manufacturer inflation rebate payments	Short
Government spending on non-drug health care services	FFS claims, MA bid data	Medium
Total government spending (drugs and non-drug health care services)	FFS claims, MA bid data, PDE, Part D bid data, Part D payment reconciliation data, Medicare enrollment files	Medium
Health Outcomes		
Adherence to insulins by type	FFS Carrier claims, MA encounter, PDE	Short
Inpatient stays for short-term diabetes complications	FFS Inpatient claims, MA encounter	Short
Blood sugar controlled (HbA1c)	HEDIS	Short
# cases of shingles	FFS Carrier and Inpatient claims, MA encounter	Medium
# cases of RSV	FFS Carrier and Inpatient claims, MA encounter	Medium
# hospitalizations for shingles	FFS Inpatient claims, MA encounter	Medium
# provider visits for RSV	FFS Carrier claims, MA encounter	Medium
# hospitalizations for RSV	FFS Inpatient claims, MA encounter	Medium
PDC for top 20 drugs	PDE	Short
Health status	MCBS, HOS	Medium
Adherence to high-cost medications	PDE	Short
Condition-specific complications	FFS claims, MA encounter	Medium
Mortality	Medicare enrollment files, National Death Index	Long
Pharmaceutical Markets/Innovation		

Measure	Data Source(s)	Anticipated Impact Timeline
ASP per quarter for biosimilars	Public ASP data files	Short
ASP per quarter for originator biologics	Public ASP data files	Short
Time to availability of biosimilars	Clarivate	Long
# new molecular entities	FDA	Long
New drug starts/Phase 1 trial starts	Clinicaltrials.gov + Pharmaprojects, Citeline + FDA	Long
Types of products under development	Clinicaltrials.gov + Pharmaprojects, Citeline + FDA	Long
Gross prescription drug prices	IQVIA prescription drug data, AnalySource data	Medium
Net prescription drug prices	SSR Health data	Medium
Launch prices for new drugs	IQVIA prescription drug data, Symphony	Long
Timing of drug approval and launch	FDA approval data and IQVIA/Symphony sales data	Long
Manufacturer rebate payments for branded and biosimilar drugs	CMS DIR data for Part D	Medium
Investment in drug development	PitchBook + DealForma	Long
# new drug approvals	FDA approval data	Long
# follow-on indications for existing drugs	FDA approval data	Long

Appendix B. Detailed Quantitative and Qualitative Methods for Impact Evaluation

A rigorous evaluation of complex interventions that include several components, target a wide range of stakeholders and their behaviors, and allow for a degree of flexibility in their designs and implementation, such as drug-focused IRA provisions, calls for a mixed-methods evaluation design (Skivington et al., 2021). Therefore, wherever possible, researchers assessing the impact of IRA's drug-related provisions should use QUAN+QUAL convergent mixed-methods evaluation designs, where quantitative and qualitative approaches are employed simultaneously (Creswell and Plano Clark, 2017).

In particular, the quantitative analysis of secondary data (where feasible) should be used to estimate the IRA's impact on the key outcomes of interest, including utilization and access, spending, health, and pharmaceutical innovation. Nonetheless, impact estimates should be augmented with comprehensive primary data collection activities and qualitative analysis of newly collected and already existing data to provide a more nuanced assessment of intended and unintended impacts of various IRA drug-related provisions on a range of stakeholders and outcomes.

While the quantitative analysis of secondary data will provide answers to "what" questions, such as the impact of a certain provision on health status, the qualitative analyses of primary data will help explain "why" and "how" this provision affected (or did not affect) health status and may help generate additional research questions and hypotheses. Qualitative analysis will be particularly useful for explaining the mechanisms of action, providing insights into why a certain desired outcome might not have been achieved, and explaining how stakeholders feel about different provisions and their impacts. Qualitative analysis and primary data collection are also key for assessing the implementation of various drug-related provisions, including the description of a wider implementation context, identifying potential unintended outcomes, and exploring spillover effects. We discuss the methods for implementation evaluation in greater detail in Appendix C.

Approaches to Analyzing Secondary Data

In this section, we describe in further detail three study designs that could be used to estimate the effects of the IRA provisions. The first design, ITS, is appropriate when no comparison group is available. The second design, DiD, is appropriate when a comparison group is available. The third design, RDD, is appropriate when individuals are sorted into exposure and comparison groups by some arbitrary threshold (such as age). Other designs, such as instrumental variables, may be applicable in some specific circumstances; however, we focus our discussion on ITS,

DiD, and RDD because these are the methods that we believe would be most appropriate for most of the relevant evaluations. We note that all evaluation design approaches discussed in the subsequent chapters consider analyses of FFS Medicare beneficiaries and MA enrollees separately, given the different incentives faced by MA plans that offer Part D coverage (MA-PDs) compared to stand-alone Part D plans (PDPs) that operate alongside FFS Medicare. In addition, analyses of Part B drug coverage changes will focus on FFS Medicare and MA separately, as PDPs do not offer Part B coverage.

Interrupted Time Series

ITS designs are appropriate for settings where all units in a study are simultaneously exposed to some intervention (e.g., IRA drug provision implementation). The simplest version of ITS is a pre-post analysis, which estimates causal effects by taking the difference between the post-intervention and pre-intervention outcomes. Pre-post analyses effectively assume that the pre-intervention average of the outcomes serves as a valid estimate of the counterfactual outcome absent intervention during the post-intervention time period.

However, pre-post analyses do not account for how outcomes may evolve over time. ITS designs generalize the pre-post design by modeling the pre-intervention outcomes as a function of time, typically using a linear trendline. These pre-intervention trends are then extrapolated into the post-intervention period and serve as a counterfactual estimate of the average outcomes absent the intervention. They key assumption underlying the ITS design is that these extrapolated pre-intervention trends reflect the expected counterfactual outcomes that would occur absent the intervention. To estimate the average causal effect, one simply averages the differences between the observed outcomes in the post-intervention period and the extrapolated pre-intervention trends. The ITS study design can also incorporate covariates, which may be desirable to include when there are other observed factors or interventions that may influence the outcome trends absent the intervention.

The ITS design is arguably most appropriate for many of the evaluation components identified for this evaluation. For example, several IRA drug-related provisions applied to all Medicare Part D beneficiaries and were implemented simultaneously. However, when a comparison group is available, other approaches are generally preferable. This is due to a key limitation of the ITS design: the design effectively assumes that all changes in trend are due to the intervention. Nonetheless, other factors that change during the study period may change the outcome trends and therefore confound estimates based on an ITS design.

Model Parameterization and Estimation

In this section we present a model that implements an ITS study design. We begin by defining notation. Assume that we observe units $i = 1, \dots, n$ over time periods $t = -m, \dots, 0, \dots, k$ where some bundle of policy changes (such as multiple IRA provisions) occurs at time $t = 0$. Y_{it} denotes some continuous outcome of interest for unit *i* at time *t*, X_t is a variable

that takes the value zero before time t = 0 and 1 afterward, and ϵ_{it} is some conditionally mean zero error term.

The following model is one possible implementation of the ITS study design. This model assumes that absent treatment, the mean outcomes would continue to follow the pre-treatment linear trendline.

$$Y_{it} = \beta_0 + \beta_1 t + \beta_2 X_t + \beta_3 t X_t + \epsilon_{it}$$

Under this model, β_2 captures the instantaneous effect of the intervention. More generally, after time zero, $\beta_2 + \beta_3 t$ gives the cumulative effect at time period t, with β_3 giving the marginal effect of the intervention for each additional time period. One can use ordinary least squares to estimate this model, using a cluster-robust covariate matrix to account for correlations within units or across time periods in the error term to obtain variance estimates.

Key Assumptions

At a high level, the ITS study design relies strongly on the assumption that the model of the pre-intervention outcomes accurately predicts the post-intervention counterfactual outcomes. This may not occur if either the pre-intervention model is mis-specified or if the outcome trajectory changes during the post-intervention period due, for example, to other policy changes. For example, if Part B coverage for a new non-insulin diabetes drug occurred at the same time or following the IRA's insulin price provisions, the estimated effects of the IRA might be confounded with the introduction of the new drug using an ITS study design. We can weaken this assumption by conditioning on observed covariates that may confound the ITS estimates and assuming instead that the ITS assumptions hold after controlling for other observed covariates.

The specific parameterization of the ITS design above imposes additional assumptions that also may be weakened, if desired. For example, the model imposes that the pre- and post-intervention outcome trends in the outcome are linear. This could be weakened to allow the outcomes to follow some more general polynomial function of time. Additionally, the model above might not be ideal if the outcomes are count or binary. In these cases, one could instead estimate a generalized linear model with an appropriate link function—for example, using a log-link and Poisson regression for count outcomes. Importantly, this then imposes that the key identifying assumptions hold on a different scale. More generally, other parameterizations of the ITS study design are possible and might be preferable in some settings.

Difference-in-Differences

When a comparison group is available, an arguably stronger method to establish causality is DiD. Unlike the ITS design, DiD can account for changes in the outcome trends that occur during the post-treatment period by using a comparison group. To be precise, DiD designs assume that the counterfactual outcome trends absent treatment would equal the observed trends

in the untreated group—the "parallel trends" assumption. By adding the observed trends in the comparison group to the pre-intervention mean outcome in the intervention group, one then obtains an estimate of the counterfactual mean outcome absent the intervention in the intervention group. To estimate the causal effect, one simply takes the difference between the observed outcome in the post-treatment period and this imputed value. The parallel-trends assumption can also be weakened to condition on observed variables; in other words, one can instead assume that parallel-trends hold within observed covariate values but not necessarily overall, which may be thought to be more plausible in some instances.

DiD designs may be used to evaluate some IRA provisions, particularly when subsets of beneficiaries, providers, or other entities can be identified that are unaffected by these provisions. For example, prior to the IRA, LIS-eligible beneficiaries already had generous cost-sharing provisions relative to non-LIS beneficiaries. Thus, one can argue that the IRA's cost-sharing provisions had limited or no impact on LIS beneficiaries. Therefore, for some research questions, comparison groups, such as LIS beneficiaries, can be used within the DiD framework to inform causal effect estimates.

Model Parameterization and Estimation

In this section we present a model that implements a DiD study design using a so-called event-study specification. We again assume that we observe $i = 1, \dots, n$ over time periods $t = -m, \dots, 0, \dots, k$ time periods and allow ϵ_{it} to be some conditionally mean-zero error term in the model below. Define A_i to be an indicator of membership to the group subject to an intervention at time $t = 0$. Then,

$$Y_{it} = \delta_t + \mu_i + \sum_{t \in [-m, \dots, -2, 0, \dots, T]} \theta_t A_i + \epsilon_{it}$$

Here δ_t represents a time trend that occurs in both the treatment and control groups absent treatment, and μ_i is a unit-specific intercept term (a unit-level "fixed effect"). Under this model, θ_t represents the cumulative treatment effect at time *t* (when *t* is greater than or equal to zero), and $\theta_{j+1} - \theta_j$ may be interpreted as the effect of being treated for a *j*-th additional time period (when *j* is greater than or equal to zero). We can use ordinary least squares to estimate this model, using a cluster-robust covariate matrix to account for possible correlations in the error term.

Key Assumptions

The validity of DiD analyses rests critically on the so-called parallel-trends assumption, which states that the outcome trends absent an intervention (e.g., the IRA drug provision implementation) in the intervention group would equal the outcome trends in the comparison group. This implies, for example, that any other post-treatment policy changes must have identical effects in the treatment and comparison groups. On the other hand, differential changes in the outcomes among these groups would violate parallel trends and therefore bias an estimate

made using a DiD design. We may weaken the parallel-trends assumption, however, when we observe covariates by conditioning on these variables. This then only requires that parallel trends hold within each fixed covariate value, which may be more plausible for some applications. Another way to weaken parallel trends is to instead assume that the difference between the outcomes in each group grows linearly over time. One can then control for group-specific time trends in a regression specification.

The model above imposes additional assumptions that may be weakened, if desired. As with the ITS model discussed above, this model might not be ideal if the outcomes are count or binary. In these cases, one could instead estimate a generalized linear model with an appropriate link function, though crucially the key identifying assumptions are now assumed to hold on a different scale. More generally, other parameterizations of the DiD study design are possible and may be preferable for some settings.

Regression Discontinuity Design

RDDs are appropriate to use when we have data on individuals that receive an intervention, or are more likely to receive an intervention, based on an observable point—or threshold—along a fixed characteristic—sometimes called the "running variable." In an RDD, causal effects are estimated by comparing outcomes just above and below the threshold of the running variable. A key assumption underlying the RDD is that individuals have similar characteristics—both observed and unobserved—just above and below this threshold (this assumption may be weakened to condition on observed covariates).

For example, we may have data from commercial insurers on beneficiaries and their health and utilization outcomes as they age into Medicare. In this case age serves as the running variable, and individuals in the commercial insurance plan who are below 65 may be subject to $100 insulin copayments, for example, while individuals above 65 who left and are newly enrolled in Medicare are subject to $35 copayments, per the IRA provisions. RDD designs would then compare the outcomes among individuals who are almost eligible for Medicare against those who are newly eligible for Medicare to estimate causal effects of the IRA insulin copayment provisions.

A key limitation of this design is that the effect estimates only generalize to individuals who are near the cutoff point—in this example, individuals who are near 65 years old. This may not be a subpopulation of policy interest. Additionally, such comparisons also assume that the only relevant policy change when switching from commercial insurance to Medicare with respect to the outcomes is the insulin copayment provision, which may not hold in practice. However, in this latter case it may be possible to address this limitation by combining the RDD with a DiD—a "difference in discontinuities" design.

Overall RDD and its extensions are worth considering if evaluators identify appropriate running variables, thresholds, and data to implement this approach.

Model Parameterization and Estimation

In this section we present a model that implements an RDD design. We again assume $i = 1, \ldots, n$ individuals, a running variable Z_i—for example, age—a cutoff point *c*, and a binary indicator D_i that is equal to 1 if $Z_i \geq c$ and equal to zero if $Z_i \leq c$. We can then specify the model,

$$Y_i = \beta_0 + \beta_1 D_i + \beta_2 (Z_i - c) + \beta_3 D_i (Z_i - c) + \epsilon_i$$

where ϵ_i is a conditionally mean-zero error term. We can then estimate this model using local linear regression, where the estimate of $\beta_1$is the RDD effect estimate (the treatment effect for individuals at the cutoff point). Other implementations of the RDD design are possible—for example, using parametric models in combination with ordinary least squares—and may be preferable in some settings. The RDD can also be extended in several ways: for example, the so-called fuzzy RDD is applicable when the cutoff does not strictly sort individuals but rather changes the probability of being in the intervention group. The RDD may also be combined with DiD—a "difference in discontinuities" design—if there is residual confounding due to other policy changes or differences in unobserved characteristics at the cutoff point. Essentially, this involves running a DiD near the cutoff point.

Key Assumptions

The validity of the RDD rests on a key assumption that individuals are effectively randomized with respect to treatment around the threshold of the running variable. In other words, individuals are expected to have similar characteristics around this threshold. A key strength of this design is that we can gather support for this assumption by examining whether other observable characteristics differ around the threshold.

However, a common scenario in practice is that multiple policies change around a threshold that might affect the outcomes of interest. As a result, even if the randomization assumption holds, the differences in outcomes might be due to any of these policy changes. Unfortunately, the basic RDD will capture all these effects. For example, an RDD using commercial insurance plans and Medicare data to study the effect of insulin copayments on health, utilization, or access outcomes might be confounded by any number of benefit design differences between Medicare and commercial insurance plans. As noted above, it is sometimes possible to combine an RDD with a DiD design using a "difference in discontinuities" design that might be useful to disentangle the effects of the policy of interest from the other policy changes.

Finally, without stronger assumptions, RDD only estimates effects for specific groups of individuals around the threshold of the running variable. For example, it may be that the effect of the insulin copayment reductions are very different for individuals over 75 than for individuals who are close to 65. However, an RDD estimate using 65 as the cutoff would not give the effects of the insulin copayment provisions for 75-year-old Medicare beneficiaries. While RDD designs

are often thought to be an especially strong study design to obtain causal effect estimates, when the goal is to obtain estimates that apply to a broader population, RDD designs may be less useful.

Determining the Causal Identification Strategy

When a comparison group is available, it is generally preferable to use this information to construct treatment effect estimates using a DiD design rather than an ITS design. However, the validity of the DiD design rests on untestable assumptions about the relationship between the observed trends in the comparison group to the counterfactual trends absent treatment in the treatment group. For some research questions, it may be that there are no credible inferential strategies that use one of the potential comparison groups. In these cases, the ITS design may be preferable. Finally, an RDD may be preferred in specific instances where a credible running variable and threshold are identified, and the generalizability of the effect estimates is not a concern. Subject area expertise should ultimately inform these decisions.

Approaches to Collecting and Analyzing Primary Data

In this section, we describe potential options for primary data collection and analysis that could be used during the impact evaluation. While most of the options described here are qualitative in nature, we also include survey data that will be analyzed quantitatively.

Primary Data Collection

Primary data could be collected using individual or small group interviews, focus groups, and surveys. The choice of the data collection method should be driven by a number of considerations, including the stakeholder group the data are to be collected from, the research question to be answered, the sample needed to answer it, feasibility of recruitment, and participation burden, among other factors. Evaluators should consider the feasibility of adding questions to existing data collection activities, such as the MCBS,[4] rather than designing their own survey data collection activities. Doing so will save time and resources, facilitate comparison over time, and ensure sample representativeness. If possible, evaluators should use existing survey instruments. If relevant previously created survey questions exist, evaluators should validate and cognitively test new survey questions they create prior to fielding them to ensure that they are clear to respondents, not too cognitively burdensome to answer, and do not yield biased responses.

If evaluators plan to administer a new survey, they should ensure adequate sample size and consider using a multimode survey platform such as Forsta HX (formerly known as Confirmit),

[4] We provide specific examples of surveys and organizations throughout this section for illustration purposes only, as RAND has yet to conduct a comprehensive review of all existing surveys, data sources, or potential organizations and trade associations that could help with recruitment or should be invited to provide input.

Qualtrics, or IdSurvey that make it possible to field surveys online, by phone, or using mail, to expedite data collection, cleaning, and analysis. Multimode administration may be particularly important for data collection from beneficiaries, because some may prefer to complete an online survey, whereas others would prefer to answer questions over the phone.

For stakeholder interviews, evaluators should consider using semi-structured interview protocols tailored to each stakeholder group with probes to prompt additional discussion. Interviews with professional stakeholders, such as insurer or drug manufacturer representatives, should last approximately one hour to allow ample time for probes and follow-up questions and conducted using a video conferencing platform like Zoomgov.com. Interviews with beneficiaries may need to be shorter and conducted over the phone. Recruitment should be done using mailed or telephone invitations, especially with hard-to-reach participants, because obtaining their email addresses might be difficult. Each interview should be audio-recorded and transcribed to ensure that the information is captured accurately.

Evaluators should consider convening focus groups when the dynamics of group discussion can be effective in stimulating responses from other participants. Such a group-based data collection technique allows for soliciting perspectives from a larger number of stakeholders and helps generate new ideas. Although focus groups may be useful for gathering information from beneficiaries, providers, pharmacists, and public officials, they may not be productive for collecting data from insurers and manufacturers representing different organizations that compete with each other. Focus groups can be conducted either in person or using Zoom. An experienced moderator skilled at managing group dynamics and familiar with the nuances of the IRA's drug-related provisions should facilitate these focus groups. Focus groups should be recorded. If discussion topics include questions that require idea generation, such as identification of potential behavioral responses or spillover effect, evaluators should consider using physical or digital whiteboards to capture suggested ideas.

Primary Data Analysis

Interviews from each stakeholder group (e.g., beneficiaries, insurers) should be qualitatively coded using a thematic analysis approach (Boyatzis, 1998) to identify common themes across interviews, as well as those unique to a particular stakeholder type or subgroup (e.g., low-income beneficiaries, manufacturers of certain types of drugs). Evaluators should combine deductive coding (Bingham, 2023) that uses the interview protocols questions to generate codes with inductive coding that focuses on concepts that emerge from the data to create codes (Thomas, 2006). Analysis of focus group data should follow a similar approach and use thematic analysis to identify common themes across participants, as well as unique themes that emerge from the comments of certain types of participants.

In analyzing survey data, evaluators should first conduct missing data analyses and descriptive analyses of unweighted and weighted data. Inferential statistics and multivariate regression models should be used to understand subgroup differences and predict the likelihood

of certain outcomes for different demographic groups or in patients with different conditions or health statuses. In cases where additional questions are added to existing surveys, the evaluators should understand the nuances of the sampling methodology used to be able to assess the data quality and apply the correct weights.

Appendix C. Methods for Implementation Evaluation and Identification of Contextual Factors

A rigorous evaluation of the IRA's drug-related provisions should not only estimate the impact they had on costs, utilization, quality, and health outcomes, but should also assess how different provisions have been implemented and what stakeholders' implementation experiences were. Doing so is particularly important for understanding what different stakeholders think about and how they respond to various provisions and explaining why certain provisions may or may not have achieved the desired outcomes. Implementation analyses should also include a focus on the implementation context and analyze larger policy context and account for demographic, health status, and health system factors that could affect implementation and impact outcomes.

The implementation evaluation should ideally encompass all provisions and the entirety of the time of implementation, starting with the biosimilar add-on fee and inflation rebates implemented in 2022 and ending with the later stages of drug price negotiation in 2028 and beyond. We note that while it may be too late to collect primary data to evaluate the implementation of those provisions that went into effect before 2024 due to recall biases, some of those provisions, such as drug price negotiation, for which implementation is still ongoing, should be included in the implementation evaluation. Lessons learned from the earlier implementation phases may affect the implementation of the same provisions in future years. An implementation evaluation of already implemented provisions, however, can still rely on the analysis of existing data.

Because a wide range of stakeholders have been involved in the implementation of the IRA's drug-related provisions, we suggest that the implementation evaluation activities should include primary data collected from policymakers, drug manufacturers, insurers, PBMs, and pharmacists, among others. Similarly, while we anticipate and have described many contextual factors that will affect implementation and outcomes of the IRA, evaluators should be mindful of potential changes in which factors are relevant as evaluations proceed. Keeping track of the evolving policy context should be an important part of the implementation evaluation process.

Research Questions

- **Implementation:**
    - To what extent has the implementation of IRA drug-related provisions been a success?
    - What challenges and opportunities affect the implementation of the IRA provisions? How are these challenges addressed?

    - Are patients and providers aware of the IRA's drug-related provisions?
    - What were the public attitudes toward the IRA provisions around the time of enactment?
- **Context:** What non-IRA federal, state, and/or local factors should be considered in evaluating IRA impacts?

Analysis of Existing Qualitative and Descriptive Data

Larger Policy Context

IRA implementation takes place in a larger policy context, which the evaluator should take into account. For example, several states have implemented laws that have affected insulin prices and the use of biosimilars. Therefore, evaluators should catalog state-level policies that might impact prescription drug costs and design their evaluation activities with this in mind. One way to keep track of relevant state-level policies is to access the information posted on the websites of two organizations, the NCSL and the NASHP Center for State Rx Drug Pricing's Legislative Tracker (National Conference of State Legislatures, 2024; The National Academy for State Health Policy, 2024). The RAND team has reviewed and abstracted the relevant information from these two websites and created a catalog, which lists states that have implemented relevant types of policies (e.g., biosimilar substitution laws, insulin price caps) and briefly summarizes the policy as implemented. This information can help evaluators think about the right comparison groups or interpret their results, among other things. For example, a state with an existing insulin price cap would likely see less of an effect of the IRA's insulin price cap.

Evaluators should also be aware of any changes in contextual factors that may impact implementation and outcomes of the IRA. Tracking these changes may require regular small environmental scans of the academic literature to identify demographic, health status, and health system variables that may impact the outcomes of the IRA, or regular refreshes of data sources (e.g., a new year's data file for a large public survey like the American Community Survey that provides demographic information). RAND has already produced a list of factors to potentially consider in the evaluation. For each factor, the RAND team included a statement describing evidence for its impact on drug prices, relevant publications where it was discussed or described, and potential data sources to be used for future analyses. Future evaluators should review this list of factors, decide which to include as controls or matching variables, and access data sources that will allow those variables to be used (e.g., demographic data from the American Community Survey, health care utilization data from the Healthcare Cost and Utilization Project, or other data sources). Some of these datasets are listed in Appendix A.

Stakeholder Awareness and Attitudes

One way to measure implementation outcomes is to look at public awareness of and stakeholder attitudes toward various provisions. While some provisions may not require

beneficiary awareness to yield the desired outcomes, such as inflation rebates or the biosimilar add-on fee, others, like cost share smoothing and LIS expansion, may require significant engagement from beneficiaries to have a meaningful impact.

To determine beneficiary awareness of and public attitudes toward the various IRA provisions, evaluators could complete an environmental scan in which they aggregate official position statements from professional societies on the IRA, review news articles from the time around IRA enactment, and search for surveys of the public conducted around the time since IRA enactment with published results.

Primary Data Collection

Implementation Experiences

Besides keeping track of the existing data, evaluators should collect primary data from different stakeholders involved in the implementation of various drug-related provisions, as well as beneficiaries themselves, on an ongoing basis. Table C.1 lists stakeholders involved in the actual implementation of various IRA drug-related provisions.

Evaluators could solicit the perspective of insurers, federal government representatives, drug manufacturers, providers, PBMs, and pharmacies, focusing specifically on implementation challenges and facilitators, perceived implementation successes, and attitudes toward and behavioral responses to various provisions. The implementation-focused questions can be developed using an implementation science framework, such as the Consolidated Framework for Implementation Research (Damschroder et al., 2022), so that challenges can be grouped and compared across different types of stakeholders. Evaluators can collect these data using interviews or surveys.

Table C.1. Inflation Reduction Act Provisions and Stakeholders Implementing

Provision	Stakeholders					
	Insurers	Federal Government	Pharmaceutical Industry	Providers	PBMs	Pharmacies
Medicare Part B						
Biosimilars	–	✓	✓	✓	–	–
Inflation rebates	–	✓	✓	–	–	–
$35 insulin copays	✓	✓	–	–	–	–
Drug price negotiation	✓	✓	✓	–	–	–
Medicare Part D						
Inflation rebates	–	✓	✓	–	–	–
$35 insulin copays	✓	✓	–	–	✓	–

	Stakeholders					
$0 copay vaccines	✓	✓	–	–	✓	–
LIS expansion	–	✓	–	–	–	–
Part D benefit redesign						
$0 catastrophic cost sharing	✓	✓	–	–	✓	–
Premium stabilization	–	✓	–	–	–	–
OOP cap of $2,000	✓	✓	–	–	✓	–
Medicare Prescription Payment Plan	✓	✓	–	–	✓	✓
Changes to financial liabilities	✓	✓	✓	–	✓	–
Drug price negotiation	✓	✓	✓	–	–	✓

SOURCE: Summarized from CMS guidance, fact sheet, and timeline documents related to IRA implementation. Note that we also use the term "pharmaceutical industry" here instead of "manufacturers" to capture the broader impacts of the IRA on innovation in the industry.

Stakeholder Awareness and Attitudes

Measuring provider and beneficiary awareness of and attitudes toward various drug-related provisions as an implementation outcome may require some primary data collection as well.

Providers: Interviews or focus groups with providers will be important for determining provider awareness of the IRA provisions focused on biosimilars, as beneficiaries are unlikely to see an impact of many provisions unless providers are prescribing lower-priced drugs. This is especially true for Part B provisions in which providers are administering the impacted drugs. These interviews can start right away because these provisions have already been implemented. Several waves of provider interviews may need to track how this awareness has changed over time. Interview or focus group questions may vary based on provider specialty, as providers who work mostly in inpatient settings would likely be more aware of Part B provisions, while providers working in outpatient settings would likely be more aware of Part D provisions.

Beneficiaries: Beneficiary awareness of and attitudes toward the various IRA provisions could be assessed by adding questions to the MCBS. These questions could be specific to individual provisions or about the IRA more generally. Evaluators may also explore the feasibility of creating a new beneficiary survey that could be fielded annually to keep track of beneficiary awareness of and perspectives on the implementation and outcomes of various provisions. The benefits of a new survey would be the ability to create a sample using administrative data, which may be more beneficial for answering certain research questions, such as asking only low-income beneficiaries about their awareness of LIS-related provisions or

asking only those beneficiaries who benefited from cost share smoothing to provide input on the impact this intervention had on them.

Analysis of Primary Data

Primary data on implementation and contextual factors will likely be collected in interviews and focus groups from all stakeholders. Once interviews and focus groups from each stakeholder group are conducted and transcribed, they should be qualitatively coded using the previously described thematic analysis approach (Boyatzis, 1998). The coded excerpts should be grouped and analyzed using an implementation science framework such as the previously mentioned Consolidated Framework for Implementation Research.

When evaluators analyze beneficiary survey data, they should understand the sampling methodology and weight data correctly. Evaluators should then perform descriptive analyses of unweighted and weighted data. Inferential statistics and multivariate regression models should be used to understand subgroup differences and predictors of attitudes or awareness for different demographic groups or in patients with different conditions or health statuses.

Appendix D. Potential Approaches to Assessing Spillover Effects

The IRA Medicare drug-related provisions might have impacts beyond the Medicare Program, including to other health insurance coverage such as commercial insurance and the Medicaid Program. Specific provisions, such as the maximum $35 insulin copays, $0 vaccine copays, inflation rebates, biosimilars payments, and drug price negotiation, might lead stakeholders to consider changes to their non-Medicare benefit design and payment strategies as well. For example, commercial insurance companies might use the MFPs negotiated as part of the drug price negotiation provisions to negotiate different prices for their commercial enrollees with drug manufacturers. This appendix briefly describes a framework for evaluating the impact of these provisions on non-Medicare health insurers and systems.

Research Questions and Stakeholders Impacted

The key research questions that could be addressed as part of an evaluation of spillover effects include:

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

The key stakeholders potentially impacted by spillover effects include enrollees in other types of insurance coverage, insurance companies, Medicaid Programs, and drug manufacturers.

Outcome Measures

Table D.1 presents a set of outcome measures that could be constructed to answer the above research questions, as well as potential data sources to use to construct the measures, the level of analysis, and the anticipated impact timeline.

Table D.1. Spillover Outcome Measures, Data Source(s), Level of Analysis, and Anticipated Impact Timeline

Measure	Selected Data Source(s)	Level of Analysis	Anticipated Impact Timeline
Drug costs in other programs – Medicaid, employer, commercial	State All-Payer Claims Databases, Medicaid data, IQVIA or Symphony prescription drug data, SSR Health	Drug	Medium
State policies on drug pricing	NCSL state policy tracker	States	Short
PDAB actions	Public PDAB announcements	State	Short
Manufacturer drug prices	AnalySource, pharmaceutical industry pricing announcements (press releases)	Drug	Short

Statistical Approach

Drug pricing outcomes can be tracked over time and modeled using an ITS design to estimate the causal effects. However, we note that these estimates, as with those from an overall IRA evaluation, will have to be interpreted with caution due to the dynamic and changing policy landscape. Specifically, it will be challenging to rule out that estimated effects were due to the IRA provisions alone and not to the broader changing economic and policy landscapes. These analyses may also need to account for possible anticipatory effects and the implementation of multiple sets of policies across multiple time points. In general, it will not be possible to isolate effects of provisions that were implemented simultaneously.

Tracking Implementation of Other Policies

The approach to tracking these policy changes should mirror that described in Appendix C.

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