Project Report

Part D Senior Savings Model Final Evaluation, 2021 to 2023

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About This Project Report

The Medicare Prescription Drug Benefit Program (Part D) offers outpatient prescription drug coverage to Medicare beneficiaries. From 2021 to 2023, the Center for Medicare and Medicaid Innovation tested the effect of lower, predictable cost sharing for insulins via the Part D Senior Savings (PDSS) Model. PDSS-participating plans offered a maximum $35 copayment per monthly supply of each prescribed insulin to beneficiaries enrolled in these plans. In addition, PDSS-participating plans could elect two optional model components: (1) a narrower first risk corridor, made available in 2021 and 2022 and designed to help plans and the Centers for Medicare & Medicaid Services (CMS) share in any unanticipated profits or losses associated with the model test and (2) a Part D rewards and incentives (R&I) program, where plans could offer incentives to beneficiaries with diabetes or prediabetes for participation in various activities, including medication therapy management. This report presents findings of a mixed-methods evaluation of the three years of the model on various outcomes, including access to insulins, health outcomes, beneficiary costs, progression through the Part D benefit phases, and financial outcomes for plans, manufacturers, and CMS.

Because the model parameters have remained constant over time, some text in this report closely mirrors the text from the two prior PDSS evaluation reports.

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Summary

Overview of Main Findings

This report describes the results of a mixed-methods evaluation of the Part D Senior Savings (PDSS) Model test during its three-year implementation period. The model **increased access** to insulins by **lowering insulin costs** to beneficiaries to a predictable maximum $35 per one-month supply.

Consistent with expectations, PDSS:

- increased access to, utilization of, and adherence to insulins
- lowered annual Part D beneficiary out-of-pocket (OOP) drug costs for insulin users
- increased enrollment by insulin users in participating plans
- increased payments made by insulin manufacturers to participating plans
- reduced Part D costs to Medicare

However, PDSS was also associated with:

- increased Part D risk scores for insulin users enrolled in participating plans
- increased total Part D costs (OOP costs plus premiums) for noninsulin users
- increased medical spending by insulin users enrolled in stand-alone prescription drug plans (PDPs) in 2021 and 2022, but decreased spending in 2023

The implementation of the **Inflation Reduction Act (IRA) insulin copayment provision** in 2023 reduced the effect sizes of the model compared with what would have been expected without the IRA. However, we still found some model impacts in 2023, even when it operated in parallel with the IRA provision.

The Medicare Prescription Drug Benefit Program, or Part D, offers outpatient prescription drug coverage to Medicare beneficiaries. In response to escalating drug costs and variation in cost sharing as beneficiaries moved through the different Part D benefit phases, the Center for Medicare and Medicaid Innovation conducted the Part D Senior Savings (PDSS) Model test (hereafter, "PDSS" or "the model") from 2021 through 2023. PDSS tested the effects of lower, predictable cost sharing for drugs, focusing specifically on insulin—a critical medication for diabetes treatment. The model allowed both stand-alone prescription drug plans (PDPs), which operate alongside Original Medicare, and Medicare Advantage Prescription Drug plans (MA-PDs) to provide insulin at a fixed copayment of no more than $35 per one-month supply during the deductible, initial coverage, and coverage gap phases of the Part D benefit.

PDSS was voluntary for insulin manufacturers and Part D plan sponsors. While insulin manufacturers and Part D plan sponsors had to apply annually to participate in the model, insulin users enrolled in PDSS-participating plans simply paid a maximum of $35 per month when filling a prescription for the selected insulins at the pharmacy. Insulin manufacturers that were selected to participate in PDSS had to enter all their insulins into the model. Part D plan sponsors that were selected to participate in the model had to choose which of their eligible enhanced

plans to enter into PDSS. Participating Part D plans had to select at least one vial and one pen dosage form for the four primary insulin types—short-acting, rapid-acting, intermediate-acting, and long-acting—to cover at the maximum copayment of $35 per one-month supply. In addition, they had to decide whether to participate in an optional narrower first risk corridor (available only in 2021 and 2022) to share any unanticipated losses or profits associated with the model with the Centers for Medicare & Medicaid Services (CMS). Finally, participating plans had to decide whether to administer an optional rewards and incentives (R&I) program to encourage beneficiaries with diabetes or prediabetes to engage in disease management or medication therapy management programs by offering them financial rewards, such as gift cards.

This report presents findings from a comprehensive, mixed-methods evaluation of the model's impact on beneficiaries, participating Part D plans, insulin manufacturers, and CMS for each year of the model's period of performance (2021 through 2023). It is structured around five outcome domains: enrollment, access, health outcomes, costs, and spillover effects. It also describes the impacts of the Inflation Reduction Act (IRA) insulin provision that went into effect in 2023 and extended the $35 monthly copayment cap for insulin included in the model to all insulins covered by all Part D plans. The implementation of this insulin-focused IRA provision overlapped with the final year of the model, leading to changed expectations of the model's impacts on key outcomes for that year.

Approach

Our mixed-methods evaluation of the model combined quantitative data modeling with qualitative data collection and analysis. We used secondary data sources, including the Medicare prescription drug event, Part D plan bid, Payment Reconciliation System, Part D direct and indirect remuneration, fee-for-service medical and service claims, MA encounter, and publicly available Part D formulary data to construct outcome measures. Following a similar approach to that used in producing the evaluation of the first year of the model test (Taylor et al., 2023), with some revisions to accommodate changes in model participation and advances in methods, we ran difference-in-differences (DD) regression analyses to isolate the association between the PDSS model and the outcome of interest based on pre- and post-model data. Before running the DD regressions, we calculated and applied weights to balance model participants and nonparticipants across various characteristics.

We ran DD regression models at the plan and beneficiary levels, separately for MA-PDs and PDPs, using nonparticipating Part D plans as the comparison group. PDSS was expected to directly impact beneficiaries enrolled in participating plans and using insulin (*insulin users*) by, for example, lowering their insulin out-of-pocket (OOP) costs, while potentially indirectly affecting those beneficiaries enrolled in participating plans and not using insulin (*noninsulin users*) via spillover effects, such as increased plan premiums. We identified comparison

beneficiaries as those enrolled in nonparticipating plans who did or did not have any insulin fills in the year before the model began.

We required that beneficiaries included in either the insulin user or noninsulin user groups be continuously enrolled in the same plan for the entire calendar year prior to their plan's joining the model and for at least one year after the plan joined the model. Because Part D plans could join the model after the first year (that is, in 2022 or 2023), we allowed new insulin users and noninsulin users to be included in the samples if they met the continuous enrollment criteria.

For the DD models at the plan level, we balanced the comparison group first to be similar to PDSS-participating plans on the pre-trends in the outcome measure of interest. After applying these weights, we found that a small set of additional plan characteristics were imbalanced for at least some outcomes. Our final weights corrected imbalances for these characteristics and the pre-period trends. For the DD models at the beneficiary level, we balanced the comparison group on various pre-period characteristics falling into the following broad categories: beneficiary demographics, insulin utilization (insulin users only), and county-level sociodemographic characteristics. We ran entropy balancing and all regression models separately for insulin users and noninsulin users. The results from the DD regression models are presented as effect estimates with the 95% confidence interval. We report results calculated separately for each year of the model (2021 through 2023) that are statistically significant at the $p < 0.05$ level.

To triangulate and contextualize the results of our quantitative analyses, we also solicited the perspectives of key stakeholder groups on PDSS, its outcomes, and additional barriers to diabetes management that might not have been addressed by the model. To do so, we conducted three waves of surveys of all PDSS-participating Part D plan sponsors, which we refer to as parent organizations (POs), and interviewed a small sample of them in the beginning of 2022, 2023, and 2024. In 2022 and 2024, we also interviewed 100 insulin users whose drug coverage was provided by a PDSS-participating plan. In 2022, we interviewed all PDSS-participating insulin manufacturers. Finally, we spoke with ten insurance agents and ten State Health Insurance Assistance Program (SHIP) counselors in the beginning of 2024. We used descriptive statistics to summarize survey results and thematic analysis to synthesize the results of our interviews.

Key Findings

Model Participation

The three largest U.S. insulin manufacturers joined the model in 2021, and all five U.S. insulin manufacturers participated in the model test in 2022 and 2023. The number of PDSS-participating plan sponsors increased over the course of the model, from 75 to 116. They entered an increasing number of MA-PDs into the model in each year, starting with 1,195 in 2021 and

ending with 2,339 in 2023. PDP consolidations led to fewer total PDSS-participating PDPs in 2022 compared with 2021, but the number of PDSS-participating PDPs increased to 324 in 2023.

Impact on Insulin Users

As expected, PDSS increased utilization of and adherence to insulins and reduced OOP costs for insulin users enrolled in PDSS-participating MA-PDs and PDPs (Figure S.1).

Figure S.1. Estimated Effect of PDSS on Insulin User Outcomes, 2021 to 2023

		MA-PD			PDP		
	Outcome	2021	2022	2023	2021	2022	2023
Access	**30-day insulin fills**	0.85***	0.74***	0.39***	0.82***	1.05***	0.59***
	**Adherence to short/rapid-acting insulins**	2.6%***	2.7%***	1.1%***	2.8%***	2.9%***	0.8%**
	Adherence to basal insulins	1.6%***	1.2%***	0.1%	0.7%***	0.8%**	0.7%*
Beneficiary Costs	**Annual total OOP drug costs**	–$214***	–$198***	–$12	–$364***	–$426***	–$69***
	**Annual total Part D costs** (including premium)	–$209***	–$199***	–$26*	–$309***	–$319***	$85**
Health Outcomes	**Part D risk scores**	0.05***	0.04***	0.04***	0.02***	0.02***	0.00
	**Inpatient stays** for short-term diabetes complications[a]	–0.9**	–0.3	–0.8	0.4	0.1	0.1
	Inpatient stays for uncontrolled diabetes complications[a]	0.0	–0.1	–1.0**	0.4	1.5***	0.3
	ED visits for short-term diabetes complications[a]	–0.7	–1.7	–3.4**	–1.1	0.8	–1.0

NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. ED = emergency department.
[a] Numbers of inpatient stays and ED visits are per 1,000 beneficiaries.

In particular, we found that PDSS was associated with:

- **Increased 30-day fills for insulin users** enrolled in both PDSS-participating MA-PDs and PDPs. PO survey results supported these findings: Most POs in all three years reported increased insulin use, which they attributed to lower copayments. Consistent with quantitative findings, the percentage of POs reporting an increase in insulin use also declined from 76% in 2021 to 56% in 2023.
- **Increased adherence to both short/rapid-acting insulins and basal insulins** for insulin users enrolled in both plan types. While most POs also reported increased adherence to insulins, some noted that increased insulin utilization was not necessarily always followed by increased insulin adherence because of increased enrollment of insulin users.

Moreover, changes in diabetes management guidelines that placed greater emphasis on noninsulin diabetes medications, such as GLP-1 agents, have affected insulin possession rates. Finally, only 13% of interviewed insulin users reported no longer skipping insulin doses and skimming on basic needs to pay for insulin, and 10% reported no longer delaying filling an insulin prescription as a result of PDSS. Most insulin users noted that the lack of opportunities to stay physically active and their inability to follow a healthy diet, rather than high insulin costs, were key barriers to diabetes management.

- **Decreased annual beneficiary Part D OOP drug costs** for insulin users in both PDSS-participating MA-PDs and PDPs. PO survey results supported the decrease in Part D OOP drug costs, which was particularly pronounced for insulin OOP costs and during the coverage gap. Moreover, 42% of interviewed insulin users reported noticing that they had additional funds to spend on other items, such as living expenses, food, and medical expenses, after their insulin copayments decreased.
- **Decreased total Part D costs** for insulin users in both plan types in 2021 and 2022. Total Part D costs were calculated as annual OOP drug costs plus 12 months of the monthly Part D plan premium. However, the effect size decreased for insulin users in MA-PDs and changed to an estimated increase for those in PDPs in 2023.
- **Decreased inpatient stays and ED visits in some years for diabetes-related complications** for insulin users enrolled in PDSS-participating MA-PDs, but increased inpatient stays for uncontrolled diabetes complications for insulin users enrolled in PDSS-participating PDPs in 2022. While most POs did not report changes in inpatient care or ED use, a few that noted changes reported seeing different outcomes. None of the interviewed insulin users reported a change in how often they went to emergency rooms or were admitted to a hospital after their insulin copayments decreased.

Nonetheless, the model was also associated with an unexpected increase in insulin user risk scores, which are based on diagnoses and used to adjust payments to plans. POs and beneficiaries, however, reported relatively small impacts of PDSS on beneficiaries' health status, and we did not find that the increased risk scores translated to higher costs to CMS.

Impact on Part D Plans, Insulin Manufacturers, and CMS

In addition to beneficiaries, other Part D stakeholders were affected by the model (Figure S.2). As expected, PDSS-participating MA-PDs and PDPs experienced estimated increases in total enrollment and enrollment by insulin users compared with nonparticipating plans. Contrary to what PO representatives told us, manufacturers increased their coverage gap discount payments and drug rebate payments to Part D plans as a result of the model. Part D costs to CMS also decreased in all three years.

Figure S.2. Estimated Effect of PDSS on Manufacturers, Plans, and CMS, 2021 to 2023

		MA-PD			PDP		
	Outcome	2021	2022	2023	2021	2022	2023
Enrollment	Total enrollment	11.5%***	14.9%***	30.8%***	18.1%***	12.6%*	2.8%
	New enrollees	23.4%***	10.7%*	50.3%***	–4.4%	–32.1%**	–9.3%
	Insulin users	27.4%***	36.6%***	38.5%***	74.8%***	92.2%***	100.1%***
Manufacturer Payments	Drug rebates	$2.27***	$3.21***	$2.52***	$7.49***	$16***	$22***
	Coverage gap discounts	$1.84***	$2.76***	$2.46***	$4.06***	$7.96***	$10***
Costs to CMS	Part D costs to Medicare	–$4.74*	–$6.51***	–$11***	–$9.33**	–$19***	–$17***
	Reinsurance payments	–$0.99	–$1.26	–$3.31*	–$7.18**	–$13***	–$13***
Medical Spending	Average spending (PMPM)	–1.2%	–1.0%	–1.3%	NA	NA	NA
	Annual spending	NA	NA	NA	15.4%***	1.6%*	–2.0%*

NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. NA = not applicable. We conducted medical spending analyses for MA-PDs using per-member per-month (PMPM) data for all plan enrollees derived from plan bids, while calculating medical spending for PDPs as an annual amount. We conducted analyses for insulin users specifically.

In particular, we found that PDSS was associated with:

- **Increased total enrollment** in PDSS-participating MA-PDs and PDPs in most years of the model. Although most POs reported that PDSS participation had no impact on enrollment, a sizable proportion (up to 43%) reported increased enrollment, and a very small proportion (no more than 4%) reported decreased enrollment. POs reporting increased enrollment often emphasized proactively highlighting lower insulin copayments in their member communication materials, including marketing and pre-sales documents. Moreover, 44% of interviewed insulin users reported specifically looking for a plan with lower insulin copayments; and 41% of these interviewees said that the person who helped them choose a plan advised them to consider insulin copayments. Finally, although insurance agents and SHIP counselors we interviewed also noted that lower insulin copayments often played a role in the beneficiary plan choice, they reported advising beneficiaries to look at their total drug OOP costs rather than insulin copayments alone.
- **Increased enrollment by insulin users** across all years of the model for both plan types.
- **Increased manufacturer payments** to PDSS-participating MA-PDs and PDPs.
- **Decreased Part D costs to CMS** for both participating plan types.

- **Increased total annual medical spending** for insulin users in PDSS-participating PDPs in 2021 and 2022, but decreased spending in 2023. We further found no impact of PDSS on PMPM medical spending for PDSS-participating MA-PDs in any year. Most POs reported no impact on medical spending, typically citing the need to wait longer or to have a lot more population to see tangible impacts on medical costs.

Spillover Effects of the Model

We also evaluated the impact of PDSS on noninsulin users in PDSS-participating plans and beneficiaries eligible for the Part D low-income subsidy (LIS). These groups would not benefit from the lower insulin copayments as part of the model, but they might have been affected by plan benefit design changes resulting from model participation. We found some evidence of spillover effects of PDSS on these groups (Figure S.3).

Figure S.3. Estimated Spillover Effects of PDSS, 2021 to 2023

		MA-PD			PDP		
	Outcome	2021	2022	2023	2021	2022	2023
Enrollment	Noninsulin users	11.5%***	16.4%***	32.1%***	18.8%***	11.2%*	19.1%*
	LIS-eligible beneficiaries	8.9%**	10.9%***	24.8%***	3.5%	–3.1%	–2.1%
Beneficiary Costs	Annual total OOP drug costs	$16***	$27***	$27***	–$18***	–$40***	–$57***
	Total Part D costs (annual OOP drug costs plus premium)	$17**	$24**	$3.41	$30***	$65***	$51***

NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$.

In particular, we found that the model was associated with:

- **Increased enrollment of noninsulin users** in PDSS-participating MA-PDs and PDPs.
- **Increased enrollment of LIS-eligible beneficiaries** in PDSS-participating MA-PDs, but no statistically significant effects for PDSS-participating PDPs in any year of the model.
- **Increased annual Part D OOP drug costs for noninsulin users** enrolled in PDSS-participating MA-PDs in 2021 and 2022, but decreased OOP drug costs for those enrolled in PDPs.
- **Increased annual total Part D costs for noninsulin users** in both PDSS-participating MA-PDs and PDPs, although the effect was smaller and not statistically significant for MA-PDs in 2023.

Impact of the IRA Insulin Provision

We note that the estimated effects for the last year of the model, 2023, were different from the effects for the first two years for several outcomes. This could be due to the implementation of the IRA provision applying the maximum $35 copayment for a month's supply of covered insulins to all Part D plans and not just PDSS-participating plans. We did not change our comparison groups for 2023 in an effort to assess whether differences still remained even after the policy took effect across all of Part D, and we generally found that the results for 2023 were smaller than those for the other years for such outcomes as total OOP drug costs, adherence to rapid/short-acting insulins and basal insulins, and Part D risk scores (though only for PDPs). However, for plan, manufacturer, and CMS cost measures, this trend did not tend to hold: The 2023 estimates indicate that PDSS was associated with similar or larger reductions in Part D costs to Medicare, manufacturer rebates, and coverage gap discount payments in that year compared with estimates in earlier years. Future analyses could explore how costs may have changed after PDSS ended and Part D plans had time to adjust to the IRA insulin cost sharing requirements.

Conclusions

Our mixed-methods evaluation of PDSS during its complete three-year test period yielded important insights into the impact of reduced cost sharing for insulins on costs, access to prescription drugs, and health outcomes. Specifically:

- We found that many of the hypothesized effects materialized in MA-PDs and PDPs in most model years, including increased utilization of and adherence to insulins, lower overall Part D insulin user OOP drug costs, increased enrollment by insulin users in PDSS-participating plans, increased payments made by manufacturers to PDSS-participating plans, and reduced Part D costs to CMS.
- For other outcomes, however, our findings varied by plan type and year. For example, we found that PDSS was associated with increases in PMPM medical spending for insulin users in PDSS-participating PDPs in 2021 and 2022 but was associated with decreases in such spending in 2023. We found no evidence of an association between PDSS and medical spending for PDSS-participating MA-PDs in any year.
- We also found that PDSS was associated with some unexpected outcomes, including increased MA and Part D risk scores for insulin users in participating MA-PDs and PDPs. However, these increased risk scores did not translate to increased Part D costs to CMS for either plan type. We also found that PDSS was associated with decreases in health care utilization for diabetes-related complications in some years for MA-PDs, and increases in one year for PDPs, with small effect sizes, suggesting that these types of outcomes may take a longer time frame to develop.
- Finally, the model had some spillover effects, including increased enrollment of noninsulin users and LIS-eligible beneficiaries who could not benefit from lower insulin costs. Those enrollees who did not use insulin also ended up with higher average total Part D costs, reflecting OOP drug costs plus the plan's premium.

Although the IRA insulin copayment provision implemented in 2023 reduced some of the effect sizes of the model compared with what would have been expected without the IRA, we still estimated some impacts of PDSS in 2023 when it operated in parallel with the IRA's insulin-focused provision. This was likely due to the fact that the IRA provision was newly implemented at the beginning of 2023, and therefore, some of its impacts would take more time to develop. Finally, the results of our evaluation suggest that future drug models might extend the application of lower cost sharing to other drugs and drug types to determine whether similar impacts on costs and quality might occur.

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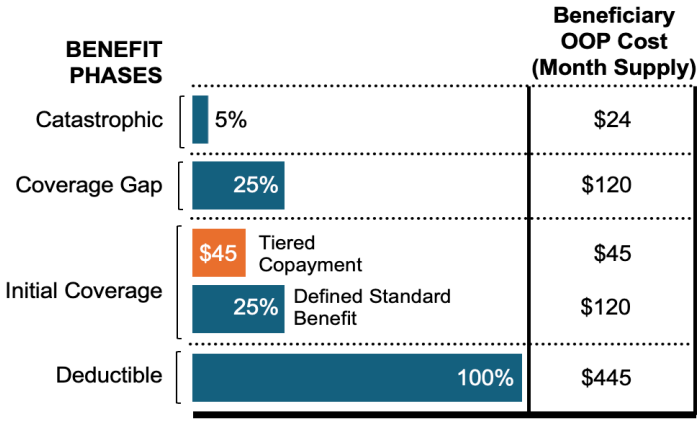
Chapter 1. Introduction

The Medicare Prescription Drug Benefit Program, or Part D, provides Medicare beneficiaries with coverage for outpatient prescription drugs filled at retail, mail-order, and specialty pharmacies. Beneficiaries can enroll in either a stand-alone prescription drug plan (PDP), which operates alongside fee-for-service (FFS) Medicare, or a Medicare Advantage plan with Part D coverage (MA-PD), which, as part of one plan, covers medical services and supplies, Part D prescription drugs, and may offer supplemental benefits and services not covered by FFS Medicare. Both PDPs and MA-PDs are offered by private insurance companies (*parent organizations* [POs]). POs establish the list of Part D covered drugs (*formularies*), the amount that enrollees pay out of pocket (OOP) for their prescriptions (*cost sharing*), and the monthly cost of enrolling in the plan (*premium*) within guidelines established by the Centers for Medicare & Medicaid Services (CMS), which oversees the Medicare Program.

While insurance coverage has been shown to reduce prescription drug OOP costs for beneficiaries (Duggan and Morton, 2010; Liu et al., 2011; Millett et al., 2010; Park and Martin, 2017), high and rising drug prices have increased the amount beneficiaries pay since 2006, when Part D was implemented (Dusetzina, Huskamp, and Keating, 2019; Erath and Dusetzina, 2020; Rome, Egilman, and Kesselheim, 2022; Congressional Budget Office, 2022). Moreover, the "phased" design of the Part D benefit exposed beneficiaries to different OOP costs as they moved through the four benefit phases during the year. Figure 1.1 shows an example of how much beneficiaries would pay for an illustrative drug with a total cost of $480 per month in 2021. In this example, beneficiaries were responsible for 100% of the drug's cost in the deductible (up to $445 in 2021); 25% coinsurance—a percentage of the drug's costs—or a fixed dollar copayment in the initial coverage phase; 25% in the coverage gap; and 5% in the catastrophic phase. Thus, a beneficiary in a plan with tiered copayments might pay $445 for the first fill in the deductible phase, $45 for fills in the initial coverage phase, $120 in the coverage gap, and $24 in the catastrophic phase, with no limit on annual spending. Beneficiaries have altered their drug use in response to the different OOP costs they face through the year (Gokhale et al., 2020; Zhang, Baik, and Lave, 2013; Kaplan and Zhang, 2013), and their OOP costs have increased as drug cost increases were passed on to beneficiaries via coinsurance.

Figure 1.1. Illustrative Example of Beneficiary OOP Costs for $480 Per Month Drug in 2021



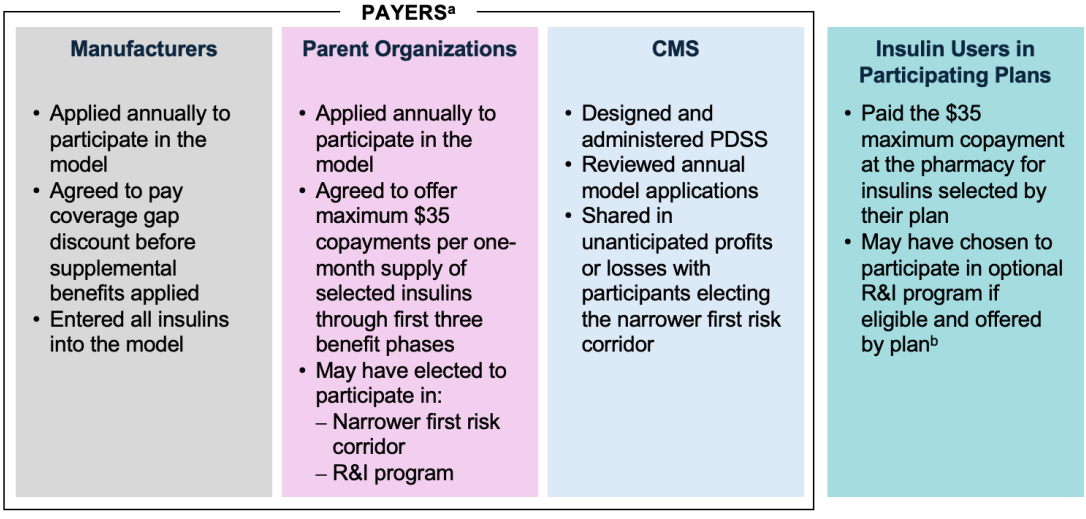
In response to increasing drug costs and concerns about variations in cost sharing that beneficiaries experienced in different Part D benefit phases, the Center for Medicare and Medicaid Innovation (hereafter, the "CMS Innovation Center") tested the Part D Senior Savings (PDSS) Model, which ran from 2021 through 2023 (CMS, undated-b). This report presents the results of a rigorous, mixed-methods evaluation of the impacts of this model on a range of enrollment, access, cost, and health outcomes for stakeholders, including beneficiaries who use insulin; Part D plans; drug manufacturers; and CMS. It also describes the impact on beneficiaries enrolled in PDSS-participating plans who were not eligible for model benefits, such as beneficiaries who do not use insulin.

Part D Senior Savings Model Description

PDSS offered participating MA-PDs and PDPs the opportunity to charge their enrollees a maximum $35 copayment for a one-month supply of selected medications through the deductible, initial coverage, and coverage gap phases of the Part D benefit. Insulins, which patients with diabetes take to manage their blood sugar (National Institute of Diabetes and Digestive and Kidney Diseases, 2022), were selected as the drugs targeted by the model because of their high and increasing costs.

Participating insulin manufacturers agreed to enter all of their insulins into the model (Figure 1.2). Because manufacturers paid 70% of brand name drug costs in the coverage gap, they also agreed to pay the manufacturer gap discount amount calculated before plans applied the Part D supplemental benefit that reduced copayments to $35 per one-month supply. (For additional details on how the model payment mechanisms worked, see Taylor et al. [2022].)

Figure 1.2. PDSS Stakeholders and Key Model Activities



NOTE: R&I = rewards and incentives.
[a] *Payers* are stakeholders that contribute to the cost of Part D.
[b] Beneficiaries with diabetes or prediabetes could be eligible for Part D R&I programs offered as part of the model.

POs interested in lowering insulin copayments for their enrollees submitted model applications for each year of participation, chose which of their eligible enhanced Part D plans to enter into the model,[1] selected insulins offered by participating manufacturers to cover as part of the model, and determined whether to cover insulins for less than the $35 maximum copayment. Participating plans were required to cover at least one vial and one pen form of the four main types of insulin—rapid-, short-, intermediate-, and long-acting—for the maximum $35 per month copayment.

The model also included two optional components: a narrower first risk corridor and a rewards and incentives (R&I) program. Part D payment includes parallel risk corridors that protect plans from unanticipated losses above a certain threshold and requires plans to share profits that exceed a certain percentage above expected costs with CMS. Because of the uncertainty around the financial impacts of PDSS, plans that participated in 2021 and 2022 could opt into a narrower first risk corridor, where CMS would begin sharing unanticipated losses or profits with plans at a smaller percentage threshold. R&I programs allowed participating plans to offer beneficiaries with diabetes or prediabetes rewards for participating in medication therapy management or other programs designed to improve their health.

Beneficiaries enrolled in participating plans who were not eligible for the Part D low-income subsidy (LIS) and who filled prescriptions for insulin did not need to take additional action to receive the $35 maximum copayment for a one-month supply if their insulin was included as part of the model. The copayment was applied automatically at the pharmacy when the beneficiary filled their prescription. Beneficiaries taking insulin who were not enrolled in PDSS-participating plans could switch their Part D plan and enroll in a PDSS-participating plan during the annual open enrollment period. Information regarding which plans were participating in the model was available on the Medicare website that provides information to beneficiaries (Medicare, undated-a).

Policy Context: Inflation Reduction Act Implementation

As originally designed, PDSS was to be tested between 2021 and 2025 (CMS, 2023c). However, in August 2022, the Inflation Reduction Act (IRA) implemented a broad set of policies designed to increase Medicare beneficiaries' access to prescription drugs (Public Law 117-169, 2022). One of the policies was the application of the $35 maximum copayment for a one-month supply of insulin to all Medicare Part D plans and enrollees, which went into effect on January 1, 2023. As a result of the enactment of the IRA insulin cost sharing provisions, the CMS Innovation Center announced that the model would end on December 31, 2023 (CMS, 2023c).

[1] Part D plans offer either *basic* benefits, which reflect the cost of coverage subsidized by the Medicare Program, or *enhanced* benefits, which provide supplemental coverage not paid for by Medicare. Enhanced Part D plans may offer reduced cost sharing, cover prescription drugs that Medicare does not cover, and may offer additional coverage in the gap. Only enhanced Part D plans were eligible to participate in PDSS.

There are several notable differences between PDSS design characteristics and the IRA's insulin provisions. First, the $35 maximum copayment applied to all Part D plans, whereas only enhanced Part D plans were eligible to participate in PDSS. Second, the $35 maximum copayment provision in the IRA applied to all insulins covered on Part D plan formularies, whereas PDSS-participating plans were able to select a subset of their covered insulins for inclusion in the model. Third, the IRA extended the cost sharing requirement to beneficiaries eligible for the Part D LIS, who were not eligible to participate in PDSS. Some LIS-eligible beneficiaries with higher cost sharing requirements may have paid more than $35 per one-month supply (Taylor et al., 2023) prior to the IRA provision. Finally, beginning in July 2023, the maximum $35 per month copayment was extended to beneficiaries using insulins delivered via a pump, which were covered by Part B of Medicare (CMS, undated-b). Insulins covered by Part B were not included in PDSS.

The enactment of the IRA meant that insulin cost sharing for all Medicare Part D enrollees in 2023 was no more than $35 per one-month supply, regardless of whether beneficiaries were enrolled in a PDSS-participating plan or not. Because the IRA was enacted after 2023 Part D bids, which included plan-projected costs of coverage and formulary benefit design details, were submitted to CMS (in June 2022), CMS subsidized the difference between the $35 per month maximum copayment as required by the IRA and what each nonparticipating plan's cost sharing would have been in the absence of the IRA for 2023 (Shapiro, 2022). For plans that participated in PDSS in 2023, this subsidy applied only to the insulins that they did not select to include in the model but were on their formularies.

In addition to the CMS IRA insulin cost subsidies, some beneficiaries enrolled in nonparticipating plans who filled insulin prescriptions in the first quarter of 2023 may have been charged more than $35 at the pharmacy because some Part D plans needed more time to update their systems to reflect the lower $35 copayment implemented as part of the IRA. Part D plans reimbursed beneficiaries for the difference between the cost sharing charged and the $35 copayment during that period (CMS, 2023a), but this transition period may have affected beneficiary utilization of insulin in the first few months of 2023. CMS also extended a Special Enrollment Period (SEP) to beneficiaries who used insulin and wanted to switch to a different Part D plan. This SEP was in operation in December 2022 after the close of the 2023 annual open enrollment period and for all of 2023 (CMS, 2023a).

The 2023 implementation of the IRA insulin provision complicated the PDSS evaluation in 2023 because it extended lower insulin copayments to all Part D plans, as well as resulted in CMS subsidy payments to plans for the differences in costs of insulin. Our evaluation approach considered 2023 effects as distinct from those for 2021 and 2022, and we describe the hypothesized impacts for 2023 in each chapter separately while considering the likely mitigating effect of the IRA provisions on most outcomes during that year.

Evaluation Approach

We conducted a mixed-methods evaluation of the impact of PDSS on such outcome domains as enrollment, access, health, beneficiary costs and progression through the Part D benefit phases, and financial outcomes. Table 1.1 shows the research questions that guided our evaluation by outcome domain and the level(s) at which such analyses were conducted. We considered the impacts on four major stakeholders: beneficiaries, Part D plans, manufacturers, and the Medicare Program.

Table 1.1. Research Questions and Levels of Analysis

Research Question by Outcome Domain	Affected Stakeholder(s)	Level(s) of Analysis
Enrollment		
What was the model's impact on participating plan enrollment, overall, and by certain subpopulations (e.g., insulin users)?	• Beneficiaries • Plans	• Plan
Access		
What was the model's impact on access and adherence to insulin?	• Beneficiaries	• Plan • Beneficiary
Health		
Did the model improve enrollees' health status and specific conditions?	• Beneficiaries	• Beneficiary
Beneficiary costs and benefit phase progression		
What was the model's impact on premiums of participating and nonparticipating plans?	• Beneficiaries	• Plan
What was the model's impact on Part D spending for insulin users in a participating plan?	• Beneficiaries	• Beneficiary
Did the model result in a change in insulin users' progression through the Part D benefit phases?	• Beneficiaries	• Beneficiary
Part D Costs and medical spending		
What was the model's impact on participating and nonparticipating plan bids and the bid's different components? If there was a change, what were the main drivers?	• Plans	• Plan
What was the model's impact on Medicare and pharmaceutical manufacturers?	• Medicare Program • Manufacturers	• Plan
What was the model's impact on medical spending? If there was a change, what were the main drivers?	• Beneficiaries • Medicare Program	• Plan
Spillover effects		
What was the model's impact on plan enrollment by subgroups not targeted by the model?	• Beneficiaries	• Plan
What was the model's impact on Part D spending for noninsulin users in participating plans?	• Beneficiaries	• Beneficiary
Did the model change noninsulin users' progression through the Part D benefit phases?	• Beneficiaries	• Beneficiary

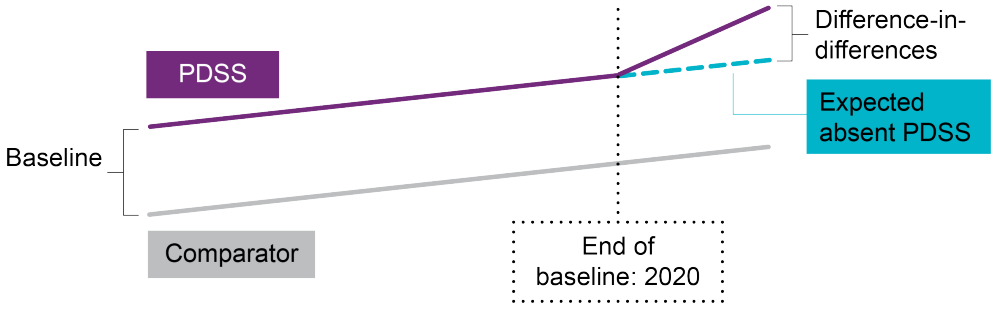
NOTE: Model generalizability is addressed throughout the report as it applies to specific research questions.

Our mixed-methods approach relied on quantitative analyses to answer the "what" and "did" questions and provide estimates of the magnitude of any impacts on specific outcomes; we used model participant surveys and interviews with beneficiaries, Part D plan representatives, insurance agents, and State Health Insurance Assistance Program (SHIP) counselors to explain "how" and "why" the model affected key outcomes of interest. Taken together, the quantitative and qualitative parts of the evaluation are intended to provide a comprehensive picture of the impact of PDSS on stakeholders across the key outcomes measured.

Quantitative Approach

We used secondary data sources, including the Medicare prescription drug event (PDE), Part D plan bid, Payment Reconciliation System (PRS), Part D direct and indirect remuneration (DIR), FFS medical claims, MA encounter, and publicly available Part D formulary data to construct outcome measures modeled in difference-in-differences (DD) regression analyses designed to isolate the impact of PDSS on the specific outcome of interest (Figure 1.3). Appendix A provides a more detailed discussion of our quantitative methods; Appendix B describes our quantitative outcome measures.

Figure 1.3. Isolation of Model Impact via Difference-in-Differences Regression



We identified PDSS-participating plans using the publicly posted PDSS participation data files on the CMS Innovation Center website (CMS, undated-b). We accessed Health Plan Management System (HPMS) data on all Part D plans offered in a given year to identify those plans that were eligible to participate in the model but did not do so in any year of the model (2021 through 2023). We included basic Part D plans, which were not eligible to participate in the model, in our comparison group because increased model participation in 2022 and 2023 resulted in a much smaller comparison group of PDPs when restricting to only those eligible enhanced plans that did not participate.

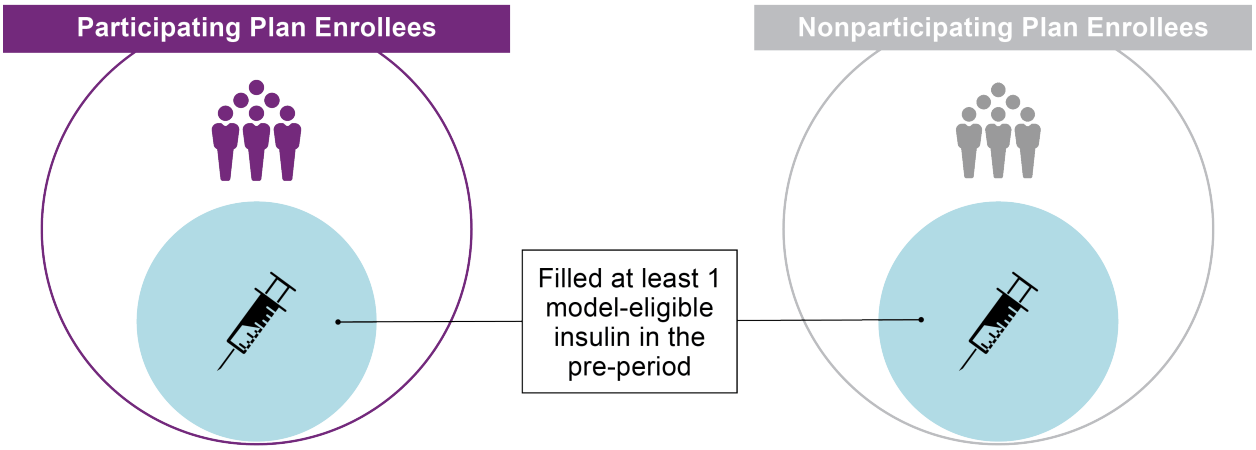
PDSS may have different effects on beneficiaries enrolled in participating plans and using insulin (*insulin users*) and participating plan enrollees who do not use insulin (*noninsulin users*). The model could reduce OOP costs for insulin users in participating plans, increase adherence to

insulin, and improve health status and health outcomes. At the same time, we hypothesized that noninsulin users in participating plans may experience increased OOP costs because of plan formulary changes in response to PDSS, as well as increased premiums if plans increased their premiums as a result of their participation in the model.

As a result, we identified two separate groups for beneficiary-level analyses: *insulin users*, who had at least one fill of insulin in the year before their plan joined the model, and *noninsulin users*, who had no fills of insulin in that same year before their plan joined the model (Figure 1.4). We identified comparison beneficiaries as those enrolled in nonparticipating plans, assigning them to the insulin user or noninsulin user comparison groups based on their pre-period insulin use or non-use. We excluded beneficiaries eligible for the Part D LIS because they were not eligible for the lower insulin copayments as part of the model.

Figure 1.4. Selection of Analytic Comparison Groups and Beneficiary Samples

Analyses examined changes in outcomes associated with PDSS separately for MA-PDs and PDPs, for both participating and nonparticipating plans. (Insulin users who were eligible for the LIS were excluded from the analyses.)



We required beneficiaries in either the insulin user or noninsulin user groups to be enrolled in the same plan for the entire calendar year prior to their plan's joining the model and for at least one year after the plan joined the model. Because Part D plans could join the model in later years (2022 or 2023), we allowed new insulin users and noninsulin users to be included in the analytic samples as long as they met the continuous enrollment criteria.

For the plan-level DD models, we first weighted the comparison group so that pre-trends for the outcome measure of interest were similar to those of the PDSS-participating plans. We also weighted the comparison group to be more similar to the PDSS-participating plans for a selected set of additional plan characteristics. For the beneficiary-level DD models, we balanced the comparison group on various pre-period characteristics that fall into the following broad categories: beneficiary demographics, insulin utilization (insulin users only), and county-level

sociodemographic characteristics. Using the balanced comparison groups for each level of analysis, we ran the DD models with plan and beneficiary fixed effects to isolate the estimated effect of PDSS on the outcome. We ran all plan-level and beneficiary-level models separately for MA-PDs and PDPs, because these two plan types have different incentives in designing their Part D coverage given that MA-PDs also cover medical benefits and the PDPs do not.

We present the results from the DD regression models as effect estimates with the 95% confidence intervals (CIs) in the accompanying figures. We report results that are statistically significant at the $p < 0.05$ level but also note findings with marginally statistically significant levels up to $p < 0.10$. To provide context for these findings, we also calculated the percentage impact implied by the effect estimate. That is, we estimated how different the result was compared with what we would have expected to see in the absence of the model. We refer to these percent effects as the change "attributable to PDSS."

Qualitative Approach

The qualitative component of our evaluation consisted of three waves of surveys and interviews with the representatives of POs that participated in PDSS, two waves of interviews with insulin users whose drug coverage was provided by a PDSS-participating plan, one wave of interviews with PDSS-participating insulin manufacturers, and one wave of interviews with insurance agents and SHIP counselors who assist Medicare beneficiaries with Part D coverage and enrollment decisions. Because we had already presented the results of the first wave of PO and beneficiary data collection, as well as our manufacturer interview findings, in the previous report (Taylor et al., 2023), we focus here primarily on the data that we collected in 2023 and 2024, which included the last two waves of PO data collection, the second wave of beneficiary interviews, and the insurance agent and SHIP counselor interviews. However, we show Wave 1 PO survey results in the report figures to allow readers to track any changes in POs' perspectives on PDSS and its outcomes across all three years of the model. While we briefly describe each of our primary data collection activities below, we provide more-detailed information on our interviews and surveys in Appendix E.

We conducted Wave 2 of PO surveys and semistructured interviews in early 2023; they focused on POs' perceptions of 2022 PDSS outcomes. In early 2024, we conducted Wave 3 of PO surveys and interviews, which covered 2023 model outcomes. Although we asked all POs that participated in PDSS in 2022 and 2023 to complete our annual surveys, we invited a carefully selected sample of 15 POs to share their thoughts on the model and its outcomes during semistructured interviews. Of the 100 POs that participated in PDSS in 2022,[2] 90 answered our Wave 2 survey questions (90% response rate). Of the 116 POs that participated in the model in 2023, 95 provided Wave 3 survey responses (82% response rate).

[2] Because of mergers and acquisitions after Wave 1 data collection, we combined several entities together to reflect their updated PO status for Wave 2 and Wave 3 data collection.

We also interviewed 46 representatives of 13 POs that participated in the model in 2022 and 51 representatives of 14 POs that participated in 2023. Our interview sample was diverse and included the largest and smallest POs, POs that entered different types of plans (such as MA-PDs and/or PDPs), POs that we had interviewed in prior years and those we had not interviewed before, and POs that offered R&I programs and those electing to participate in the narrower first risk corridor component of the model. Our survey and interview questions focused on the benefits and drawbacks of model participation, barriers to insulin adherence, plan- and beneficiary-level outcomes achieved, and lessons learned, among other topics.

To further explore the impacts of PDSS on beneficiaries, better understand factors that negatively affect diabetes management, and identify the extent to which lower insulin costs affect Part D plan choice and insulin utilization, we interviewed 100 insulin users enrolled in PDSS-participating plans. We conducted these Wave 2 beneficiary interviews between March and April 2024. Our sample included 64 insulin users from PDSS-participating MA-PDs and 36 from PDPs. It also included 54 beneficiaries who switched plans in 2023 to allow us to better explore the role insulin costs played in a Part D plan choice.

Finally, between January and May 2024, we interviewed a convenience sample of ten independent insurance agents and ten SHIP counselors from five states with the highest number of Medicare beneficiaries (California, New York, Florida, Pennsylvania, and Texas). These semistructured interviews focused on PDSS awareness and the role of insulin copayments in the beneficiary choice of Part D plans, among other topics.

We analyzed survey results descriptively and relied on thematic analysis to summarize interview findings. Where possible, we tried to quantify interview data to identify the most and the least common sentiments and themes among various stakeholders and waves of data collection. Ultimately, our goal was to triangulate the evaluation findings by combining the results of data modeling with the insights from our qualitative data collection from POs, beneficiaries, and insurance agents and SHIP counselors to provide a more comprehensive assessment of whether, how, and why PDSS affected key outcomes of interest. To protect the confidentiality of POs, insurance agents, and SHIP counselors, we randomly assigned them identification numbers, such as PO A, Counselor A, or Agent A. We retained the same identification for POs whose representatives we interviewed more than once.

Report Road Map

The following chapters present our findings from the evaluation of all three years of PDSS. Chapter 2 provides information on model participation by manufacturers, POs, and beneficiaries. This chapter also describes PO and beneficiary perspectives on the model and beneficiary awareness of the lower insulin copayments provided by PDSS-participating plans. The subsequent five chapters describe the effects of the model on plan enrollment and choice of plan (Chapter 3), access to insulins (Chapter 4), health outcomes (Chapter 5), beneficiary costs and

progression through the benefit phases (Chapter 6), and Part D financial outcomes, including Part D bids, gross drug costs, manufacturer payments, and costs to Medicare (Chapter 7). Chapter 8 presents the results of analyses designed to identify any spillover effects of the model on beneficiaries not taking insulin or not eligible for the model and enrolled in PDSS-participating plans. Chapter 9 summarizes our findings, places the results for 2023 in the context of the IRA insulin copayment provisions, describes evaluation limitations, and concludes with several lessons learned from the model. The appendices provide additional information on our quantitative methods and detailed results (Appendices A through D) and qualitative data collection and analyses (Appendix E).

Chapter 2. Model Participation and Stakeholder Perspectives

CHAPTER KEY TAKEAWAYS

- All five U.S. insulin manufacturers participated in PDSS by 2023, entering between one and 12 insulins.
- PO participation increased from 75 to 116. Most POs entered only MA-PDs into the model.
- Participating POs joined PDSS to be able to lower insulin OOP costs and increase enrollment.
- MA-PD participation increased steadily from 2021 to 2023.
- PDP participation declined from 2021 to 2022 due to plan consolidations but increased in 2023.
- Most participating plans elected the optional narrower first risk corridor in 2021 and 2022, but few elected to offer optional Part D R&I programs.
- The number of beneficiaries who used insulin in PDSS-participating plans increased over the course of the model, reaching more than 1 million in 2023.
- Most interviewed insulin users confirmed that they paid no more than $35 for a one-month supply of insulin.
- SHIP counselors and insurance agents—a critical source of information for beneficiaries enrolling in Part D plans—were aware of the model via their professional roles and training.

This chapter presents information on the manufacturers and POs that participated in PDSS each year. We describe how participation changed over the three model years, including the insulins that manufacturers entered into the model, and discuss characteristics of participating POs and plans. We also present descriptive statistics on the characteristics of beneficiaries who used insulin during the model and who were enrolled in PDSS-participating plans. Using primary data collected from POs, beneficiaries, insurance agents, and SHIP counselors, we also present stakeholder perspectives on the model and describe beneficiary awareness of the model benefits.

Participating Manufacturers and Model-Eligible Insulins

All five U.S. insulin manufacturers participated in the model at some point between 2021 and 2023. Three insulin manufacturers joined the model in its first year: Eli Lilly, Novo Nordisk, and Sanofi-Aventis. Two additional manufacturers, MannKind Corporation and Viatris/Biocon Biologics, formerly Mylan Specialty, joined in 2022.[3] All five manufacturers continued their

[3] While Semglee, the biosimilar insulin manufactured by Viatris/Biocon Biologics, was not brought to the market until November 2021, MannKind, the maker of Afrezza, the only inhaled insulin on the market, found out about the model in 2021.

participation in the model in 2023. Table 2.1 shows each manufacturer and the insulins they entered into the model.

Table 2.1. Participating Manufacturers and Model Drugs, 2021 to 2023

Manufacturer (# of Model Drugs)	Product Brand Name	Generic Name	Brand, Authorized Generic, or Biosimilar Status (Reference Product)
Eli Lilly (11)	Basaglar	Insulin glargine	B
	Humalog	Insulin lispro	B
	Humalog Mix	Insulin lispro protamine and insulin lispro	B
	Humulin Mix	Isophane insulin human and insulin human	B
	Humulin N	Isophane insulin human	B
	Humulin R	Insulin human	B
	Humulin R 500	Insulin human	B
	Insulin lispro	Insulin lispro	AG (Humalog)
	Insulin lispro mix	Insulin lispro protamine and insulin lispro	AG (Humalog Mix)
	Lyumjev	Insulin lispro-aabc	B
	Rezvoglar*	Insulin glargine-aglr	I (Lantus)
Novo Nordisk (12)	Fiasp	Insulin aspart	B
	Insulin aspart	Insulin aspart	AG (NovoLog)
	Insulin aspart mix	Insulin aspart protamine and insulin aspart	AG (NovoLog Mix)
	Insulin degludec*	Insulin degludec	AG (Tresiba)
	Levemir	Insulin detemir	B
	Novolin Mix	Human insulin isophane and human insulin	B
	Novolin N	Isophane insulin human	B
	Novolin R	Insulin human	B
	NovoLog	Insulin aspart	B
	NovoLog Mix	Insulin aspart protamine and insulin aspart	B
	Tresiba	Insulin degludec	B
	Xultophy	Insulin degludec and liraglutide	B
Sanofi-Aventis (6)	Admelog	Insulin lispro	BI (Humalog)
	Apidra	Insulin glulisine	B
	Insulin glargine*	Insulin glargine	AG (Lantus)
	Lantus	Insulin glargine	B
	Soliqua	Insulin glargine and lixisenatide	B
	Toujeo	Insulin glargine	B
Mannkind (1)	Afrezza	Insulin regular (human)	B
Viatris/Biocon Biologics (3)	Insulin glargine-yfgn	Insulin glargine-yfgn	AG, BI (Lantus)
	Semglee (yfgn)	Insulin glargine-yfgn	I (Lantus)
	Semglee[a]	Insulin glargine	BI (Lantus)

SOURCE: Features formulary information provided to the authors by the PDSS-monitoring contractor and information on model formularies posted to the CMS Innovation Center website (CMS, undated-b).
NOTE: An asterisk (*) denotes a new model insulin for 2023. AG = authorized generic; B = brand; BI = biosimilar; I = interchangeable biosimilar. Authorized generics are versions of the brand-name drug authorized for production by a manufacturer while the brand-name version is still on the market. The four-letter tag for some generic names indicates a biologic or biosimilar approved after 2017 (Matli et al., 2021).
[a] Semglee was phased out in 2021 after the manufacturer achieved interchangeability for Lantus with Semglee-yfgn (Viatris, 2021).

The number of model-eligible insulins per manufacturer ranged from 1 to 12 at the product-brand level. (We counted Humulin R 500 as a separate insulin because it is highly concentrated.)

Not all insulins were offered in all years, particularly as some newer insulins were approved over the course of the model (e.g., Rezvoglar). Mannkind offered the only inhaled insulin, but PDSS-participating plans were not required to include an inhaled form as one of the plan-selected model insulins. Four of the five manufacturers entered authorized generics or biosimilars into the model, including insulin lispro (and mix), insulin aspart (and mix), and insulin degludec. Authorized generic versions of brand name drugs are produced by the same manufacturer and sold at lower list prices than the brand name versions (Dusetzina et al., 2021; Dusetzina, Keating, and Huskamp, 2021).

PDSS-Participating Parent Organizations

A total of 75 POs participated in the model in 2021, increasing to 106 in 2022 and 116 in 2023. The number of POs entering only MA-PDs into the model increased from 67 in 2021 to 103 in 2023, while the number entering only PDPs decreased from three to one (Table 2.3). The number of POs that entered both MA-PDs and PDPs increased from five to 12 during the three model years.

Table 2.3. PDSS PO Participation, by Plan Type Entered, 2021 to 2023

Plan Type Entered	2021	2022	2023
Only MA-PDs	67	94	103
Both MA-PDs and PDPs	5	10	12
Only PDPs	3	2	1
Total	**75**	**106**	**116**

SOURCE: Authors' analysis of PDSS participation data provided by the CMS Innovation Center.

There was some churn in participating POs across the three model years (data not shown), with four POs offering only MA-PDs exiting the model after 2021 and 14 exiting after 2022. Two of the four POs that exited after 2021 rejoined the model in 2023. No POs offering only PDPs exited the model; the reduction in the total number of POs offering only PDPs was due to one PO adding MA-PDs to the model in 2022 and another one doing so in 2023. Two POs offering both MA-PDs and PDPs exited the model after 2022.

Thirty-three new POs offering only MA-PDs entered the model in 2022, and 24 entered in 2023 (with two of those 24 rejoining after leaving after 2021). Two new POs offering both MA-PDs and PDPs entered in each of 2022 and 2023. No new POs offering only PDPs joined the model after 2021.

POs participating in the model that entered only MA-PDs on average had smaller Part D enrollment compared with POs that entered both MA-PDs and PDPs, as well as those that entered only PDPs (Table 2.4). Average enrollment also fell from 2021 to 2022; this decrease is likely due to newly entering POs that had smaller overall enrollment for the "Entered only MA-

PDs" and "Entered both" groups. The drop in average enrollment for "Entered only PDPs," however, is due to a PO that had entered only PDPs in 2021 also entering MA-PDs starting in 2022, which shifted its counts to the "Entered Both" category. POs that entered both MA-PDs and PDPs had average Part D enrollment of more than 2.5 million beneficiaries in each year of the model. A larger proportion of POs that entered only MA-PDs offered Part D in one or two states (about 70% of POs in each year), while about 40% of POs that entered both MA-PDs and PDPs offered Part D in only one or two states (data not shown).

Table 2.4. Characteristics of PDSS-Participating POs, by Plan Type Entered, 2021 to 2023

PO Characteristic	2021	2022	2023
Mean PO Part D enrollment			
Entered only MA-PDs	120,239	43,696	44,723
Entered both	3,657,542	2,716,643	2,589,850
Entered only PDPs	515,361	55,508	84,051
Percentage of eligible plans in model			
Entered only MA-PDs	79.2%	83.7%	85.0%
Entered both (% MA-PDs)	66.8%	54.6%	71.8%
Entered both (% PDPs)	75.1%	80.1%	87.6%
Entered only PDPs	91.7%	100.0%	50.0%

SOURCE: Authors' analysis of data from the HPMS plan enrollment file for July of each year and PDSS landscape file (2021–2023).

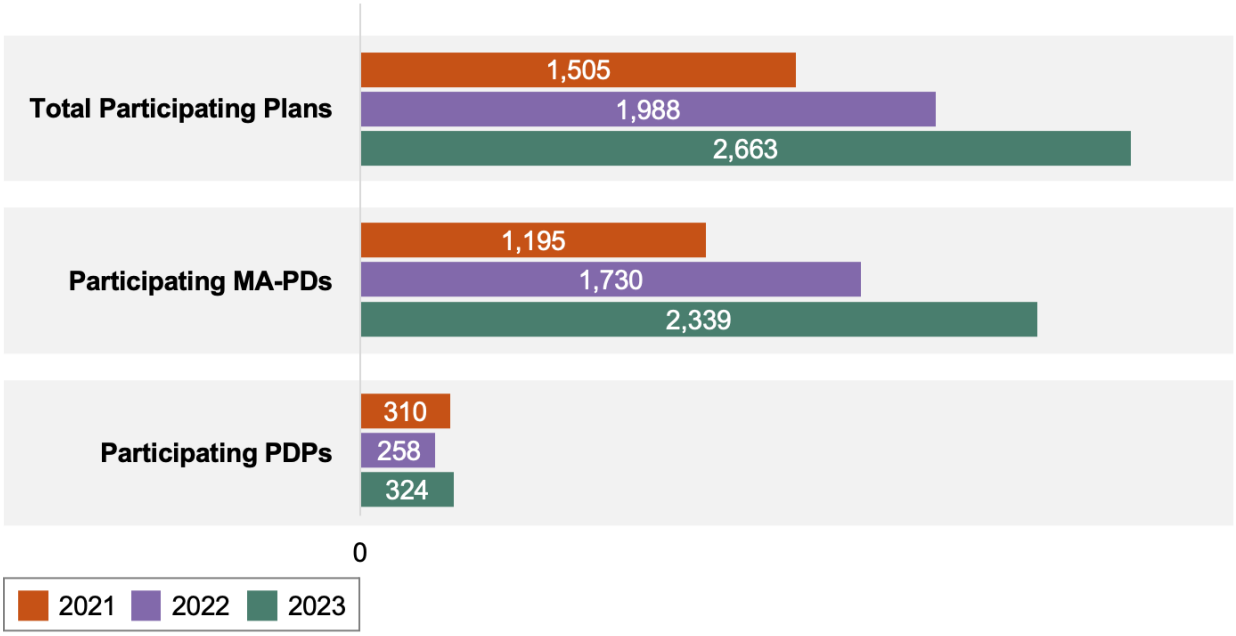
PDSS-participating POs that entered only MA-PDs entered almost 80% of their eligible plans into the model in 2021 and more than 80% in 2022 and 2023. The percentage of eligible MA-PDs entered by POs that entered both plan types declined from roughly 67% in 2021 to 55% in 2022 and then increased to nearly 72% in 2023, while the percentage of eligible PDPs entered increased from about 75% in 2021 to nearly 88% in 2023. Finally, the proportion of eligible PDPs entered by POs that entered only PDPs was more than 90% in 2021 and 2022 but decreased to 50% in 2023.

These results are broadly consistent with our PO survey findings. Most POs that completed our annual surveys reported implementing PDSS in all their eligible plans (58% in 2022 and 66% in 2023). Those POs that did not enter all their eligible plans generally said that they had excluded certain plan types, such as Chronic Condition Special Needs Plans (C-SNPs), or wanted to test the model in a subset of plans before expanding to all plans: "We wanted to gain experience in select plans before expanding into additional plans," said representatives of PO AC. Some POs like PO BW, stated that they wanted to differentiate between their plans, and thus entered only some plans into PDSS, they "only offered [PDSS] on one enhanced plan to keep [a] differential between [the] second enhanced plan."

Plan Participation in PDSS

The total number of PDSS-participating plans increased from 1,505 in 2021 to 2,663 in 2023 (Figure 2.1). The increase was largely due to increased participation by MA-PDs, which represented the largest share of participating (and eligible) plans in all three years. Participation by PDPs declined from 2021 to 2022 due to a substantial number of plan consolidations that reduced the overall number of PDPs. However, the number of participating PDPs increased from 2022 to 2023, with a total of 324 PDSS-participating PDPs in the last year of the model.

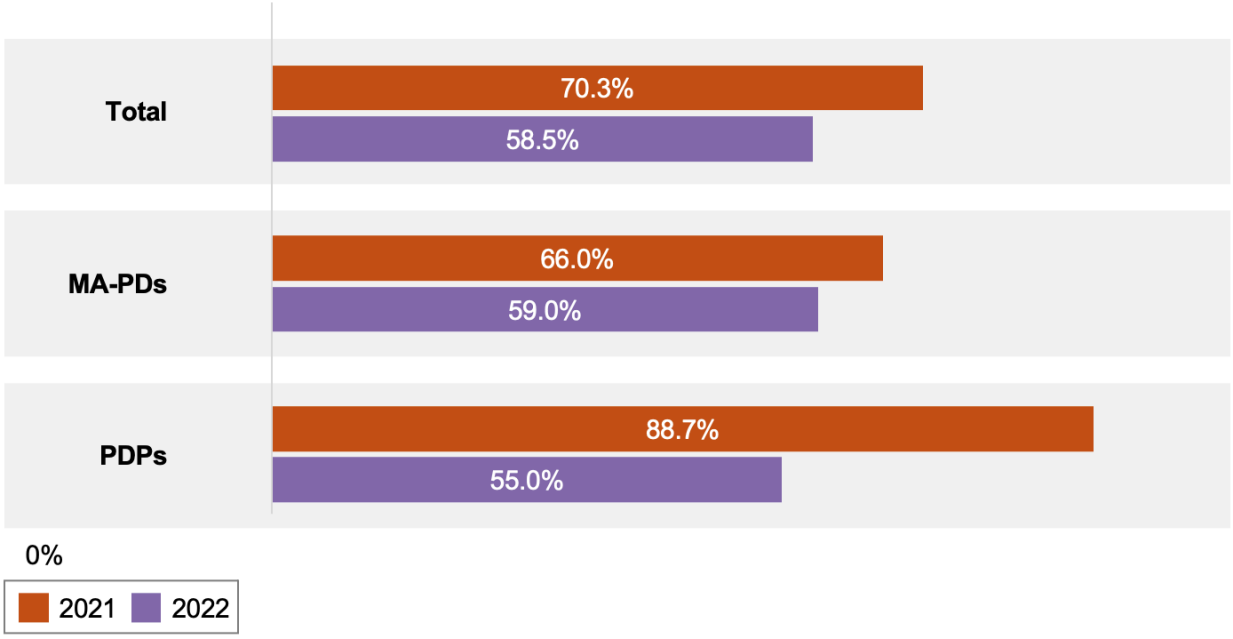
Figure 2.1. Number of PDSS-Participating Plans, by Plan Type, 2021 to 2023



SOURCE: Authors' analysis of publicly available PDSS participation files for 2021 through 2023. See Appendix A for a detailed list of data sources.

Slightly less than three-quarters (70.3%) of all participating plans participated in the optional narrower first risk corridor in 2021, with 66.0% of MA-PDs and nearly all (88.7%) of PDPs electing this component (Figure 2.2). Fewer PDSS-participating plans chose the narrower first risk corridor in 2022 compared with those that did in 2021: 59.0% of MA-PDs and 55.0% of PDPs.

Figure 2.2. Percentage of PDSS-Participating Plans That Elected the Narrower First Risk Corridor, by Plan Type, 2021 and 2022



SOURCE: Authors' analysis of PDSS participation data provided by the CMS Innovation Center.
NOTE: The narrower first risk corridor option was available only in 2021 and 2022.

Only five POs elected to offer the optional R&I program component within 32 MA-PDs in 2021 (see Appendix C for additional details on R&I programs offered in different model years). By 2023, 16 POs had offered them within 85 MA-PDs; no PDPs participated in this component in any of the model years. The five POs that offered the R&I component in 2021 operated five distinct R&I programs (one PO offered two types of R&I; two other POs offered the same R&I program). Four of the five 2021 R&I programs identified eligible beneficiaries based on prescription fill criteria; the fifth program was offered to beneficiaries with a diabetes diagnosis who met the criteria to receive a Comprehensive Medication Review (CMR). Three of the R&I programs offered rewards for completing a CMR consultation, and the other two provided $50 to $75 in gift cards per year for achieving adherence to statins or specified diabetes medications.

There was some churn in the participation patterns for the R&I component across the three years of the model. Six additional POs offered R&I programs beginning in 2022, while one PO declined to offer it after 2021. For 2023, eight POs continued to offer R&I programs (having offered them in 2022 or in both 2021 and 2022), and five new POs began offering R&I programs. The targeting criteria remained largely the same over the course of the model, although one PO changed its criteria from "eligibility for the Star Ratings diabetes measure" to eligibility "based on diagnosis of diabetes." The activities required to receive a reward largely focused on completing CMRs, maintaining a minimum adherence to diabetes medication, and

filling statin prescriptions. Gift cards to various types of stores or over-the-counter (OTC) cards remained the most common rewards offered for completing the R&I program activities.

PDSS-Participating Plan Characteristics

There were a total of 1,195 PDSS-participating MA-PDs in 2021; 1,730 in 2022; and 2,339 in 2023, compared with 1,698 MA-PDs that did not participate in any of those years (see Appendix D for the detailed descriptive statistics presented in this section). In general, beneficiary ages were similar across participating and nonparticipating MA-PDs. Nonetheless, nonparticipating MA-PDs had a slightly lower average percentage of enrollees whose original reason for Medicare entitlement was age (72.3% for nonparticipants vs. 75.7% to 76.6% for participants) rather than disability or end-stage renal disease (ESRD). Nonparticipating MA-PDs also had a lower percentage of insulin users (7.1%) than participating MA-PDs (7.8–8.6%) and a slightly lower percentage of enrollees using noninsulin antidiabetic drugs.

The proportion of MA-PD enrollees who ended the year in the catastrophic phase was 8.2% among nonparticipants, compared with 5.4% to 6.3% among PDSS-participating MA-PDs. On average, nonparticipating MA-PDs also had enrollees with higher mean Part D risk scores (1.02 vs. 0.92 to 0.94) and slightly higher median household income ($70,020 vs. $67,242 to $67,959). Mean plan deductibles decreased over time among PDSS-participating MA-PDs, from $103 in 2021 to $64 in 2023, while the mean deductible was $153 in 2023 among nonparticipating MA-PDs. The mean Part D buydown increased over time for PDSS-participating MA-PDs ($54 in 2021 to $71 in 2023), while the buydown amount was $50 for nonparticipating MA-PDs in 2023.

There were 310 PDSS-participating PDPs in 2021, 258 in 2022, and 324 in 2023, compared with 490 nonparticipating PDPs in all three years of the model. In contrast to MA-PDs, mean enrollee age was lower among nonparticipating PDPs (70.6 years) than participating PDPs (between 74.0 and 74.8, depending on the year). Nonparticipating PDPs had a lower percentage of enrollees whose original reason for Medicare entitlement was age (75.4% for nonparticipants vs. 86.7% to 88.7% for participants) rather than disability or ESRD. Nonparticipating PDPs had a lower percentage of insulin users (5.6%) than PDSS-participating PDPs (7.7%–9.6%), as well as a lower percentage of noninsulin antidiabetic medication users. The proportion of enrollees who ended the year in the catastrophic coverage phase was 10.5% among nonparticipants, compared with 7.4% to 8.3% among PDSS-participating plans. On average, nonparticipating PDPs also had enrollees with higher mean Part D risk scores (0.97 vs. 0.85–0.87), while median household income was similar between participating and nonparticipating PDPs. Mean plan deductibles were substantially lower among PDSS-participating PDPs ($205–$254), compared with nonparticipating PDPs ($480).

PO Perspectives on the Model

Advantages of Participating in PDSS

PO representatives identified five main benefits of model participation. The most frequently reported benefit of PDSS participation was the ability to lower insulin OOP costs for their enrollees, especially in the coverage gap phase. This was also a major reason why many POs joined the model: "I still think it's important to limit those cost shares for our members whenever possible. Most of our Medicare beneficiaries are on a limited income. If we can help out in any way, we're happy to do so," said a PO U representative. POs assumed that improved insulin coverage for beneficiaries, especially in the coverage gap, would lead to greater access to insulin, which, in turn, would improve beneficiary adherence. Here is how a representative from PO H described this benefit:

> The end result of [the model would be] that members [would have] more constant adherence through the different phases of the [Part D] benefit, [because they would not have experienced] hugely variable cost sharing throughout the year. . . . We believe that members were non-compliant once they hit the gap, because they couldn't afford the medication.

The second advantage of being in the model was the desire to grow enrollment in certain plans. Some POs reported that offering lower insulin copays was a competitive advantage that can help retain members and reduce the likelihood of beneficiaries switching to competitors. Others also noted that plan growth was the reason why they elected to participate in PDSS to begin with:

> Initially we elected to participate as a way to differentiate one of our three plans. And prior to the IRA requirement where all plans were covering insulin at $35, [the model] was a good differentiator. We felt like it brought new membership to that plan that we may not have gained otherwise. (PO BW)

The third benefit of PDSS participation was that it helped plans implement the 2023 insulin-focused IRA provisions. Model participants reported gaining early insights into insulin pricing dynamics and changes in insulin utilization from the model, which helped inform their future pricing and bidding strategies when the IRA normalized insulin copayments across all plans. As one PO representative explained:

> The fact that we had the PDSS model in advance of the IRA, kind of gave us a chance to get some of those learnings around how it affects things like utilization of insulin. . . . From a pricing perspective, the model was helpful in that we were able to see the experience, the utilization experience, that supports the bids for upcoming years. (PO E)

The fourth advantage of model participation was the ability to retain the gap discount payments from manufacturers while offering the lower insulin copayments as a supplemental benefit: "There was an advantage that we could continue to offer the insulins at the lower copay

through the gap coverage phase, and you still get the benefit of the gap discount," said a PO DS representative.

Finally, a few POs also mentioned the advantage of being able to offer rewards to beneficiaries through the R&I component of the model.

Disadvantages of Model Participation

At the same time, PO representatives identified three disadvantages of participating in the model in 2023, the first year when the IRA's insulin provision went into effect. The most frequently cited disadvantage was financial drawbacks associated with participating in PDSS, including taking on more costs for insulin coverage than nonparticipating plans because of the subsidies paid by the federal government to these nonparticipating plans for the difference in cost sharing between the new $35 maximum per month copayment and the amount of cost sharing that plans would have charged in the absence of the IRA. One PO H representative explained that "the plans that didn't participate [in 2023], they got subsidies back to cover the cost sharing that had to go to zero for those members or to $35 for those members. So, whereas we just paid for it through the bid process."

Moreover, some POs noted that the IRA had resulted in a loss of any competitive advantage or differentiation that POs gained by participating in the model. "[The IRA] kind of eliminated or made more challenging some of the differentiation we thought we would get from participating," said a PO A representative.

The second reported drawback of participation was increased administrative costs associated with model implementation, including additional costs to address beneficiary confusion around the differences between the model and the IRA, as well as the costs associated with communicating about the changes to insulin copayments to beneficiaries. In particular, PDSS participants noted that all their participating plans had to update documents referring to PDSS and those plans that charged less than $35 for a one-month supply of insulin had to communicate that the IRA was not raising beneficiaries' insulin copayments. Here is how a PO E representative discussed the operational challenges and time costs associated with the need to update their communication materials:

> We certainly did our best to ensure that communications were updated and clear. I think it was kind of an operational challenge. We had to manage that overlapping benefit and ensure that we were really clear with who was impacted by the $35 insulin cap. It was a lot of work internally to ensure that we avoided any confusion for those enrollees.

While the first two drawbacks were related to the IRA's expansion of the $35 insulin copay rather than the model itself, the third disadvantage was related to the need to provide additional documentation to CMS as part of PDSS participation. PO BE representatives noted on the survey that one of the disadvantages was "the additional work to participate in the model. We had to file additional pieces in our bid and formulary which was a burden to our teams."

Characteristics of Beneficiaries Using Insulin in PDSS-Participating Plans

The number of beneficiaries who used at least one insulin and were enrolled in PDSS-participating MA-PDs and PDPs increased in each year of the model (Table 2.5). Specifically, the number of insulin users in PDSS-participating MA-PDs increased from approximately 421,000 in 2021 to more than 650,000 in 2023, and the number enrolled in PDSS-participating PDPs increased from 314,000 to more than 387,000. These changes likely reflect increased participation by both plan types in the model over the model period and increased enrollment by insulin users in PDSS-participating plans, as evidenced by a decrease in insulin user enrollment from 2021 to the end of the model period in nonparticipating plans.

Table 2.5. Number of Insulin Users in PDSS-Participating and Nonparticipating Plans, by Plan Type and Year

Insulin Users by Plan Type	2021	2022	2023
PDSS-participating plans			
MA-PDs	420,569	534,115	650,978
PDPs	314,162	361,526	387,431
Total	734,731	895,641	1,038,409
Nonparticipating plans			
MA-PDs	196,436	192,380	193,848
PDPs	238,230	197,335	195,266
Total	434,666	389,715	389,114

SOURCE: Authors' analysis of Part D event and other data. See Appendix A for a detailed list of data sources.

Insulin users in PDSS-participating MA-PDs and PDPs were similar in terms of average age (ranging from approximately 72 to 75) compared with those in nonparticipating plans across the model years. Insulin users in PDSS-participating MA-PDs were less likely to be entitled to Medicare by reason of age (69.8% to 71.3%) compared with insulin users in nonparticipating MA-PDs (72.3% to 75.4%). We observed similar patterns for PDSS-participating PDPs compared with nonparticipating PDPs, and the percentage of insulin users entitled to Medicare due to age for PDPs was substantially higher than for MA-PDs (82% to 85% for PDPs on average).

PDSS Awareness

Beneficiary Awareness of the Model

During Wave 2 of our beneficiary interviews, we did not ask insulin users directly about their awareness of PDSS because our previous research showed that beneficiaries do not know the model names (Taylor et al., 2023; Eibner et al., 2018). Instead, we asked them about their insulin

OOP costs and whether those had changed in recent years. Overall, 83 of 100 interviewed beneficiaries (83%) reported that their insulin cost was $35 or less for a one-month supply. Of the remaining beneficiaries, 14% reported that their insulin cost was more than $35 per month, and 3% were unsure of the amount they paid for insulin. About three-fifths (62%) of interviewed beneficiaries said that the amount they paid for insulin had changed in the past couple of years, about one-third (36%) reported no change in the amount paid, and 2% were unsure. One beneficiary described high insulin costs before PDSS, saying that "you had to decide if you're gonna get medication or if you're gonna eat."

Of the beneficiaries reporting a recent change in insulin copayments, 77% reported a decrease, 20% reported an increase, and 3% reported being unsure of the direction of change. Because all interviewed insulin users were from a PDSS-participating plan, they were highly unlikely to experience a recent increase in insulin copayments, which suggests possible confusion between insulin and noninsulin diabetes medications among beneficiaries, or may indicate that beneficiaries take multiple insulins, or illustrates recall bias where the interviewed beneficiaries misremembered a recent reduction in insulin copayments (Taylor et al., 2023).

Because copay consistency was another characteristic of PDSS, we asked our interviewees whether they noticed paying the same amount for insulin throughout the year. More than two-thirds (68%) reported saying that they did, while the remaining 32% said that they had not noticed that. One beneficiary described liking the consistent OOP cost, saying, "[Insulin out-of-pocket costs] stayed consistent. I just wish they would do it for the rest of the medications that I need because insulin is not the only diabetes medication that I take."

Awareness of PDSS Among SHIP Counselors, Insurance Agents, and Their Clients

We took a different approach to measuring PDSS awareness during our interviews with SHIP counselors and insurance agents and asked whether they were aware of PDSS (also known as the insulin model) or changes in insulin benefits. Most interviewed SHIP counselors and agents were well aware of the model or changes in insulin benefits; only two agents and one SHIP counselor said that they knew "a little bit" (Counselor J) or not more than "anybody who listens to the news" (Agent F).

Most of our interviewees said that they were aware of PDSS because of their roles as either a SHIP counselor or an insurance agent and that they received training about PDSS's benefits, reviewed relevant information in the CMS newsletter they received, or read about the model in another professional newsletter. They generally understood the nuances of the model, including the maximum copay amount, the fact that the copayments stayed the same across different drug benefit phases (excluding the catastrophic phase), and that not all plans participated in the model. Here is how Agent E described their understanding of PDSS:

> The $35 copay will be applicable to the most common insulin medications. They would not be subject to deductibles or donut holes. . . . When that first year happened and we started looking at different plans, not all Part D plans actually

> had that. . . . There were a few companies that did, but to my experience, not all Part D plans had that type of situation for the insulin. But that was in the beginning. Today, it's different.

When asked if their clients knew about PDSS, our interviewees said that beneficiary awareness varied. As Agent C explained:

> Some might have said that they heard about it. Some might not have known about it but came to me about changing their plan because maybe one or two of their drugs wasn't covered under the current plan and needed to change. And when the Senior Savings program came out and they're taking insulin, I said, "Well, we can switch you to a plan where you're limited to $35 for your insulin." And they were thrilled.

According to other interviewees, insulin users often knew about PDSS benefits. "The ones who were aware were the ones who were using insulin. Those are the ones that I saw and heard about how they were satisfied with [the] reduced cost of their insulin," said Counselor I.

Those who did not know about PDSS were educated by their SHIP counselor or insurance agent. Here is how Counselor D described it:

> Even if the client didn't know [about PDSS benefits] until we told them, the client was educated to know that the government was doing something to try and make medicines less expensive, and certainly lifesaving medicines. Prior to that, I did have people that [sic] would be out of insulin, couldn't afford it yet. They couldn't get it till the next month. . . . I do think that that was an effective way to at least show the public that the government, the big bad government, was trying to work more on their behalf.

While most interviewed SHIP counselors and insurance agents waited for their clients who took insulins to come to them during the open enrollment period to let them know about PDSS benefits, one interviewee decided to be more proactive and reached out to their clients with diabetes directly: "I was jumping for joy when that stuff first came out. I thought that it was great. . . . I decided to call some of them that I knew were diabetic and make sure they knew about the plan. And so, they found that very helpful" (Counselor D).

Summary

PDSS participation by insulin manufacturers and POs increased over the three years of the model. All five U.S. insulin manufacturers participated in the model in its final two years. PDSS-participating POs were more likely to enter MA-PDs than PDPs into the model, and participation by MA-PDs increased steadily over each year of the model. Participation by PDPs declined due to plan consolidations in 2022 but increased again in 2023. POs participating in the model reported several benefits to participation, in particular the ability to offer lower insulin OOP costs to their enrollees and increase their plan enrollment levels, but POs also noted a few drawbacks to participation, including the financial disadvantages of model participation in 2023 as the IRA insulin copayment provision was implemented and PDSS-participating plans did not

benefit from the CMS subsidies available for the lowered insulin copayments. Most interviewed insulin users from PDSS-participating plans confirmed that they paid no more than $35 per month for their supply of insulin and reported paying the same amount for insulin throughout the year. Most interviewed SHIP counselors and insurance agents were also aware of PDSS and reported educating their clients who used insulins about the model's benefits.

Chapter 3. Enrollment Outcomes

CHAPTER KEY TAKEAWAYS

- PDSS was associated with increases in **total enrollment** for both plan types and across years, except for PDPs in 2023.
- MA-PDs experienced increases in **new enrollment**, while there were no changes for PDPs in 2021 or 2023. However, PDPs experienced estimated decreases in new enrollment in 2022.
- **Insulin user enrollment** increased for both MA-PDs and PDPs in all years of the model.

- Beneficiaries, insurance agents, and SHIP counselors indicated that **prescription drug costs and coverage** were among key factors affecting beneficiary choice of prescription drug coverage.
- More than two-fifths of the interviewed insulin users said that the insulin costs were a key factor in their plan enrollment decision.

In this chapter, we report the results of our mixed-methods analyses that assessed the effect of PDSS on various plan-level enrollment outcomes shown in Table 3.1. The hypothesized effect of PDSS on total plan enrollment and on the number of new plan enrollees is unclear, because PDSS-participating plans might attract insulin users by offering lower, more predictable insulin cost sharing, but they might lose enrollees who are noninsulin users if they altered their benefit designs or increased premiums due to PDSS implementation.

Table 3.1. Enrollment Outcome Measures

Measure	Analysis Level	Description
Total plan enrollment	Plan	Number of beneficiaries enrolled in the plan as of July 1st of the year
Number of new enrollees	Plan	Number of beneficiaries enrolled in the plan as of July 1st who were enrolled in a different plan (or not enrolled at all) as of December 1st of the previous year
Insulin users	Plan	Number of insulin users enrolled in the plan as of July 1st of the year

NOTE: More details on measure selection and construction can be found in Appendix B.

We ran DD regression models using all nonparticipating plans as the primary comparison group. We converted enrollment numbers calculated at the plan level to a $ln(y + 1)$ scale to assess the effect of the model on the percentage change in enrollment rather than the numerical change in enrollment. We supplemented the results of quantitative analyses with the insights from our PO surveys and interviews. This chapter also includes a summary of our interviews with beneficiaries enrolled in PDSS-participating plans, insurance agents, and SHIP counselors that sheds light on the factors affecting beneficiary choice of Part D coverage and the extent to which

lower insulin copayments might have affected their prescription drug plan choice. Appendix F provides details on the factors that affect the choice of a particular MA-PD or PDP, as well as the reasons for switching plans.

Total and New Plan Enrollment

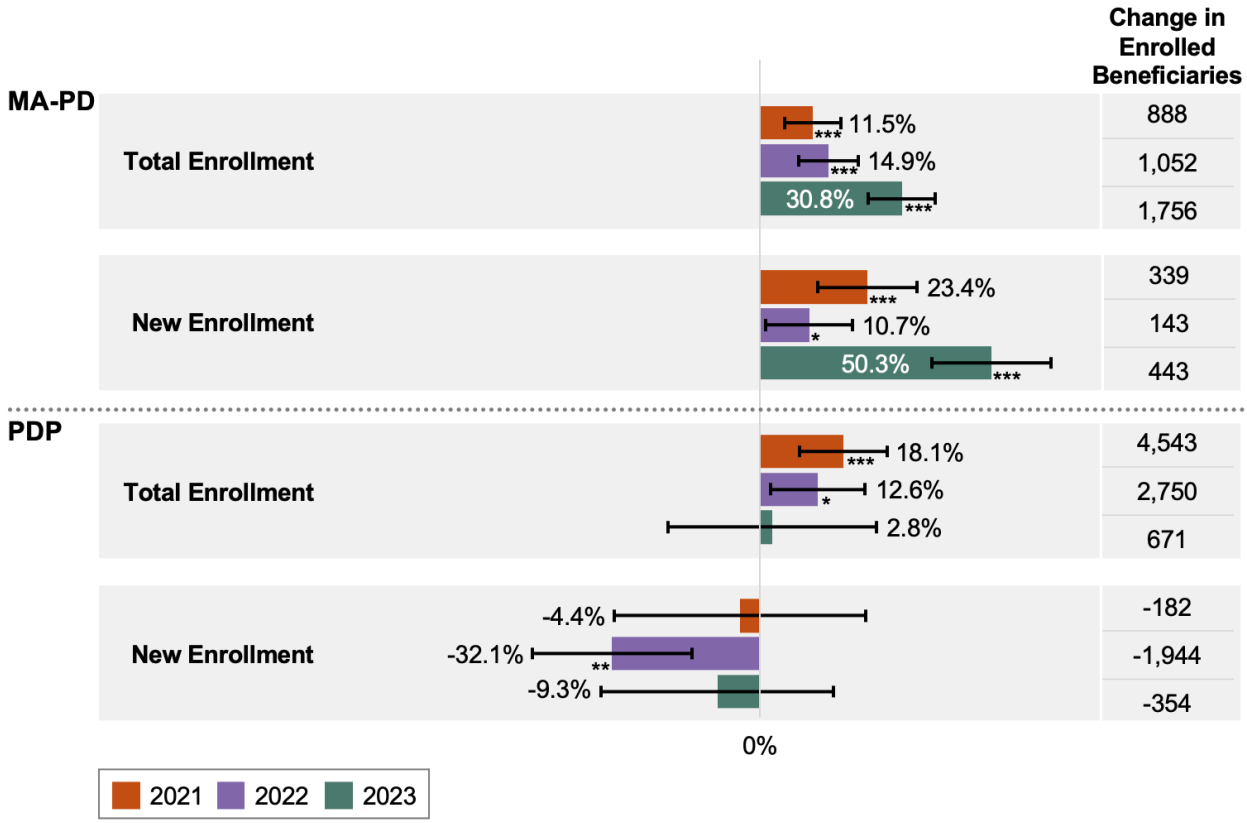
Enrollment	Hypothesized Effect of PDSS	Anticipated 2023 IRA Impact
Total and New Plan	**Uncertain** impact on total and new enrollment in PDSS-participating plans	Because cost sharing and formularies for noninsulin drugs were established before the IRA was enacted, effects on enrollment for 2023 are expected to be **similar to** those in earlier model years

The model was associated with a statistically significant increase in total and new plan enrollment for MA-PDs participating in the model, relative to expected enrollment in the absence of the model (Figure 3.1). Total enrollment for MA-PDs increased by an average of 11.5%, 14.9%, and 30.8% across the model years (2021–2023) (all $p < 0.001$). This trend translated to 888 additional individuals enrolled, on average, per PDSS-participating MA-PD in 2021; 1,052 in 2022; and 1,765 in 2023 above what would have been expected in the absence of the model.

Among PDSS-participating PDPs, PDSS was associated with statistically significant increases in total enrollment of 18.1% in 2021 ($p < 0.001$) and 12.6% in 2022 ($p = 0.01$). The model did not have a statistically significant effect on total enrollment in PDSS-participating PDPs in 2023. This effect amounted to an average 4,543 additional enrollees per PDSS-participating PDP in 2021 and 2,750 additional enrollees in 2022, relative to what would have been observed in the absence of the model.

We also examined the impact of PDSS on *new plan enrollment*, defined as beneficiaries enrolled in the plan on July 1 who had been enrolled in a different plan as of December 1 of the preceding year. The new plan enrollment measure is different from the total enrollment measure because the latter also includes beneficiaries who were previously enrolled in the same plan. New plan enrollment in MA-PDs increased by 23.4% in 2021 ($p < 0.001$), 10.7% in 2022 ($p = 0.03$), and 50.3% in 2023 ($p < 0.001$) as a result of the model. On average, these effects translated to 339 additional new enrollees per PDSS-participating MA-PD in 2021, 143 additional new enrollees in 2022, and 443 additional new enrollees in 2023.

Figure 3.1. Estimated Effect of PDSS on Total and New Plan Enrollment, by Plan Type and Year



SOURCE: Authors' analysis of Part D enrollment and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the plan-level DD regression models for each year of the model. The comparison groups consisted of nonparticipating plans. The column labeled "Change in Enrolled Beneficiaries" indicates the number of additional (or fewer, if negative) beneficiaries enrolled in PDSS-participating plans compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

The effect of PDSS on new plan enrollment in PDPs was statistically significant only in 2022, resulting in a 32.1% ($p = 0.01$) decrease in new plan enrollment, which translated to an average 1,944 fewer new enrollees in PDSS-participating PDPs that year. While the PDSS effect on new plan enrollment in PDPs in 2022 was negative and significant, we note that the effect on total enrollment in PDPs that year was positive and significant. In terms of raw enrollment numbers, total enrollment in nonparticipating PDPs *decreased* from 2021 to 2022, while total enrollment in PDSS-participating PDPs increased slightly (data not shown), contributing to the finding of a positive and significant effect. The number of new enrollees in 2022 decreased in both participating and nonparticipating PDPs but decreased by more among PDSS-participating PDPs. This finding suggests that more people left nonparticipating PDPs than PDSS-participating PDPs.

Although most POs completing our survey each year reported that PDSS participation had no impact on enrollment, a sizable percentage reported increased enrollment, and a very small percentage of POs reported decreased enrollment (Figure 3.2). We note that on the survey, our unit of analysis was a PO rather than a plan. Representatives of POs who reported no impact on enrollment generally said that they either could not establish a causal relationship between PDSS participation and enrollment or felt that other factors had a greater impact on plan enrollment. Here is how PO AH representatives explained it:

> During the years where the Senior Savings Model was active, there was also just a lot of volatility in the marketplace. . . . We were seeing other carriers have plan design changes and premium increases. . . . Typically, a beneficiary is doing their shopping based on their total out-of-pocket cost, taking into consideration other medications that they may be taking and the cost sharing associated with those, along with premium change. Because of those changes, there may have been members moving away from some of those Senior Savings Model plans into other products that better suited their needs more holistically.

Figure 3.2. PO Survey Results on Perceived Impact of PDSS on Plan Enrollment, 2021 to 2023

SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

While the percentage of POs reporting no impact on enrollment increased from 53% in 2021 to 72% in 2023, the percentage reporting increased enrollment decreased from 43% to 25% over the same period. Increased uptake of the model among eligible plans was one of the main reasons why the number of POs reporting a positive impact of PDSS on enrollment decreased. Here is how PO CD representatives explained it:

> We were the only local regional plan in our market areas that opted into the model. So, we did have some national players that are competitors as well, but we were the only [participant] in the first year. We were the only local plan to sign up for the model, and we did see an increase in enrollment [that year].

PO AO representatives agreed by saying that their market was very competitive, and they were no longer an outlier in 2022: "Everyone's kind of racing to the top in terms of what you can offer, and so we weren't an outlier in terms of offering any Part D–related benefits that would be above and beyond the competitor." Finally, PO H representatives explained that their plan enrollment was not affected because they "weren't alone, and that most others in the market had also [participated in PDSS]. If we were looking at this as a differentiator, like it really didn't differentiate, it's kind of just everybody kind of did the same."

As mentioned in Chapter 2, some PO representatives stated that PDSS provided a valuable opportunity for their POs to grow enrollment and increase profitability. This was because the model increased manufacturer gap discount payments rather than raising plan costs in the coverage gap, and the model also reduced insulin copayments. PO BW representatives said that the manufacturer drug rebates on insulin fills were financially attractive enough to want "to attract these insulin users because of the [drug] rebate trade-off. And we saw that these members could be profitable." To increase enrollment, representatives of PO H "highlighted [their] PDSS participation in a lot of [their] member communications, including pre-sales documents, to really hit on that predictable cost sharing benefit."

Finally, several interviewees whose POs entered both MA-PDs and PDPs into the model noted that the impact on enrollment varied by plan type. According to PO A representatives, the impact was slightly more pronounced in PDPs than MA-PDs: "There probably was a bit more of an increase in plan enrollment for the PDP versus the MA-PD, probably because of the zero-dollar copays that we had. It was just maybe a little bit more attractive."

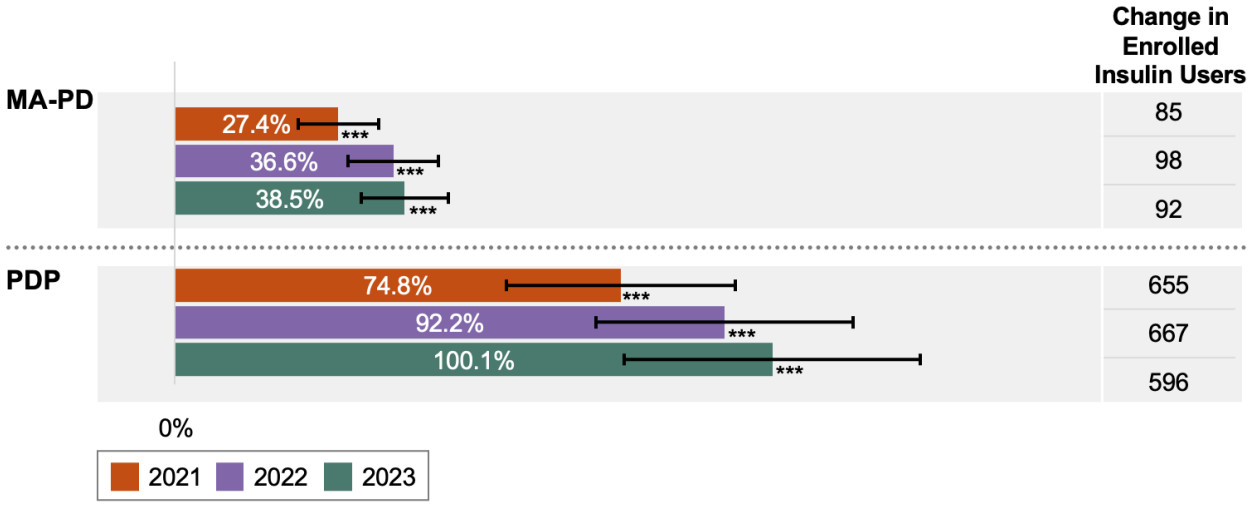
Insulin User Enrollment

Enrollment	Hypothesized Effect of PDSS	Anticipated 2023 IRA Impact
Insulin Users	**Increase** in the number of insulin users enrolled in PDSS-participating plans	Lower insulin copayments in nonparticipating plans and the SEP allowing insulin users to switch to plans may **reduce or eliminate** the anticipated impact of the model

PDSS was associated with a statistically significant increase in the number of insulin users enrolled in PDSS-participating MA-PDs in each year of the model. We estimated that insulin user enrollment was on average 27.4% higher in 2021, 36.6% in 2022, and 38.5% higher in 2023 (all $p < 0.001$) than it would have been in the absence of PDSS (Figure 3.3). The estimated effect of PDSS for PDSS-participating MA-PDs translated to an average of 85 additional insulin users enrolling in 2021, 98 in 2022, and 92 in 2023 relative to what would have been expected in the absence of the model.

PDSS was associated with even larger percent effects on insulin user enrollment for PDSS-participating PDPs. Enrollment of insulin users was 74.8% higher in 2021, 92.2% in 2022, and 100.1% in 2023 (all $p < 0.001$), relative to what would have been expected in the absence of the model. This estimated effect translated to an average of 655 additional insulin users in 2021, 667 in 2022, and 596 in 2023. Effects were similar but of a lesser magnitude for enrollment of beneficiaries with diabetes, although the effect was not significant for PDPs in 2023 (results not shown).

Figure 3.3. Estimated Effect of PDSS on Plan Enrollment of Insulin Users, by Plan Type and Year



SOURCE: Authors' analysis of Part D enrollment and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the plan-level DD regression models for each year of the model. The comparison groups consisted of nonparticipating plans. The column labeled "Change in Enrolled Insulin Users" indicates the number of additional (or fewer, if negative) insulin users enrolled in PDSS-participating plans compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

Choosing Part D Coverage

When individuals become eligible for Medicare, they must decide what to do about their health coverage. They generally have two main options to obtain medical and prescription drug coverage: (1) choose Original Medicare, purchase a stand-alone PDP, and, possibly, buy a Medigap policy;[4] or (2) select an MA plan that provides all Original Medicare–covered services, typically offers supplemental benefits not covered by Original Medicare, such as dental and vision benefits, and also covers Part D drugs.[5] Beneficiaries are not required to purchase a Part D plan when they first become eligible for Medicare. However, if they do not have prescription drug coverage that is at least as good as that provided by a Part D plan and decide to enroll in Part D at a later date, they may face higher premiums. The third option is not as popular as the other two and therefore not discussed in this section. Beneficiaries can change their coverage during annual open enrollment periods from October to December of each year or under a limited set of circumstances throughout the year. The coverage choice decision is both important

[4] Medigap is supplemental health insurance provided by a private company that helps cover those OOP costs that Original Medicare does not cover, including deductibles, copayments, and coinsurance. Beneficiaries could choose from ten Medigap plan types offered by multiple carriers that charge various premium amounts for the same plan type (Medicare, undated-b).

[5] Beneficiaries may also choose either Original Medicare or an MA plan and obtain prescription drug coverage from another source (e.g., an employer or former employer), but this option was not the focus of these interviews.

and difficult because Medicare is complex. Indeed, in 2023, Medicare beneficiaries had, on average, 43 MA-PDs and 24 PDPs to choose from (Biniek et al., 2023). This is why individuals with Medicare often turn to insurance agents and SHIP counselors to help them choose coverage that meets their needs. It is not surprising that of the 100 interviewed beneficiaries, 65 reported seeking an insurance agent's help and seven reported working with a SHIP counselor.

In discussing beneficiary choice of Original Medicare or MA, 20 of the interviewed insurance agents and SHIP counselors mentioned four main factors: (1) cost considerations and beneficiary income, (2) prescription drugs taken, (3) provider network, and (4) amount of travel (see Appendix F for additional discussion of factors that affect the choice of a particular MA-PD or PDP and the reasons for switching plans). The majority ($N = 12$) said that costs and financial reasons were the number one factor. Beneficiaries, many of whom have very limited incomes, often choose MA health maintenance organization (HMO) plans that do not have monthly premiums (per Agent C),[6] low or no copayments, and no coinsurance. Here is how Counselor E described such choices:

> They almost all go with [Medicare] Advantage now, because of the 20% [coinsurance] scares them. We explain what that means and what it is. The Advantage plan is a blessing and a curse offering these extra [supplemental] benefits. . . . You kind of feel it out, explain to them what it would look like if they had . . . Original Medicare and a PDP [versus an MA-PD]. I have several clients who made that choice [selected Original Medicare]. And they like it. It's simple, and they just hand their Medicare card. Others, [however], want to know what their copays are. They don't like that mystery number, the 20%.

Of the 64 beneficiaries who chose an MA-PD in our sample, 47% said that cost was the reason why they made this decision. Some said that paying for a Medigap policy and a stand-alone PDP was more expensive than paying for an MA-PD. Others liked the fact that there are no deductibles and coinsurance, no copayments for primary care, and low copayments for specialist visits. As one beneficiary who appreciated the ease of MA explained, "It was easier to just go with Medicare Advantage. And I felt that the deductibles were covered. I didn't have to do the Medicare deductibles. . . . It worked out better for me."

All interviewed agents, SHIP counselors, and beneficiaries indicated that prescription drugs were an important factor in choosing a plan because of their perception that compared with MA-PDs, PDPs have higher premiums, less generous drug coverage, and do not cover various high-cost medications. As Counselor C put it, "When I'm looking up stand-alone Part D drug costs for a client, many times, the stand-alone Part D drug costs are more than the [MA-PD] costs." Beneficiaries had a similar perspective. In fact, one-third of beneficiaries who chose MA-PDs said that they did so because of prescription drug coverage. "I have so many prescriptions, and it was going to cost an arm and a leg if I were to go with a separate prescription drug plan," said

[6] HMO plans are a type of private health insurance plan that have lower beneficiary OOP costs but limit coverage to nonemergency care provided only by in-network providers and hospitals.

one beneficiary. Several others agreed that MA-PDs were "a better deal" than PDPs given all the medications they were taking. As one interviewee who took 12 medications put it, an MA-PD "offered the cheapest way to get my medications."

Moreover, according to insurance agents and counselors, beneficiaries choosing PDPs often just look at monthly premiums, without considering total OOP costs and deductible amounts. They also do not reconsider their options annually, which may not be the best approach. According to Counselor F, "when it comes to prescription drug plans, you want to shop them every year and go with the lowest bidder but not the lowest bidder just by premium but [also] adding up the cost of your copays." That is why they also tell their clients to consider the costs of all drugs they are taking or are likely to take in the future before deciding their Part D coverage.

Our interviewees, however, had different perspectives on the importance of having access to preferred providers. In discussing provider networks, insurance agents and SHIP counselors noted that the flexibility to see any provider was very important to their clients who choose Original Medicare and a PDP, especially to those who have winter homes in other states or want to receive care from a particular facility or a specialist. Interestingly, ongoing relationships with specialists and hospitals were viewed as more important than relationships with primary care providers. According to Counselor G, "the sweet spot for the Medicare Advantage selection is [an HMO] plan that charges the least for drugs [the beneficiary is taking] and has all [their] doctors in network"; otherwise, the options are a Preferred Provider Organization MA plan or Original Medicare.

Nonetheless, not many of the interviewed beneficiaries named access to preferred providers or wide provider networks as a factor that affected their decisions. Of the 36 beneficiaries in our sample who chose Original Medicare, only four (11%) reported that they wanted the flexibility to see any provider who accepts Medicare rates or that they did not want to be limited by a small number of MA-PDs or narrow provider networks in their area.

One other notable difference between beneficiaries, insurance agents, and SHIP counselors is that beneficiaries cited their poor opinion of MA as a reason for choosing Original Medicare, while agents and counselors did not mention this reason at all. Slightly more than a fifth (22%) of our interviewed beneficiaries who chose Original Medicare reported doing so because they did not like MA. Here is how one interviewee described it:

> People get in [MA plans] because there is a low or no premium, and there are advertisements about their wonderful benefits like food and transportation, but those benefits don't pan out. The whole program is set up differently. There are expenses people don't expect, and they only benefit you if you aren't very sick at all. If you then become sick, you have to be underwritten to get out of it to get into a [Medigap] plan. So, many people are really stuck with all sorts of serious medical problems, and they're stuck in the [Medicare] Advantage plan.

The Role of Lower Insulin Copayments in Plan Choice

Regardless of the type of Medicare coverage that our interviewed beneficiaries had, 44% of them reported looking specifically for a plan with lower insulin copayments. Because, before PDSS, many interviewees "paid [the] astronomical cost of $500 for insulin," it is not surprising that they reported considering insulin copayments, plan premiums, and deductibles while choosing coverage. One beneficiary even considered insulin to be "the main driver" of their plan selection process. Another used to buy OTC insulin that could be purchased without a prescription and wanted to make sure that their plan provided good insulin coverage. Some, however, said that after the start of PDSS, "there was not much of a difference or spread in the copayments for insulin between health plans" in their area. This finding is consistent with our PO interview results, which showed that in highly competitive markets, all major players joined PDSS by 2023 and offered lower insulin copayments. Regardless of this lack of variation in insulin copayments between plans, several beneficiaries stated that looking for better insulin copayments was important for them because saving on insulin allowed them to afford other medications, including noninsulin diabetes medications, such as GLP-1 agonists.

Moreover, 41% of our interviewees said that the person who helped them choose a plan advised them to consider insulin copayments. Beneficiaries working with an insurance agent or a SHIP counselor, however, noted that they were asked about all of their medications, including insulin, and were advised to look for a plan with the lowest overall costs that covered the specific brand and type of insulin they were taking. Therefore, while lower insulin copayments played a role in the process of selecting a plan, insurance agents and SHIP counselors advised beneficiaries to look at their total drug OOP costs rather than insulin copayments alone.

Summary

Among both MA-PDs and PDPs, PDSS was generally associated with statistically significant increases in total plan enrollment, new plan enrollment, and enrollment of insulin users. Nonetheless, among PDPs, PDSS was associated with an increase in total enrollment in 2021 and 2022, but a decrease in new plan enrollment in 2022, suggesting that the increase in total enrollment relative to nonparticipating PDPs was driven by fewer beneficiaries leaving the plan rather than new plan enrollment. As expected, given the reduced cost sharing for insulins under PDSS, we found that enrollment of insulin users increased substantially in PDSS-participating plans. Our beneficiary interviews generally support the results of our quantitative analysis in that they show that financial factors, such as copayments and premiums, and covered drugs, including insulins and other expensive medications that beneficiaries take, affect plan choice. Indeed, slightly less than half of our interviewees cited insulin copayments as a key factor in their Part D plan selection because it helped reduce their insulin OOP costs and afford other medications. Insurance agents and SHIP counselors said that they advise clients not to look at the cost of just one medication and focus on total OOP costs for all drugs taken.

Chapter 4. Access Outcomes: Utilization and Adherence

CHAPTER KEY TAKEAWAYS

- PDSS had a modest impact on the **number of insulins covered** at the maximum $35 copayment for both plan types.
- POs stated that their enrollees were pleased with their insulin offerings and generally preferred consistency in insulin coverage.

- The **number of 30-day insulin fills** increased for insulin users in PDSS-participating plans in all model years.

- PDSS was associated with increased **adherence** to basal insulin, though the effect was not significant for insulin users in MA-PDs in 2023.
- **Medication possession ratios** for rapid/short-acting insulins increased in all three years of the model for both plan types.
- Fewer interviewed insulin users reported using **cost-coping strategies** to address high insulin costs over the course of the model.
- POs reported that the model's predictable copayments increased insulin utilization and adherence but noted that changing diabetes care guidelines led to a general shift away from using insulin.

- Beneficiaries and POs identified different **challenges** in managing diabetes. Insulin users reported maintaining a healthy diet and weight as the biggest challenges. POs described cost barriers and management of complex medication regimens as the biggest barriers.

This chapter describes how insulin coverage in PDSS-participating plans changed throughout the model and presents the results of our analyses on the impact of PDSS on insulin utilization and adherence. We hypothesized that lower insulin copayments would remove a key financial barrier to accessing insulins, thereby increasing utilization of and adherence to insulins by insulin users enrolled in PDSS-participating plans. Table 4.1 summarizes the outcomes used in this chapter, which are similar to those used in our last report (Taylor et al., 2023).

Table 4.1. Insulin Utilization and Adherence Outcome Measures

Measure	Analysis Level	Description
Number of covered insulins	Plan	Average number of model-eligible insulins covered by PDSS-participating plans in each year
Number of 30-day insulin fills	Beneficiary	Number of insulin fills for each beneficiary in the insulin user group, normalized to a 30-day supply
Persistence to basal insulin	Beneficiary	A measure of adherence to long- and intermediate-acting insulins where a beneficiary is persistent if they refill their prescription within a defined period after the previous fill
Medication possession ratio (MPR)	Beneficiary	The proportion of days in a year in which a short- or rapid-acting insulin was available, among insulin users with at least two fills of this type

NOTE: More details on measure selection and construction can be found in Appendix B.

We ran DD regression models with insulin users in nonparticipating plans as the primary comparison group. We supplemented the results of quantitative analyses with the insights from our PO surveys and interviews with both POs and beneficiaries in PDSS-participating plans.

Insulin Formulary Changes as Part of the Model

PDSS-participating plans were required to include at least one vial dosage form and one pen dosage form of a rapid-acting, short-acting, intermediate-acting, and long-acting insulin at U-100 concentration for a maximum $35 copay for one month's supply in the deductible, initial coverage, and coverage gap phases of the Part D benefit. Plans were not required to include other insulin forms in the model. Table 4.2 shows the types of insulins that manufacturers entered into the model. Only two insulin manufacturers—Eli Lilly and Novo Nordisk—produced all model-required insulin types.

Insulin Types

Rapid-acting insulins*: Taken at mealtime; start working in approximately 15 minutes, peak in 1 hour, last up to 4 hours.
Short-acting insulins*: Taken at mealtime; start working in approximately 30 minutes, peak in 2–3 hours, and last up to a half-day.
Intermediate-acting insulins*: Taken once a day; start working in approximately 1–1.5 hours, peak 4–8 hours after being taken, and last up to 18 hours.
Long-acting insulins*: Taken once a day or less frequently; start working 3–6 hours later and evenly lower glucose levels throughout the day. Effects can last up to 42 hours.
Pre-mixed insulins: Products combining short- and long-acting insulins in different proportions to reduce the number of injections.
Combination insulins: Products combining insulin with other antidiabetic drugs to help maintain better blood sugar control.
Concentrated insulins: Products with higher insulin doses that reduce the number of daily insulin injections.

* Participating plans are required to offer this insulin type as part of the model.

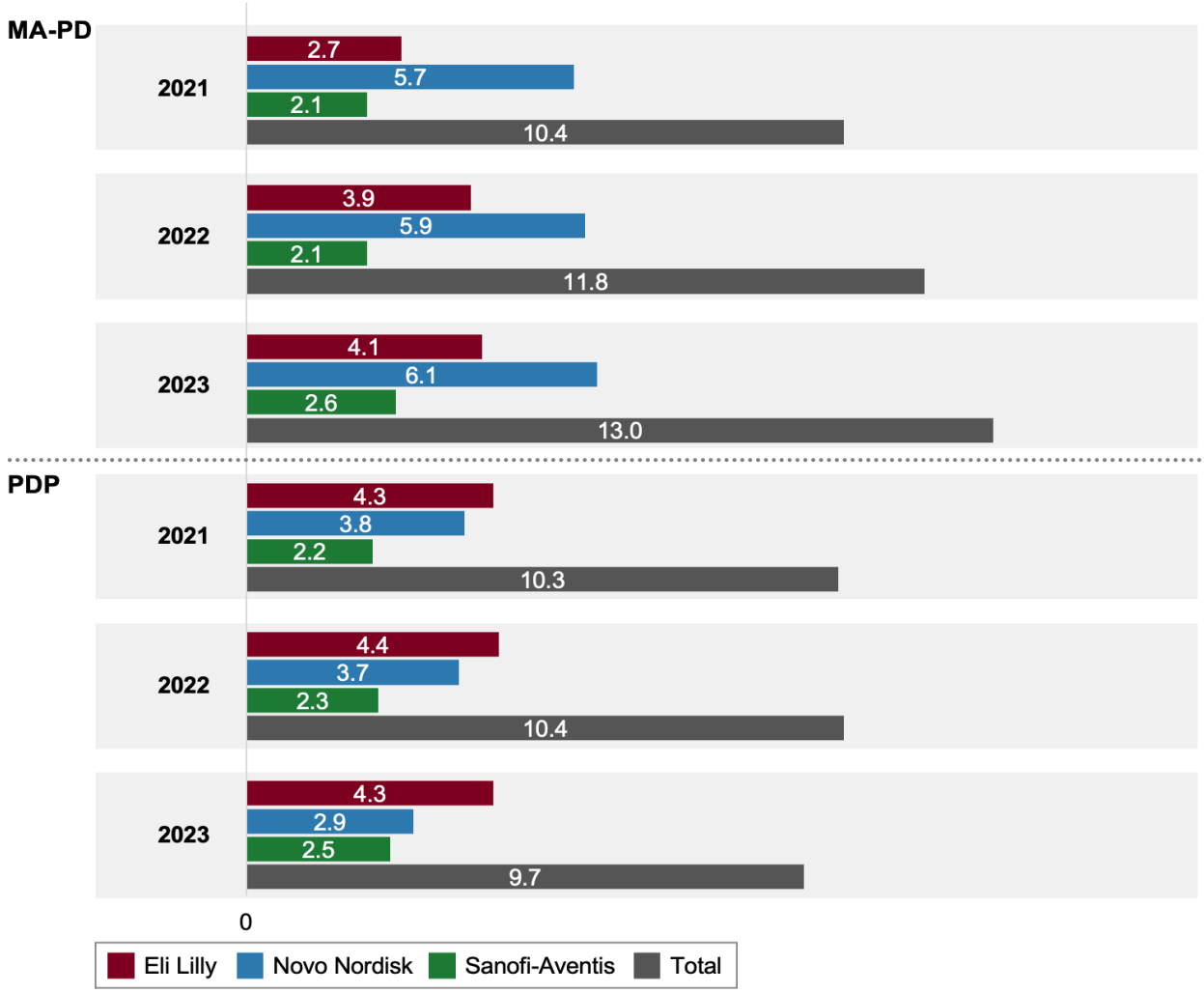
Table 4.2. Number of Model Insulins by Type and Manufacturer

Manufacturer	Rapid-Acting	Short-Acting	Intermediate-Acting	Long-Acting	Pre-Mixed	Combination	Concentrate	Total
Eli Lilly	3	1	1	2	3	—	1	11
Novo Nordisk	3	1	1	3	3	1	—	12
Sanofi	2	—	—	3	—	1	—	6
MannKind	1	—	—	—	—	—	—	1
Viatris/Biocon Biologics	—	—	—	3	—	—	—	3
Total	9	2	2	11	6	2	1	33

SOURCE: Formulary information provided by the PDSS monitoring contractor and information on model formularies posted to the CMS Innovation Center website (CMS, undated-b).
NOTE: A dash (—) indicates that a manufacturer did not produce a given type of insulin.

As we note above, plans do not have to cover all insulins from all manufacturers on their formularies. Participating plans made relatively few changes to the number of covered insulins on their formularies across the three years of the model (Figure 4.1).

Figure 4.1. Mean Number of Plan-Specified Model Insulins Covered by PDSS-Participating MA-PDs and PDPs, 2021 to 2023



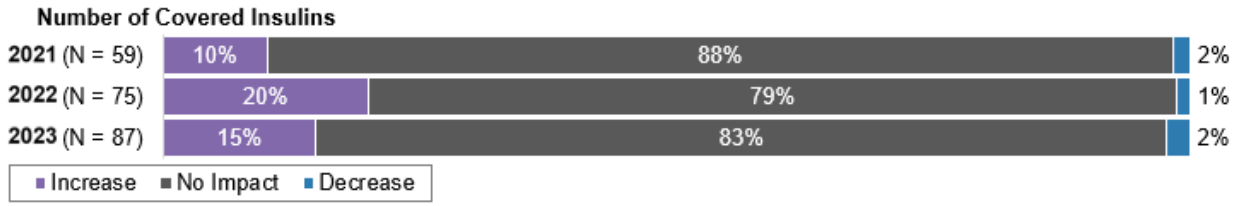
SOURCE: Authors' analysis of Part D plan formulary and information from the PDSS monitoring contractor.
NOTE: The total number of plan-selected model drugs was 25 in 2021, 26 in 2022, and 31 in 2023. A drug is defined by a unique combination of manufacturer, type, name, and Medi-Span GPI10 category. Drug coverage statistics were calculated at the PO level because most POs cover the same number of drugs across all participating plans. Mannkind insulin coverage is not shown because none of the POs covered insulins manufactured by this company in any year of the model. Similarly, Viatris/Biocon Biologics insulin coverage is not shown because only one plan type (MA-PD) covered any Viatris/Biocon Biologics insulins in only one year of the model (2023).

PDSS-participating MA-PDs increased the average number of plan-specified model insulins from 10.4 in 2021 to 13.0 in 2023. In contrast, PDSS-participating PDPs slightly increased the average number of insulins covered from 10.3 in 2021 to 10.4 in 2022, and then decreased the average number covered to 9.7 in 2023. On average, MA-PDs covered more Novo Nordisk insulins than PDPs, while both MA-PDs and PDPs covered similar numbers of Eli Lilly insulins by 2022 and 2023 (with PDPs covering slightly more Eli Lilly insulins than MA-PDs). Both MA-PDs and PDPs covered a similar number of Sanofi insulins each year. None of the POs

covered the Mannkind's inhaled insulin (Afrezza), and very few included the Viatris/Biocon Biologics insulins (Semglee and insulin glargine-yfgn).

Results of our PO surveys generally supported these findings by showing that participation in PDSS did not have a major impact on insulin formularies (Figure 4.2). The vast majority of POs completing our survey reported that the model did not affect the number of insulins on their formularies (88% in 2021, 79% in 2022, and 83% in 2023).

Figure 4.2. PO Survey Results on Perceived Impact of PDSS on Covered Insulins, 2021 to 2023



SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

During the interviews, PO representatives stated that their enrollees were pleased with their insulin offerings and generally preferred consistency in coverage. According to PO H representatives, because the PO received "some positive feedback . . . [in] prior years of participation in the model, [the PO] just wanted to keep things stable and not make any primary strategic adjustments since what we had in place was pretty much working for us." Other POs reported having a broad formulary that covered a wide variety of insulins even before PDSS, which made formulary changes unnecessary during the model period: "Our strategy in this market has always been a broad formulary to make sure we're maximizing [beneficiary] needs regardless [of] the opportunity that the PDSS program provided" (PO U, Wave 3).

Interestingly, most of the remaining POs (10% to 20%, depending on the year) reported increasing the number of insulins on their formularies as a result of PDSS. POs generally increased covered insulins to fill gaps in coverage and ensure the comprehensiveness of their insulin coverage. For example, PO AH reported working with its pharmacy benefit manager (PBM) to add Lantus and Toujeo to the formulary. Only one or two POs reported decreasing the number of insulins on their formularies each year. These POs, however, were not included in our interview sample, so we do not know their motivations behind reducing their insulin coverage.

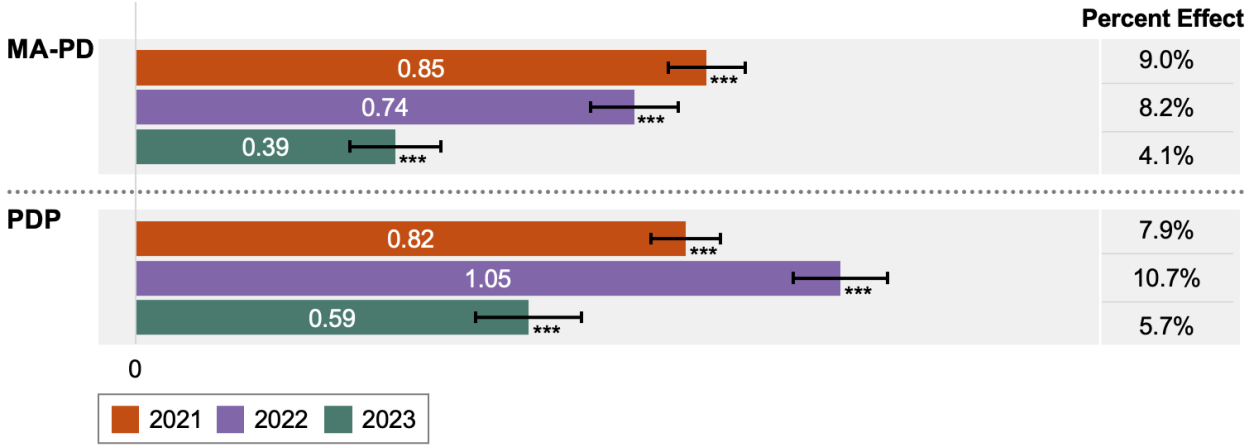
More than three-quarters of POs reported having the same plan-specified model insulins across all PDSS-participating plans (data not shown) for simplicity and ease of administration. However, some POs reported having different drug formularies in different plans and plan types (MA-PDs vs. PDPs) to address the specific needs of the different markets in which they operated. It is worth noting that Humulin R U-500 was often excluded from the plan-specified model insulins because this highly concentrated insulin was usually placed on a higher formulary tier.

Insulin Utilization

Access		Hypothesized Effect of PDSS	Anticipated 2023 IRA Impact
	Insulin Utilization	**Increase** in the number of 30-day insulin fills by insulin users in PDSS-participating plans	Utilization of insulins in nonparticipating plans expected to increase, thereby **reducing or eliminating** the estimated impact of the model

PDSS was associated with statistically significant increases in the number of 30-day insulin fills for insulin users in both PDSS-participating MA-PDs and PDPs in all three years of the model (Figure 4.3).

Figure 4.3. Estimated Effect of PDSS on Insulin Users' Number of 30-Day Fills, by Plan Type and Year



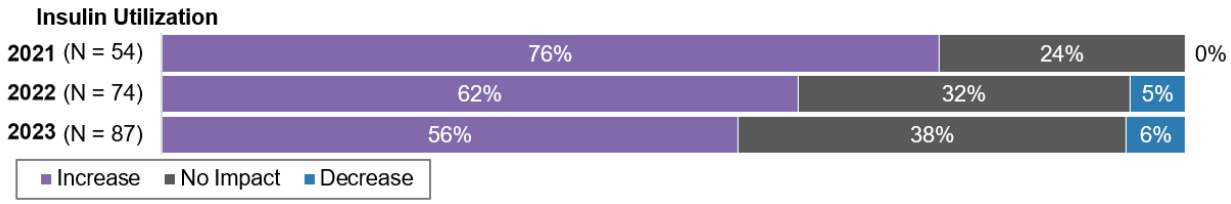
SOURCE: Authors' analysis of Part D event and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the beneficiary-level DD regression models for each year of the model. The comparison groups consisted of insulin users enrolled in nonparticipating plans. The column labeled "Percent Effect" indicates the percentage by which the estimated effect is lower (or higher) compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

Specifically, the number of 30-day fills increased for insulin users in PDSS-participating MA-PDs by 0.85 in 2021, 0.74 in 2022, and 0.39 in 2023 (all $p < 0.001$). These effects translated to a 9.0%, 8.2%, and 4.1% increase in each year, respectively, compared with what would have been expected in the absence of the model. Insulin users in PDSS-participating PDPs experienced average estimated increases of 0.82 in 2021, 1.05 in 2022 and 0.59 in 2023 (all $p < 0.001$). For 2022, this translated into a 10.7% increase in the number of 30-day fills.

Consistent with the results of our quantitative analyses, our PO survey results show that most POs in all three years reported increased insulin utilization as measured by the number of 30-day fills, but the percentage of those reporting an increase declined over time from 76% in 2021 to

56% in 2023 (Figure 4.4). At the same time, the percentage of POs reporting no impact of PDSS on insulin utilization increased from 24% in 2021 to 38% in 2023.

Figure 4.4. PO Survey Results on Perceived Impact of PDSS on Insulin Utilization, 2021 to 2023



SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

During the interviews, PO representatives gave two primary reasons for the increase in insulin utilization. First, they said that changes in copayments directly affect drug utilization: "Generally, we see changes in utilization across the board even with dollar shifts in copays . . . any shift can move utilization patterns," said a PO DS representative. Second, some PO representatives said that an increase in insulin users, rather than an increase in the number of fills per beneficiary using insulin, drove their responses to this survey question. As a PO AH representative put it, "We definitely saw the number of insulin users rise, which was hopefully [because of] a barrier of entry that this program helped address."

Some of the interviewed beneficiaries said that the model gave them more reliable access to insulin, though they were in the minority (see Table 4.3 below for more detail on insulin-using behaviors). One interviewed insulin user said that the model "gave me comfort to know that I could take what I needed for medication without having to skip medicine or not take it at all." Another described the impact of PDSS by saying:

> I have no qualms about taking insulin now. I might have been a little more circumspect before. Not that I was rationing it, but I would look at it and go with a lower dose just because I thought it would [be] fine. . . . In a way it has changed things in the sense that I feel not worried about [rationing] anymore.

For the few POs indicating a decrease in insulin utilization, their survey responses were driven by changing care guidelines that focus on other drug classes. We discuss these perspectives below in the insulin adherence section.

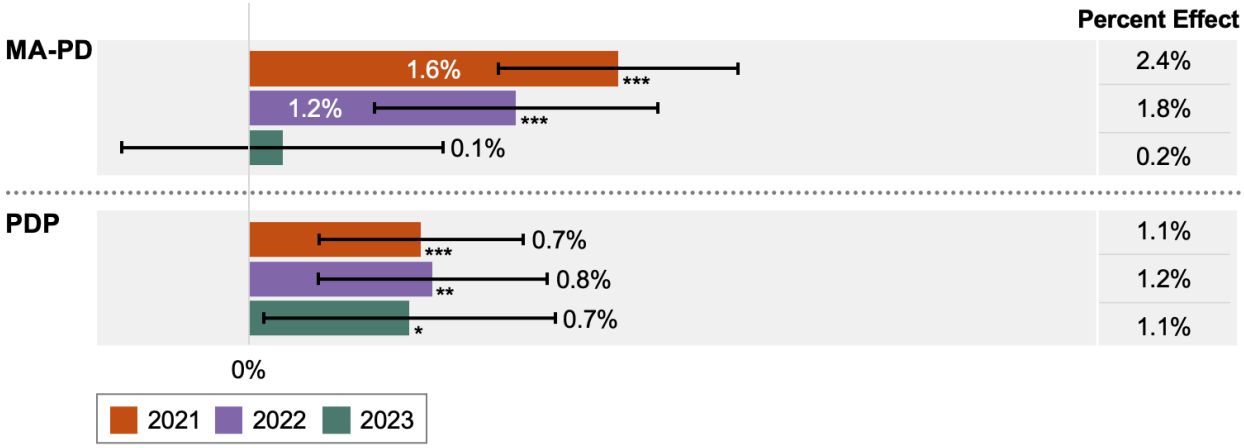
Insulin Adherence

Access		Hypothesized Effect of PDSS	Anticipated 2023 IRA Impact
	**Insulin Adherence**	**Increase** in adherence to rapid/short-acting and basal insulins	Adherence to insulins in nonparticipating plans expected to increase, thereby **reducing or eliminating** the estimated impact of the model

Persistence to Basal Insulin

PDSS was associated with an increased probability of being persistent to basal insulin among insulin users in PDSS-participating MA-PDs in 2021 and 2022 (Figure 4.5). The increase in the probability of being persistent to basal insulin was highest for PDSS-participating MA-PDs in the first year of the model at 1.6% and then declined to 1.2% in 2022 ($p < 0.001$ for both years). The magnitude of the increase was smaller and no longer statistically significant in 2023. For PDSS-participating PDPs, the effect of participating in PDSS on persistence to basal insulin was smaller in magnitude than the estimated effect for PDSS-participating MA-PDs (an increase of between 0.7% and 0.8%), but it was statistically significant in all three years of the model.

Figure 4.5. Estimated Effect of PDSS on Insulin Users' Probability of Being Persistent to Basal Insulin, by Plan Type and Year



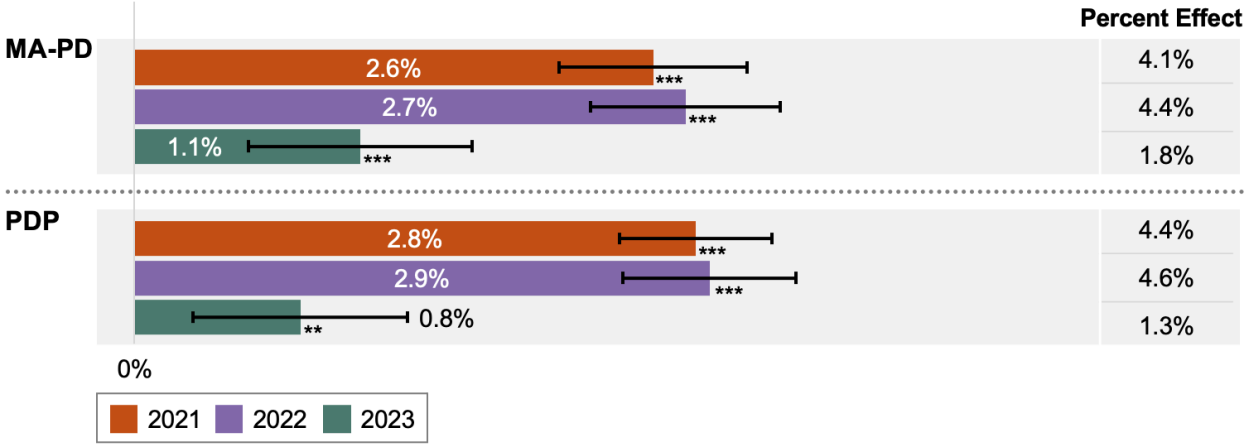
SOURCE: Authors' analysis of Part D event and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the beneficiary-level DD regression models for each year of the model. The comparison groups consisted of insulin users enrolled in nonparticipating plans. The column labeled "Percent Effect" indicates the percentage by which the estimated effect is lower (or higher) compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

Medication Possession Ratio for Rapid/Short-Acting Insulins

PDSS was associated with a statistically significant increase in MPRs for rapid/short-acting insulins for insulin users in MA-PDs and PDPs in all three years of the model (Figure 4.6). The MPR increased for insulin users in PDSS-participating MA-PDs compared with insulin users in nonparticipating plans by 2.6% in 2021, 2.7% in 2022, and 1.1% in 2023 ($p < 0.001$ for all three years). This translated to a 4.1% increase in 2021 and a 4.4% increase in 2022 over what would have been expected in the absence of the model. Similarly, PDSS was associated with statistically significant ($p < 0.001$) increases in the MPR among insulin users in PDSS-participating PDPs of 2.8% in 2021, 2.9% in 2022, and 0.8% in 2023. The percent effects were

slightly higher for PDSS-participating PDPs in 2021 (4.4%) and 2022 (4.6%) compared with those observed for PDSS-participating MA-PDs.

Figure 4.6. Estimated Effect of PDSS on the Medication Possession Ratio for Rapid/Short-Acting Insulins, by Plan Type and Year



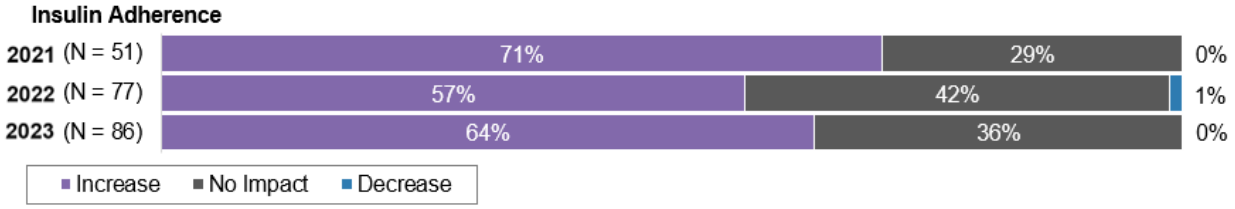
SOURCE: Authors' analysis of Part D event and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the beneficiary-level DD regression models for each year of the model. The comparison groups consisted of insulin users enrolled in nonparticipating plans. The column labeled "Percent Effect" indicates the percentage by which the estimated effect is lower (or higher) compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

For the MPR analysis, we required beneficiaries to have at least two fills of the specified type of insulin each year to ensure that they were regular users of insulin. We conducted a sensitivity analysis removing the restriction that beneficiaries have at least two fills of the insulins of this type to be included in the measure. The results were similar to the results presented in this chapter, although the effect sizes were slightly larger (see Appendix D for the detailed results).

PO Perspectives on Insulin Adherence

Results of our PO surveys also show that PDSS led to improvements in insulin adherence, with a somewhat larger percentage of POs reporting increased adherence in 2021 (71%) than in subsequent years (57% and 64%, respectively). This trend is consistent with our quantitative results that show a positive association between PDSS and adherence, which declined after 2021.

Figure 4.7. PO Survey Results on Perceived Impact of PDSS on Insulin Adherence, 2021 to 2023



SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

During the interviews, some POs noted that lower cost sharing in the coverage gap was a key factor in improving insulin adherence. For example, PO E representatives reported that they "estimated about a 6% [increase in] a 90-day insulin persistence. So that's kind of looking at the population that refills insulin within a certain number of days of running out of [insulin]." PO H noted that:

> [M]embers had more constant adherence through the different phases of the benefit, and they didn't experience hugely variable cost sharing throughout the year because of this smooth cost sharing. And I think to that end, it's exactly what we were hoping for. I think the metrics we saw on adherence not dropping off in the coverage gap anymore was exactly what we were hoping for.

Some model participants, however, reported increased insulin utilization without any changes in adherence. Theoretically, increased insulin utilization at the beneficiary level should lead to increased insulin adherence for those same beneficiaries. However, plans often responded with the experience of the whole plan in mind where insulin utilization could increase if more insulin-using beneficiaries enrolled in their plans, and not necessarily lead to increased utilization on the beneficiary level. Nonetheless, PO BW representatives said that adherence may not improve because "insulin is difficult to manage for many members." Moreover, PO AY noted that plan-level insulin adherence measures may not improve "if you gain membership, and some of those members have diabetes, who either come in using insulin or come in using a noninsulin antihyperglycemic and switch to insulin, we're going to have an increase in insulin utilization" without necessarily impacting adherence.

In addition, several PO representatives noted that recent changes in diabetes care guidelines that placed greater emphasis on noninsulin diabetes medications have affected their insulin utilization and adherence metrics. Starting from 2022, we asked POs about the impact of PDSS on the utilization of noninsulin diabetes medications. Although most POs reported no impact in response to this question, the percentage of POs reporting an increase in the use of noninsulin diabetes medication increased from 21% in 2022 to 26% in 2023 (Figure 4.8). According to PO CD representatives, the impact of PDSS on insulin utilization and adherence was dampened by the increased use of new noninsulin diabetes medications, such as GLP-1 agents:

> [The guideline] no longer recommends metformin as first line for everyone. . . . The GLP-1s have become a favorite. I mean, we're seeing

> something like 30% increases every year in utilization in that class—and they're very expensive medications. . . . We've seen insulin utilization in general kind of come down over the last several years. I think people are switching from insulins to some of these other products, mostly based on guideline changes and . . . things like weight loss that are associated with GLP-1s is very—is something our patients want.

Figure 4.8. PO Survey Results on Perceived Impact of PDSS on Noninsulin Diabetes Medication Use, 2022 to 2023

SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

Indeed, PO AD representatives further clarified the link between PDSS, guideline changes, and noninsulin diabetes medication utilization by saying that:

> Insulins are more affordable [now]; therefore, [beneficiaries with diabetes] would be more adherent to their other [diabetes] medications because they'd be able to afford those. . . . We saw increased utilization in both GLP-1, SGLT-2s. We believe that they're first line in not only the diabetic guidelines, but now they're in the heart guidelines and then you also have the kidney guidelines. And so, it's a trend driver, and we're not the only ones talking about it.

Beneficiary Perspectives on Insulin Use and Adherence

Besides asking POs about the impact of the model on insulin utilization and adherence, we wanted to hear directly from insulin users. To gather beneficiary perspectives on the impact of PDSS on insulin use and adherence, we asked whether they used five different strategies that may negatively affect proper diabetes management before and after their insulin copayments became $35 or less for a one-month supply (summarized in Table 4.3). Only 28% beneficiaries reported ever using any of these strategies—a reduction from 36% in the first wave of the beneficiary interviews that we conducted in 2022 (data not shown).

PDSS may have had the largest impact on insulin dose skipping and skimping on basic needs to pay for insulin, with 13% of interviewees noting that they stopped using each of these strategies after PDSS. One beneficiary said that "when I was out of [insulin] and didn't have the money, say, I was out of it on Wednesday and I didn't get paid till Friday, then I had to skip a dose. . . . [But I no longer skip doses] on purpose, [only when] my memory makes me skip." Another beneficiary who recently became eligible for Medicare noted that they used to skip insulin doses and took less insulin per dose after they were laid off from their last job and essentially "went for many months without having my insulin."

Table 4.3. Percentage of Beneficiaries Who Reported Using Cost-Coping Strategies to Address High Insulin Costs

Strategy	Had Done Before, Have Not Done After (%)	Had Not Done Before, Have Done After (%)	Had Done Both Before and After (%)	Had Not Done Either Before or After (%)
Skipped insulin doses (*N* = 98)	13	1	4	82
Spent less money on food, heat, or other basic needs so that you would have money for insulin (*N* = 97)	13	2	5	79
Delayed filling an insulin prescription (*N* = 98)	10	0	5	85
Taken less insulin per dose (*N* = 98)	8	4	4	84
Used someone else's insulin (*N* = 98)	4	1	3	92

SOURCE: Authors' analysis of data from a sample of 100 insulin users in PDSS-participating plans interviewed in 2024.
NOTE: Counts of beneficiaries answering a given question are shown in parentheses. Responses refer to strategies employed before and after PDSS began.

About one-tenth of our interviewees also noted that they stopped delaying filling their insulin prescriptions. One beneficiary noted that they "used to get headaches by not taking [insulin] as often as [they] should have, but now [they] don't miss the dosage." Of our interviewees, 8% reported no longer taking less insulin per dose, and 4% said that they no longer use someone else's insulin.

About 5% of beneficiaries (data not shown), however, still reported continuing to skip insulin doses, taking less insulin per dose, delaying filling prescriptions, or using other strategies that negatively affect proper diabetes management. For example, one beneficiary noted that there are still times when they

> have had to cutback [on insulin], because I knew I wasn't going to get money. I have to wait for when my [Social Security] checks come in. . . . I am trying to [garage] sale to get rid of the things I haven't used, even though they're good memories. I put them in a garage sale to sell them, because every little dollar helps.

Another said that they still stretch insulin out as long as they can and worked with their doctors "to find the safest way to lower my cost. So, before I take half of [a] dose, I talk with my doctor to discuss [potential effects]."

The majority of the interviewed beneficiaries (between 79% and 92%, depending on the strategy), however, reported not using any of these strategies either before or after their insulin copayments were reduced, which suggests that insulin cost may not be the biggest barrier to proper diabetes management among beneficiaries ineligible for the LIS. We discuss non-cost barriers to diabetes management in the next section.

Barriers to Insulin Adherence

By design, PDSS primarily addressed one barrier to diabetes management—insulin copayments. Although an important impediment, insulin copayments may not be the only barrier to diabetes management and insulin adherence. R&I programs were also an available option to address other barriers as part of the model, but PO uptake of this component was low (e.g. only 13 out of 116 participating POs [11%] offered this option). Moreover, POs offered these programs only in their PDSS-participating MA-PDs. To understand the factors that may affect beneficiary diabetes management, we asked PDSS-participating POs (both on the survey and during interviews) and 100 insulin users enrolled in PDSS-participating plans to identify key challenges to appropriate insulin adherence and diabetes management.

PO Perspectives on Barriers to Diabetes Management

During all three waves of the PO survey, we asked participants to use a four-point scale to rate the extent to which they agree that certain factors or barriers affected appropriate medical management of diabetes among their beneficiaries. Table 4.4 shows the percentage of POs that either agreed or strongly agreed that a particular factor was a barrier for their beneficiaries in each of the three years of the model. We added barriers throughout the evaluation to reflect new information from PO and beneficiary interviews, so not all factors listed were included in all three waves of the PO survey.

Although the order of the top five barriers in each survey wave changed, as measured by the highest percentage of POs agreeing or strongly agreeing that a given factor was a barrier, their composition remained relatively stable. The top five barriers each year included cost-related barriers, such as beneficiary costs in the coverage gap, overall beneficiary costs, costs of taking specialty drugs, noninsulin diabetes medications, or multiple medications, as well as medication management barriers, such as taking multiple drugs (*polypharmacy*) or taking drugs with complex dosing regimens. Furthermore, the bottom three barriers in each survey wave did not change, as measured by the lowest percentage of POs agreeing or strongly agreeing that a given factor was a barrier. The bottom three barriers were limited access to health care providers, provider knowledge about diabetes management, and ability to keep insulins refrigerated.

Table 4.4. PO Perspectives on Barriers to Appropriate Diabetes Management

Barrier	2021 (*N* = 65)	2022 (*N* = 89)	2023 (*N* = 92)
Cost barriers			
Beneficiary costs in the coverage gap	89	92	85
Beneficiary costs associated with taking "specialty drugs" (high-cost medications)	89	94	91
Beneficiary costs associated with taking multiple drugs	89	96	96
Beneficiary costs (deductibles, copayments, coinsurance)	83	82	79
Beneficiary costs associated with taking noninsulin diabetes medications	NA	86	89
Medication management barriers			
Taking multiple drugs (polypharmacy)	93	89	93
Taking drugs with complex dosing regimens (when and how often drugs are taken)	90	78	86
Low health literacy levels (not having the knowledge to manage condition)	79	75	74
Lack of self-efficacy (feeling like they cannot manage condition)	81	69	73
Underuse of medication therapy management/reconciliation services	70	57	59
Mode of insulin administration (e.g., hesitancy to use needles; pen versus vial)	65	52	64
Negative side effects of insulin (e.g., weight gain, low blood sugar)	59	50	63
Lack of provider-led patient education on diabetes management	NA	NA	46
Knowledge among physicians about diabetes management	NA	38	22
Confusion around changing guidelines for diabetes treatment	NA	NA	48
Keeping insulins refrigerated	NA	20	26
Access barriers			
Nutritious food	69	70	66
Transportation	56	56	57
Physical activity opportunities	51	50	52
Health care providers	27	41	40

SOURCE: Authors' analysis of responses from three waves of PO surveys conducted in 2022, 2023, and 2024 that asked about barriers experienced in 2021, 2022, and 2023, respectively.
NOTE: PO representatives used a 4-point agreement scale to answer the following question: "To what extent do you agree or disagree that the following are barriers limiting the appropriate medical management of diabetes among beneficiaries in your plan?" Numbers reported in the table are the percentages of POs that strongly agreed or agreed that a particular barrier limited the appropriate medical management of diabetes. Ns reported per year are the maximum number of POs that responded to questions about barriers in that year; some POs did not answer some questions. NA = not applicable (this question was not asked in a given year).

During the interviews, PO representatives said that while the model helped alleviate some of the main cost barriers to insulin use, plans may need to do more to address behavioral, knowledge, and attitudinal gaps that complicate diabetes management. A key component of education provided by plans should include information on both insulin and noninsulin diabetes

medications. Here is how a PO U representative described both the impact of PDSS and lingering gaps:

> I don't think that we have the right secret sauce yet. . . . Cost is certainly a factor, but the members are still lacking a lot of education regarding controlling their disease and the role that they play within their nutritional management of managing that disease. We do see folks tend to navigate, because of the recommendation of their physicians, to other higher cost drugs, Trulicity being one, to help control some of the outcomes of the disease. My initial reaction was [that] there are other ways to do that . . [which can lead to] behavior change. That's a very emotional process, and the support mechanisms we know are still weak in that area.

Proper insulin adherence and diabetes management require behavior change, which, according to PO AM representatives, can happen only if beneficiaries trust their providers and the medical field as a whole and if other non-cost barriers are addressed:

> One of the challenges is certainly trust in health care, trust in modern medicine, . . . trust in their physicians. . . . Transportation is a challenge. Somebody who doesn't have a car to get to a pharmacy who isn't comfortable with mail order or has lived in an area that mail order refuses to deliver to because packages are stolen, and pharmacies won't deliver for the exact same reason. I mean, so we can't go and think that, in general, just reducing cost itself is going to solve a problem.

To address some of the non-cost barriers that were not in the scope of PDSS, PO C representatives suggested offering MA supplemental benefits in MA-PDs to "wrap around and support the member in terms of their needs." Indeed, several POs, including PO H, reported that they supplement PDSS benefits with MA supplemental benefits, such as healthy food, transportation, and utility support, to better address the needs of their beneficiaries. Other POs included R&I programs as part of their PDSS design, where they financially rewarded beneficiaries for participating in care management and medication therapy management programs designed to better educate members on diabetes management. According to PO AH, these R&I programs may be particularly useful for stand-alone PDPs because they cannot offer MA supplemental benefits:

> Whereas on MA plans, there's transportation and other supplemental benefits that they can access or get that holistic package of care. On stand-alone PDP[s], there's not as many levers and it's really upon the beneficiary to make sure they're adherent and their physician. . . . [Therefore,] reward and incentive [programs are] another thing I would say could be helpful.

Beneficiary Perspectives on Barriers to Diabetes Management

Besides soliciting POs' perspectives on barriers to effective diabetes management, we asked a sample of 100 insulin users from PDSS-participating MA-PDs and PDPs to comment on a similar set of potential barriers to managing their blood sugar. While 18% of interviewed

beneficiaries reported experiencing no barriers, some reported experiencing as many as nine barriers (mean = 3.4 barriers).

In contrast to PO representatives who stated that cost and medication management were the top barriers, most of the interviewed beneficiaries reported that the lack of opportunities to stay physically active (55%) and their ability to follow a healthy diet (50%) were the key barriers that they experienced (Table 4.5). Moreover, while roughly the same percentage of beneficiaries and POs considered a lack of physical activity to be an important barrier, a much higher percentage of POs (more than 65% in each wave of data collection) than beneficiaries (only 12%) considered limited access to nutritious food to be a barrier.

Table 4.5. Beneficiary Perspectives on Barriers to Effective Diabetes Management

Barrier	Percentage Reporting
Cost barriers	
Paying for all the drugs that you may be taking	26
Paying for insulin (copayments, deductibles)	20
Paying for diabetes testing supplies or continuous glucose monitors	16
Medication management barriers	
Managing side effects of insulin (e.g., weight gain, low blood sugar)	29
Knowing how to manage high blood sugar	16
Knowing when and how often to take insulin	7
Taking multiple drugs	7
Overcoming hesitancy using needles to deliver insulin	5
Keeping insulin cold	4
Access barriers	
Accessing nutritious food	12
Getting appointments with a doctor who helps you manage high blood sugar	11
Finding a reliable way to get to medical appointments (transportation issues)	2
Lifestyle barriers	
Being physically active	55
Following a diet	50

SOURCE: Authors' analysis of data from a sample of 100 insulin users enrolled in PDSS-participating plans interviewed in 2024.
NOTE: Beneficiaries stated whether or not they experienced each of the listed barriers by answering the following question: "Have you had difficulty . . . ?"

In many cases, the lack of opportunities to be physically active was related to beneficiaries' health status. "I have bad feet," said one beneficiary. "I've had issues with them for years. It's hard for me to walk sometimes. If something hurts, you're not as likely to go out there and start walking every day because it's not fun if it hurts when you're walking." In contrast, difficulties

following a diet were sometimes related to structural barriers, such as living arrangements that make cooking healthy meals difficult. Here is how one beneficiary described this: "I'm limited by the fact that I don't have a kitchen. So, I have a little refrigerator, I have a microwave, I have a small electric skillet—maybe 6 inches square—and I have a toaster, so that limits what I can prepare food-wise."

While more than half of interviewed beneficiaries named physical activity and diet as barriers, only about one-quarter named managing side effects of insulin (29%), paying for all the drugs they are taking (26%), and paying for insulin (20%) as barriers. One beneficiary described negative side effects of insulin by saying that their new treatment plan did not work too well:

> The plan [my doctor's] got me on isn't working right. It's more pills, more insulin—that's what her plan is. And the more insulin caused me to have weight gain problems, water swelling in my legs and feet, and just generally not feeling that great, you know? It's been not just a little bit, but a lot.

In general, our 2024 beneficiary interview results closely mirror our findings from the previous evaluation report (Taylor et al., 2023), with one exception. The percentage of beneficiaries reporting difficulties paying for insulin decreased from 26% in 2021 to 20% in 2023, possibly indicating a positive impact of PDSS.

Summary

Over the three PDSS years, participating plans made limited changes to their insulin coverage. PDSS-participating MA-PDs generally increased the average number of plan-specified model insulins, while PDSS-participating PDPs slightly decreased the average number. Most POs reported that PDSS had little impact on their formularies, with many POs reporting that they maintain a broad variety of insulins to meet beneficiary needs, and a small number of POs reporting increasing their insulin coverage to fill gaps. We found that PDSS was associated with increases in insulin utilization and adherence during the first two model years. The IRA's insulin provisions, however, reduced the magnitude of effects in 2023 because insulin copayments were reduced to no more than $35 per one-month supply in all Part D plans. Although PO representatives also reported that lower and more predictable insulin copayments, especially in the coverage gap phase, increased insulin utilization and adherence, some PO representatives noted that changing diabetes care guidelines led to beneficiaries using less insulin and using other diabetes medication classes, such as SGLT2s or GLP-1s. Moreover, in our 2024 interviews with beneficiaries, fewer insulin users reported relying on cost-coping strategies to address high insulin costs than in our 2022 interviews (Taylor et al., 2023). Beneficiaries continued to report that maintaining a healthy diet and weight were their biggest challenges in managing their diabetes. In contrast to the beneficiary perspectives shared via interviews, POs cited cost as a major factor in managing diabetes in all years of the model, stemming from the mix of drugs beneficiaries often take. Relatedly, POs also noted that managing complex medication regimens

was a continued barrier to diabetes management. Finally, a substantially larger proportion of POs than interviewed insulin users reported that access to nutritious foods was a barrier to effective diabetes management.

Chapter 5. Health Outcomes

CHAPTER KEY TAKEAWAYS

- PDSS was associated with increased **risk scores** for insulin users in both plan types, but the effect sizes decreased in 2023 and were no longer statistically significant for PDPs.
- Although some POs noted improved **health status** for their enrollees, most interviewed insulin users reported no changes in their health status because of lower insulin copays.
- There was no association between the model and **blood sugar control** among insulin users in MA-PDs, but some PO representatives reported improvements in this metric.
- PDSS was not consistently associated with changes in **emergency department visits or inpatient stays** for diabetes-related complications for insulin users, likely because these outcomes take time to occur.
- Most POs did not report any impacts of PDSS on utilization of inpatient or emergency care.

In this chapter, we report the results of our analyses on the effect of PDSS on health outcomes. Improved adherence to insulin may slow the development of other health care conditions for beneficiaries with diabetes. Delayed or deferred development of other conditions may, in turn, slow the growth in beneficiary risk scores, which CMS uses to adjust payments to MA-PDs and PDPs to account for anticipated higher or lower risk of spending by each plan enrollee, relative to anticipated average spending. In addition, assuming that adherence to insulin increases, we expected to see reduced health complications associated with suboptimal diabetes control. We have focused our analyses on short-term diabetes complications because these are most likely to be affected over the three years of the model. Table 5.1 shows the health outcome measures we assess in this chapter, along with a brief description of each measure.

Table 5.1. Health Outcome Measures

Measure	Analysis Level	Description
Risk scores (Part C and Part D)	Beneficiary	Beneficiary's assigned risk score for MA and Part D (separately) for the year in which diagnoses occurred. Risk scores for 2023 were based on mid-year diagnoses and were not yet final when this report was written
Blood sugar controlled	Beneficiary	Whether or not a beneficiary's blood sugar was controlled during the year
Short-term diabetes complications	Beneficiary	Number of inpatient admissions or ED visits in year for diagnoses associated with short-term diabetes complications
Number of inpatient admissions for uncontrolled diabetes	Beneficiary	Number of inpatient admissions in year for diagnoses associated with uncontrolled diabetes

NOTE: More details on measure selection and construction can be found in Appendix B.

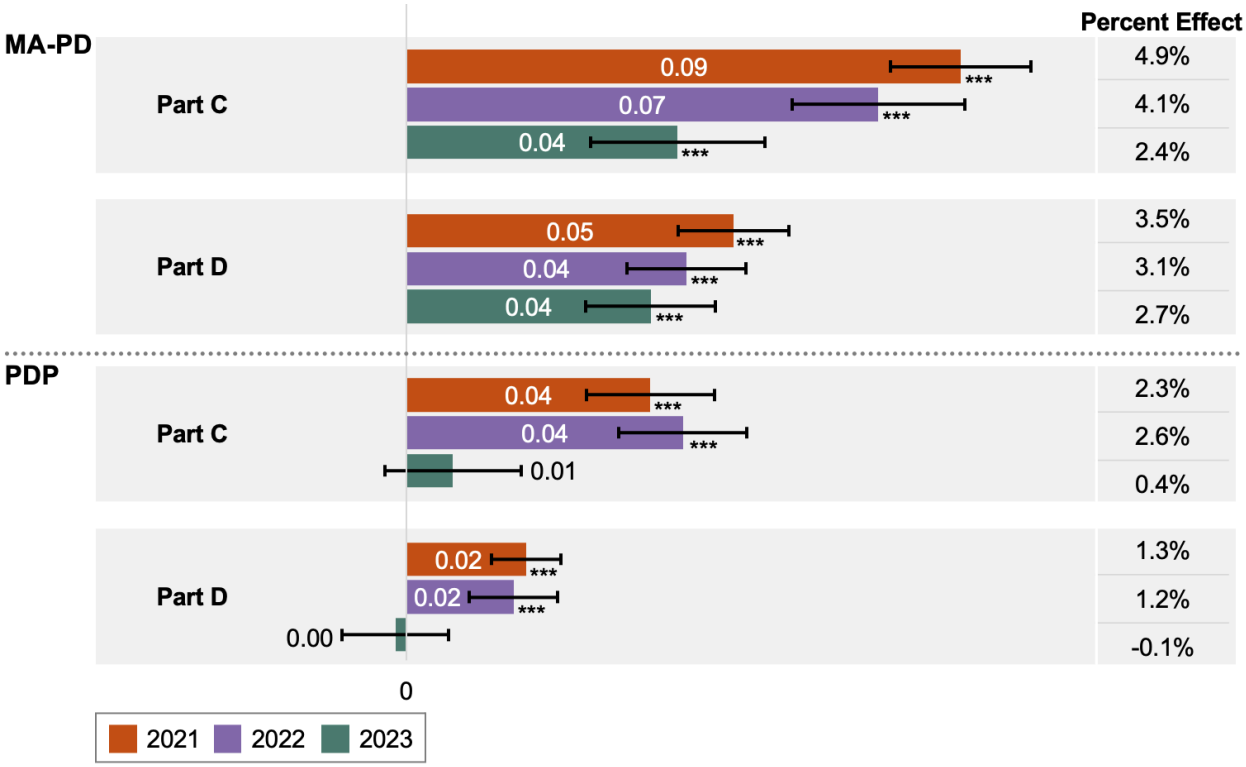
We ran DD regression models using insulin users enrolled in nonparticipating plans as the primary comparison group. For the outcome measure assessing blood sugar control, the data source was limited to those insulin users sampled by their MA-PDs in a given year for the Star Ratings measure. This resulted in very few beneficiaries from our cohorts who appeared in the measure data for both pre- and post-model years. As a result, instead of the DD regression approach described in Chapter 1, we used a modified DD regression method that balanced insulin users in our pre-period and post-period groups prior to running the DD analysis for this specific outcome measure to counter potential compositional changes over time within treatment groups. We supplement the results of these quantitative analyses with insights from our PO surveys and interviews with both POs and beneficiaries. Appendix A provides additional details on the quantitative methods, and Appendix B has detailed measure descriptions.

Risk Scores

Health Outcomes	Hypothesized Effect of PDSS	Anticipated 2023 IRA Impact
Risk Scores	**Slower growth** in risk scores for insulin users in PDSS-participating plans	Increased adherence to insulins in nonparticipating plans may slow growth of risk scores, thereby **reducing or eliminating** the estimated impact of the model

PDSS was associated with increased Part C and Part D risk scores for insulin users in PDSS-participating MA-PDs in all three years of the model (Figure 5.1). We estimated an average 0.09 point increase in Part C risk scores in 2021; the effect declined slightly in each of the following two years to 0.07 and 0.04 ($p < 0.001$ for all years). While beneficiaries enrolled in PDPs do not have a Part C risk score that applies directly to payment, a Part C risk score is still calculated for them based on their Original Medicare claims. We found that PDSS was associated with a statistically significant increase of 0.04 Part C risk score points in both 2021 and 2022 ($p < 0.001$), but in 2023, the effect was smaller and not statistically significant (0.01 point, $p = 0.18$). The effect sizes for both MA-PDs and PDPs represent risk scores that were 4.1% to 4.9% (MA-PDs) and 2.3% to 2.6% (PDPs) higher in 2021 and 2022 relative to what would have been expected in the absence of the model.

Figure 5.1. Estimated Effect of PDSS on Beneficiary Risk Scores, by Plan Type and Year



SOURCE: Authors' analysis of Part D event and other data. See Table A.1 in Appendix A for the complete list of data sources.

NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the beneficiary-level DD regression models for each year of the model. The comparison groups consisted of insulin users enrolled in nonparticipating plans. The column labeled "Percent Effect" indicates the percentage by which the estimated effect is lower (or higher) compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

The model was also associated with an increase in Part D risk scores in both MA-PDs and PDPs. Similar to the results for the Part C risk score, the effect sizes for the Part D risk scores were smaller for PDPs compared with those for MA-PDs, and the estimated effect was not statistically significant for PDPs in 2023. Effect sizes in 2021 and 2022 for PDSS-participating MA-PDs were 0.04 to 0.05 points ($p < 0.001$ in both years) and 0.02 for PDPs ($p < 0.001$ in both years), staying at a 0.04 increase for MA-PDs ($p < 0.001$) and declining to a statistically insignificant 0.002 reduction for PDPs in 2023 ($p = 0.68$). These effect sizes represented a 3.1% to 3.5% increase in Part D risk score points for MA-PDs and slightly more than a 1% increase for PDPs in 2021 and 2022, diminishing somewhat in 2023 for MA-PDs to an average 2.7% increase, relative to what we would have expected in the absence of the model.

On the survey, 80% of POs reported no impact on risk scores in 2023, the only year when we asked this question. While 16% reported an increase in risk scores, 5% reported a decrease (data not shown). None of the PO representatives discussed the impact of the model on risk scores during the interviews.

POs and beneficiaries reported relatively small impacts of PDSS on health status compared with other outcome types. While most POs (between 59% and 68%, depending on the year) reported no impact on health status on the survey, about one-third of POs (between 30% and 41%, depending on the year) reported an improvement in beneficiary health status (Figure 5.2). Moreover, slightly more than 10% of POs completing the survey reported that improvement in health status was the most important outcome they had seen from the model in 2023 (data not shown).

Figure 5.2. PO Survey Results on Perceived Impact of PDSS on Health Status, 2021 to 2023

SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

Those reporting no impact on health status generally said that overall health outcomes are hard to "tease out of the data" (PO DS) because of the overall trends in health among Medicare beneficiaries and the impact of the coronavirus disease 2019 (COVID-19) pandemic. Some also noted that the model had not been in place long enough to have an impact: "[It is] too early to really see the benefits of insulin adherence on medical outcomes at that point," said a PO AH representative.

Although our interview sample did not include any POs that reported seeing improvements in health outcomes, some interviewees hypothesized that they may see an impact in the future. A PO DH representative said:

> We need more data to see an impact . . . but typically when a member is on insulin, that are type two diabetics, they'll be on one or two other medications. You might even see because insulin is working, sometimes they might even stop the other medications [because their health status improved].

Finally, about 2% of POs completing our surveys noted decreased health status among their beneficiaries taking insulin, with some attributing this to adverse selection or increased new plan enrollment of insulin users that negatively affected the average health status of all insulin users in their PDSS-participating plans.

We also asked insulin users enrolled in PDSS-participating plans whether they had noticed any changes in their health after they started paying $35 or less for a one-month supply of their insulins. Of the 98 beneficiaries who answered this question, 70 (71%) reported no impacts on their health in 2023. Of the remaining 28 beneficiaries who reported changes in health, 15 (54%) attributed them to the lower insulin copayments. Of these 15 beneficiaries, six reported at least one positive change and nine noted at least one negative change. Among the six reporting

positive changes in their health, all reported some weight loss, one reported fewer infections, including foot infections, and one noted a reduction in urination frequency. Of the nine beneficiaries reporting negative changes in their health, six noted worsening vision, two noted weight gain, one reported additional infections, and another reported increased urination frequency.

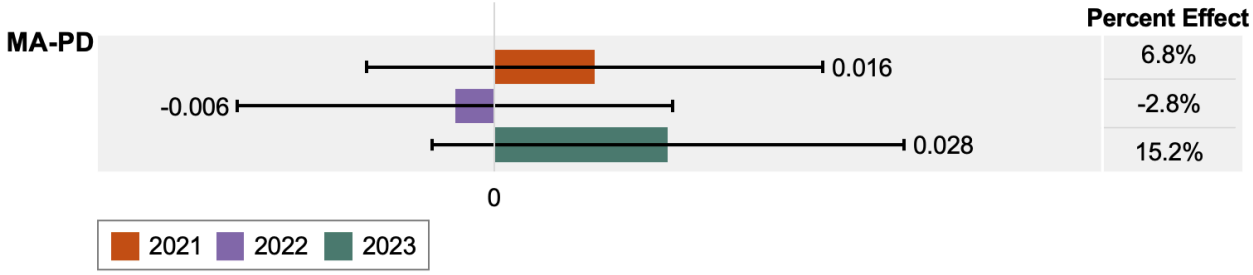
Although it does not seem that many beneficiaries experienced major improvements in their health status attributable to lower insulin copayments, they might have become more empowered to better manage their blood sugar levels. Here is how one beneficiary described this: "I think [the lower insulin copay] has made me have a more positive attitude about controlling my diabetes because I know the medication is affordable."

Blood Sugar Control

Health Outcomes	Hypothesized Effect of PDSS	Anticipated 2023 IRA Impact
Blood Sugar Control	**Increase** in the number of insulin users in PDSS-participating plans with their blood sugar controlled	Utilization of insulins in nonparticipating plans expected to increase, thereby **reducing or eliminating** the estimated impact of the model

We found no statistically significant association between PDSS and the probability that insulin users enrolled in PDSS-participating MA-PDs had their blood sugar under control (Figure 5.3). We note that the Healthcare Effectiveness Data and Information Set (HEDIS) data were only available for insulin users enrolled in MA-PDs; therefore, we could not analyze the effects of PDSS on blood sugar control for those enrolled in PDPs.

Figure 5.3. Estimated Effect of PDSS on Blood Sugar Control for Insulin Users in PDSS-Participating MA-PDs, by Year



SOURCE: Authors' analysis of HEDIS and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the beneficiary-level DD regression models for each year of the model. The comparison groups consisted of insulin users enrolled in nonparticipating plans. The column labeled "Percent Effect" indicates the percentage by which the estimated effect is lower (or higher) compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

During our PO data collection, we did not ask about the blood sugar levels of the insulin users enrolled in PDSS-participating plans. However, several PO representatives, including those from PO E and PO DH, noted during the interviews that better blood sugar control among their enrollees in PDSS-participating plans helped increase their Star Ratings. For example, a PO E representative said that they "saw an improvement in some clinical indicators for diabetes health management, such as A1C control."

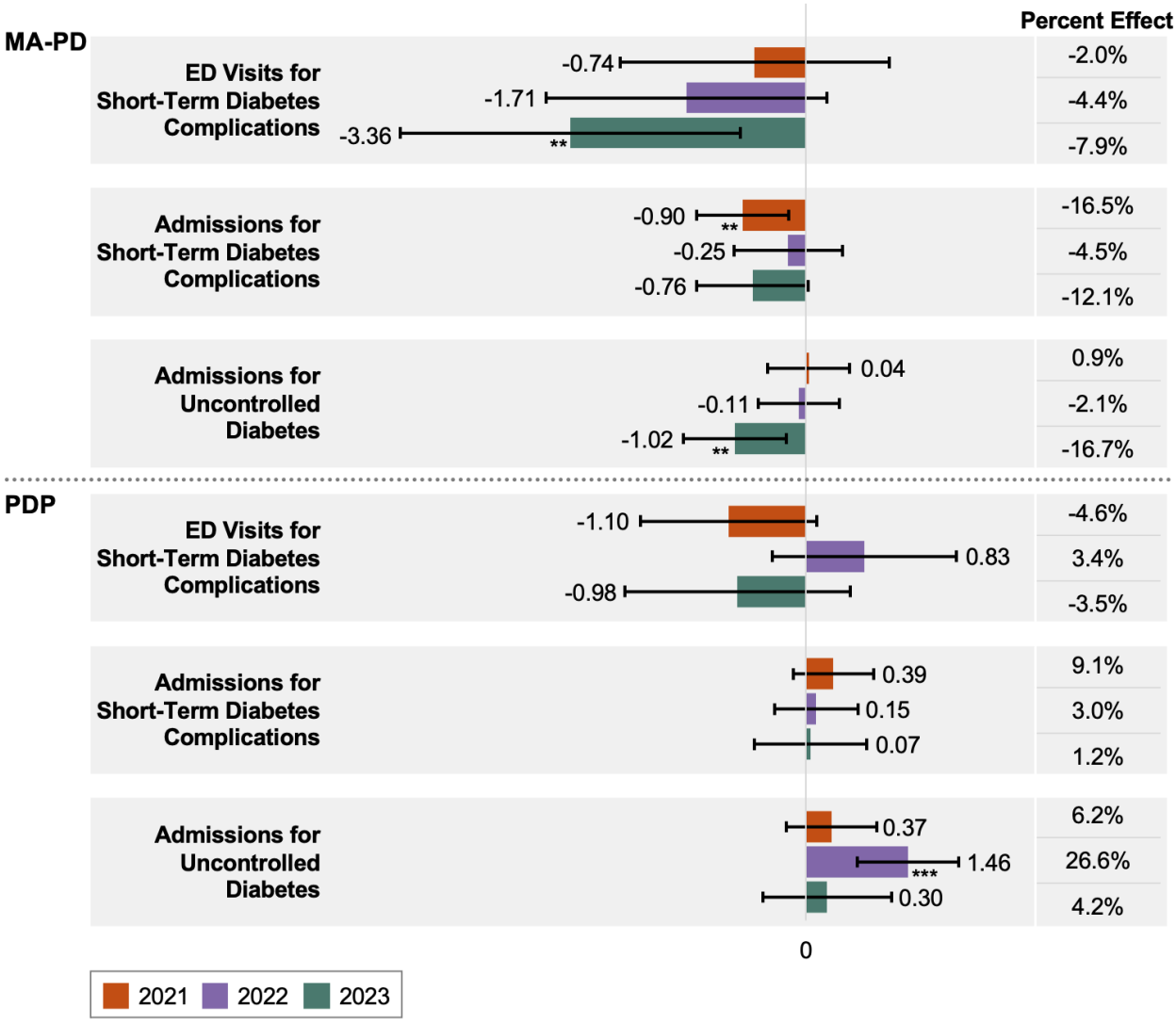
Moreover, when asked what their doctors thought about their blood sugar levels, 46% of beneficiaries said that their doctors noted no change in their blood sugar, 27% reported a positive change, and 2% said their doctors had noted a negative change. The remaining 25% were unsure of what their doctors said, reported that their doctor would like the blood sugar level to decrease further, or never discussed this topic with their health care provider.

Health Care Utilization (Hospitalizations and Emergency Department Visits)

Health Care Utilization	Hypothesized Effect of PDSS	Anticipated 2023 IRA Impact
Hospitalizations and ED Visits	**Decrease** in short-term diabetes complications for insulin users enrolled in PDSS-participating plans	Utilization of insulins in nonparticipating plans expected to increase, thereby **attenuating or eliminating** the estimated impact of the model

PDSS was associated with a statistically significant reduction in inpatient admissions for short-term diabetes complications for insulin users enrolled in PDSS-participating MA-PDs in 2021. In particular, we estimated a reduction of 0.9 stays per 1,000 beneficiaries in 2021 (p = 0.01) (Figure 5.4). We also found statistically significant associations of PDSS with the two other health care resource utilization outcomes for insulin users in PDSS-participating MA-PDs in 2023. First, the model was associated with reductions in ED visits for short-term complications, with an average reduction of 3.4 visits per 1,000 beneficiaries (p = 0.01). It was also associated with a reduction in inpatient admissions for uncontrolled diabetes for insulin users in PDSS-participating MA-PDs in the same year, 2023, with an estimated average decrease of 1.0 inpatient admissions per 1,000 beneficiaries (p = 0.01). These two effect sizes represent a 7.9% decrease in the average estimated number of ED visits and a 16.7% reduction in the number of inpatient admissions attributable to PDSS. We note that the associations between PDSS and two other outcomes, inpatient admissions for short-term complications in 2023 and ED visits for short-term complications in 2022, were also negative and marginally statistically significant (p = 0.06 and p = 0.09, respectively).

Figure 5.4. Estimated Effect of PDSS on the Number of ED Visits and Inpatient Stays per 1,000 Insulin Users, by Plan Type and Year



SOURCE: Authors' analysis of Part D event and other data. See Table A.1 in Appendix A for the complete list of data sources.

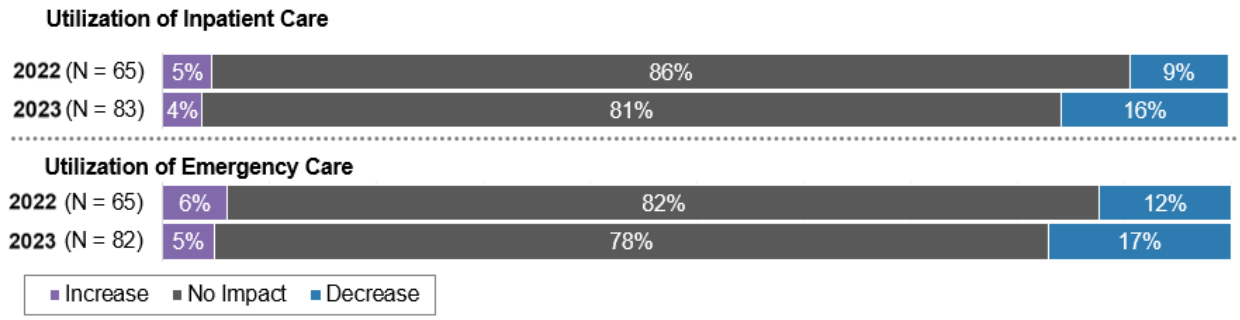
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the beneficiary-level DD regression models for each year of the model. The comparison groups consisted of insulin users enrolled in nonparticipating plans. The column labeled "Percent Effect" indicates the percentage by which the estimated effect is lower (or higher) compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

While we found no statistically significant evidence of an effect for most health care utilization outcomes and years for insulin users enrolled in PDSS-participating PDPs, we did find positive and statistically significant effects for one outcome in 2022. Specifically, we found an estimated statistically significant average increase of 1.5 inpatient admissions per 1,000 beneficiaries for uncontrolled diabetes in 2022 ($p < 0.001$). This effect size represented a 26.6% increase in the average number of inpatient admissions for this type of complication, relative to

what we would have expected in the absence of PDSS. We also note that we found an estimated decrease of 1.1 ED visits per 1,000 beneficiaries in 2021, although this effect was marginally statistically significant ($p = 0.09$).

On the survey, about four-fifths of POs reported no impact on beneficiary utilization of inpatient and emergency care in 2022 and 2023. However, the percentage of those reporting decreases in inpatient stays and ED visits attributable to PDSS increased by 5–7 percentage points from 2022 to 2023 (Figure 5.5).

Figure 5.5. PO Survey Results on Perceived Impact of PDSS on Utilization of Inpatient and Emergency Care, 2022 to 2023



SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

During the interviews, POs generally echoed this lack of impact of PDSS on utilization of inpatient and emergency care, often saying that they had not seen changes or had not done analyses looking at this type of utilization. However, representatives of PO A who looked at utilization metrics noted that they had not seen much impact as of early 2023:

> The first brush didn't show a significant change, but I think, with a little bit more time and maybe kind of slicing the data differently, I would expect you'd see . . . small decrease in utilization. . . . There have been plenty of other studies out there that have demonstrated that an increase in adherence would lead to reduction in inpatient care and reduction in emergency department care.

Those noting changes in the utilization of inpatient and emergency care often observed different outcomes. On the one hand, PO E representatives said that they "saw a decrease in preventable diabetes admissions and [ED] visits . . . [when] we did a propensity score match study." On the other hand, PO H representatives reported an increase in inpatient stays and ED visits but were a little hesitant to link those changes to the model: "We have seen increases in both [inpatient stays and emergency care], but I don't necessarily know if it was related to this [insulin] benefit. We were still at the tail-end of COVID[-19] and . . . [saw] an influx of [utilization] related to flu."

Finally, it is interesting to note that none of the interviewed beneficiaries reported a change in how often they went to emergency rooms or were admitted to a hospital after their insulin copayments decreased.

Summary

Most of the interviewed insulin users did not observe improvements in their health status that they attributed to the lower insulin copays. Although about one-quarter of insulin users said that their doctors noted improvements in their blood sugar levels and several POs cited improvements in their Star Rating for the blood sugar control measure, we found no statistically significant evidence of an effect of PDSS on blood sugar control. PDSS was associated with increased Part C and Part D risk scores for insulin users in both PDSS-participating MA-PDs and PDPs, although the effects did not translate to increased costs to CMS and attenuated by 2023. PDSS was also associated with decreases in inpatient admissions and ED visits for short-term diabetes complications for insulin users enrolled in PDSS-participating MA-PDs in 2023, although we found statistically significant evidence of an increase in inpatient admissions for insulin users in PDSS-participating PDPs in 2022. However, most POs responding to the survey did not expect to see any impacts of PDSS on utilization of these health care services, and none of the interviewed insulin users reported changes in the number of their ED visits or hospital admissions attributable to the model.

Chapter 6. Beneficiary Cost Outcomes

CHAPTER KEY TAKEAWAYS

- PDSS was not associated with changes in the **total monthly Part D premium** in 2021 or 2023. However, it was associated with an average increase of about $5 for PDPs in 2022.
- While most POs did not report premium increases, roughly 40% noted increased premiums in all three years.

- The model was associated with decreases in **Part D OOP drug costs** for insulin users in all three years, but the 2023 effect sizes were smaller, likely due to the IRA. Moreover, less than half of insulin users interviewed noticed the savings associated with reduced insulin OOP costs.
- Average **total Part D costs** (OOP drug costs plus 12 months of the plan premium) decreased for insulin users in 2021 and 2022. This finding remained consistent for 2023 for MA-PDs, but the effect size was smaller.
- However, insulin users in PDPs experienced an average increase in total Part D costs in 2023, suggesting that premium increases offset the estimated decrease in total OOP drug costs.

- PDSS was associated with increases in the time spent in the **coverage gap** and a higher probability of ending the year in the gap for insulin users in both plan types in all years.

This chapter presents the results of our analyses on the impact of the model on beneficiary costs, including Part D premiums and OOP drug costs. PDSS was funded by supplemental premiums in Part D. These premiums could be reduced by MA-PDs using MA rebate dollars that plans received if their bid was below the area benchmark and they achieved a minimum Star Rating. Because MA-PDs could buy down their Part D premiums using these MA rebate dollars, we hypothesized that PDSS would not have an impact on PDSS-participating MA-PD premiums for Part D. We do note, though, that if Part D premiums increased and the MA rebate remained the same, in order to avoid an increase in the Part D premium for enrollees, MA-PDs would need to reduce the amount of MA rebate dollars spent on other benefits for MA-PD enrollees, such as supplemental MA benefits, lower cost sharing for medical services, and reductions in the Part B premium. Because PDPs do not have access to MA rebate dollars, they charge beneficiaries the full amount of the Part D supplemental premium. Therefore, we anticipated that PDSS-participating PDPs would increase their premiums due to participation in the model.

PDSS lowered copayments for insulins specifically but did not target cost sharing for other drugs. Given that insulin users received the direct benefit of the lower insulin copayments, we hypothesized that their total OOP drug costs would decrease as a result of the model. We further anticipated that this decrease would be driven by declines in their insulin OOP costs specifically. If insulin users responded to the lower copayments for insulin by increasing their utilization of other noninsulin drugs, we might have seen increases in OOP costs for noninsulin drugs. However, insulin users might have also reduced their utilization of noninsulin drugs if PDSS-

participating plans increased cost sharing for the drugs they used as a response to the model. As a result, the anticipated effect of the model on OOP costs for noninsulin drugs is uncertain.

We also assessed the impact of the model on beneficiary progression through the various Part D benefit phases and on the probability of ending the year in either the coverage gap or catastrophic phase (separately). Because beneficiaries advance through the deductible and initial coverage phases based on their *total drug spending* (plan payments plus beneficiary OOP drug costs), we hypothesized that increased insulin utilization would result in a faster progression through the deductible and initial coverage phases to reach the coverage gap. Beneficiaries might have stayed longer in the coverage gap phase as a result of the model, because beneficiaries advance through the coverage gap based on beneficiary OOP drug costs and manufacturer gap discount payments only, not on total drug costs. Beneficiary OOP drug costs for insulin would be lower in the gap for those enrolled in PDSS-participating plans, but increased utilization and higher manufacturer gap discount payments as a result of the model might have advanced beneficiaries through the gap faster than they otherwise might have done. As a result, the anticipated impact of the model on beneficiary progression through the different phases is unclear.

We show the measures analyzed and presented in this chapter in Table 6.1.

Table 6.1. Beneficiary Cost Outcome Measures

Measure	Analysis Level	Description
Part D premium	Plan	The total monthly Part D premium paid by beneficiaries who enroll in the plan. The total premium can be split into basic and supplemental premiums as well.
Total OOP drug costs, also split into: • Insulin • Noninsulin	Beneficiary	The total OOP amount that beneficiaries were responsible for paying for all of their drug fills in a year, total and separately for insulin and noninsulin drug fills.
Total Part D costs	Beneficiary	The sum of total OOP drug costs plus 12 months of the Part D premium for the plan
Time spent in benefit phases: • Initial coverage • Coverage gap • Catastrophic	Beneficiary	The number of 30-day periods that beneficiaries spent in each of the Part D benefit phases (converted to days for the purpose of reporting DD model effects)
Ended year in the coverage gap or catastrophic phase	Beneficiary	Binary measure of whether a beneficiary ended the year in the coverage gap or catastrophic phase (separately for each group and for each of the two benefit phases)

NOTE: See Appendix B for more details on measure selection and construction.

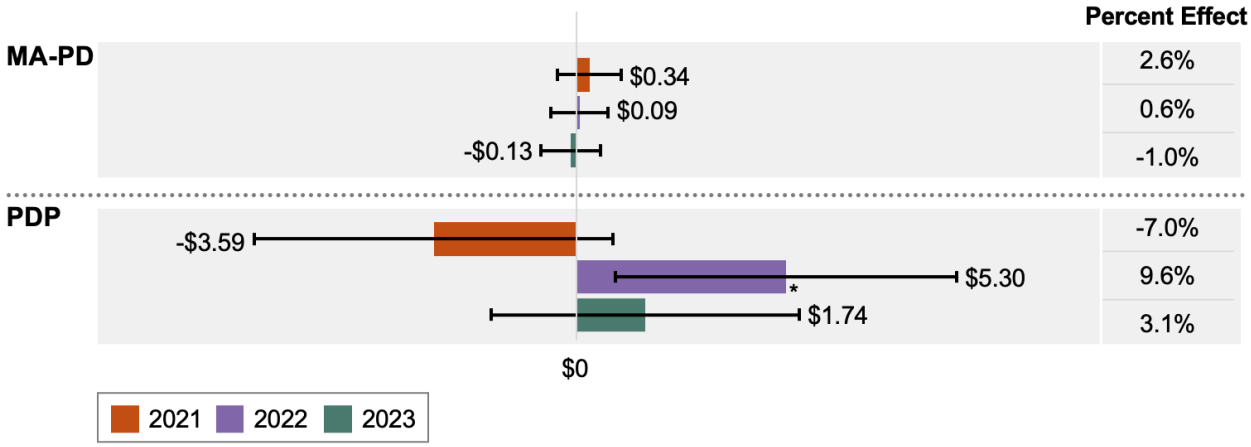
We ran DD regression models using insulin users enrolled in nonparticipating plans as the primary comparison group. We supplement the results of our quantitative analyses with insights from our PO surveys and interviews with both POs and beneficiaries.

Part D Premiums

Beneficiary Cost Outcomes		Hypothesized Effect of PDSS	Anticipated 2023 IRA Impact
	Part D Premiums	**No change** in MA-PD Part D premiums and an **increase** in PDP Part D premiums for PDSS-participating plans	Part D premiums were established before the IRA insulin provision was enacted, therefore the **same impacts** described above were expected

We found no evidence of a statistically significant effect of PDSS on total Part D premiums paid by plan enrollees for MA-PDs in all three years (Figure 6.1). Among PDPs, the effect of PDSS on the total premium was statistically significant only in 2022, with an estimated average increase of $5.30 per month in the Part D premium ($p < 0.01$).

Figure 6.1. Estimated Effect of PDSS on Total Monthly Part D Premiums, by Plan Type and Year



SOURCE: Authors' analysis of Part D premium and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the plan-level DD regression models for each year of the model. The comparison groups consisted of nonparticipating plans. The column labeled "Percent Effect" indicates the percentage by which the estimated effect is lower (or higher) compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

Although about 40% of POs reported premium increases in all three years, a larger share of POs (between 47% and 57%) reported no impact on premiums as a result of PDSS. The percentage of those reporting decreased premiums went down from 14% in 2021 to 2% in 2023 (Figure 6.2). Some POs explained that increases in premiums were small; they attributed them to the lower copayments for insulins, which were recorded in the bids as a Part D supplemental benefit and passed through to beneficiaries as part of the supplemental Part D premium: "Lowering the copays on insulin has a small impact on the premium," said a PO DS representative. However, representatives of other POs, such as PO AL, noted that there was no impact on premiums for their participating plan because they entered a $0 premium plan into the

model and did not want to increase the premium. As noted above, MA-PDs could reduce premiums using their MA rebate dollars, a tool not available for PDPs.

Figure 6.2. PO Survey Results on Perceived Impact of PDSS on Part D Premiums, 2021 to 2023

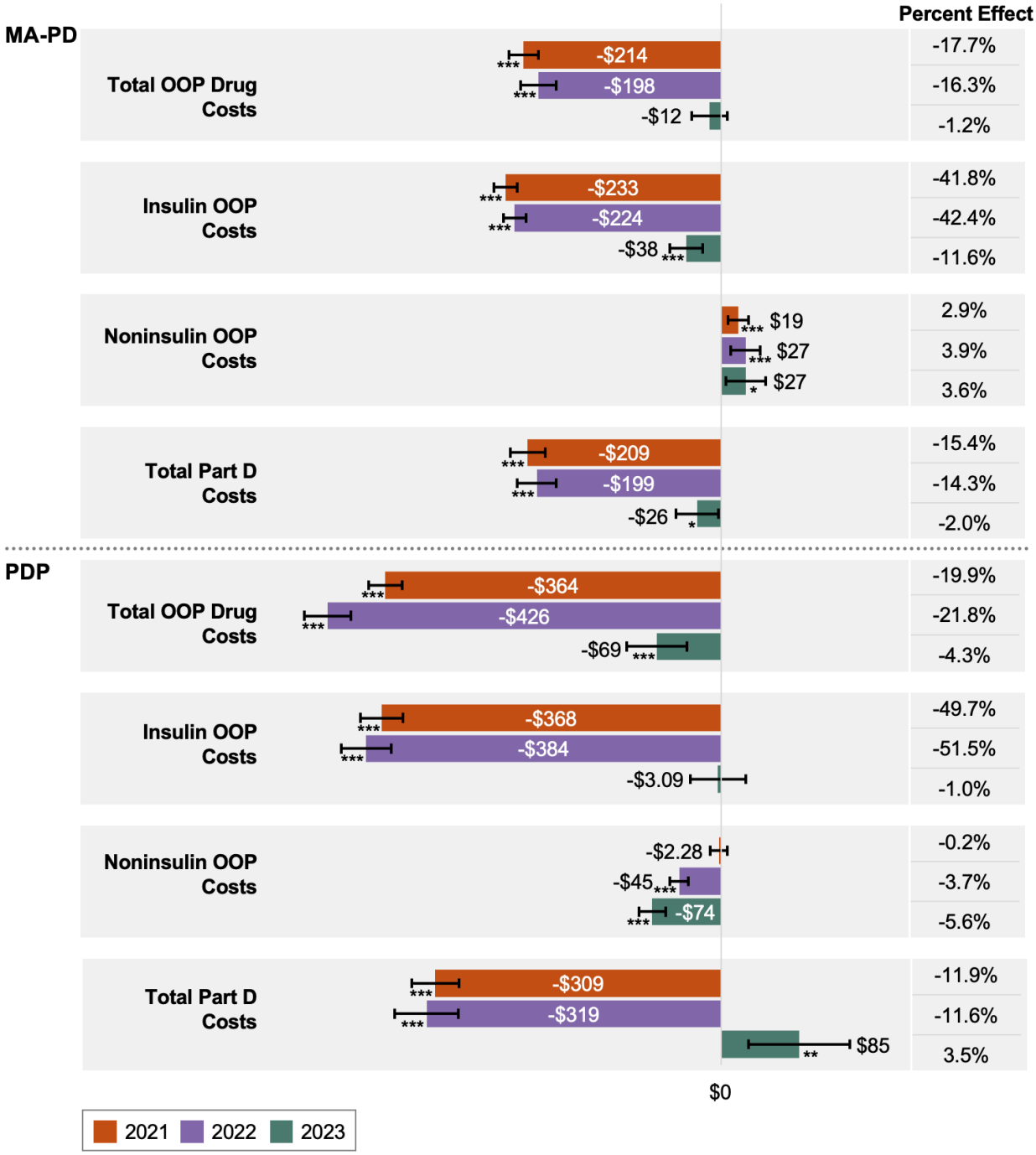
SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

Insulin User Out-of-Pocket Costs

Beneficiary Cost Outcomes	Hypothesized Effect of PDSS	Anticipated 2023 IRA Impact
Insulin User OOP Costs	**Decrease** in total Part D OOP drug costs for insulin users in PDSS-participating plans. **Uncertain impact** of the model on total Part D costs including premiums	Copayments for insulins dispensed to insulin users in nonparticipating plans decreased, thereby **reducing or eliminating** the estimated impact of the model

PDSS was associated with decreases in insulin user OOP drug costs for beneficiaries enrolled in both MA-PDs and PDPs (Figure 6.3). Insulin users enrolled in MA-PDs experienced statistically significant decreases in average total OOP drug costs of $214 in 2021 and $198 in 2022 ($p < 0.001$ for both years). The 2023 estimated effect for MA-PDs was much smaller in magnitude (–$12) and not statistically significant ($p = 0.20$). Insulin OOP costs drove the estimated decreases in all years, with an estimated average decrease of $233, $224, and $38 in each respective year ($p < 0.001$ for all years). In contrast, OOP costs for noninsulin drugs increased by a statistically significant $19 in 2021 to $27 in 2022 and 2023 ($p < 0.001$ for 2021 and 2022, $p = 0.01$ for 2023). The effect sizes for total OOP drug costs for MA-PDs represented 17.7%, 16.3%, and 1.2% decreases relative to what would have been expected in the absence of the model. The estimated effect of PDSS on noninsulin OOP costs represented 2.9% to 3.9% increases in costs in each year.

Figure 6.3. Estimated Effect of PDSS on Insulin User Part D Out-of-Pocket Costs, by Plan Type and Year



SOURCE: Authors' analysis of Part D event and other data. See Table A.1 in Appendix A for the complete list of data sources.

NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the beneficiary-level DD regression models for each year of the model. The comparison groups consisted of insulin users enrolled in nonparticipating plans. The column labeled "Percent Effect" indicates the percentage by which the estimated effect is lower (or higher) compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

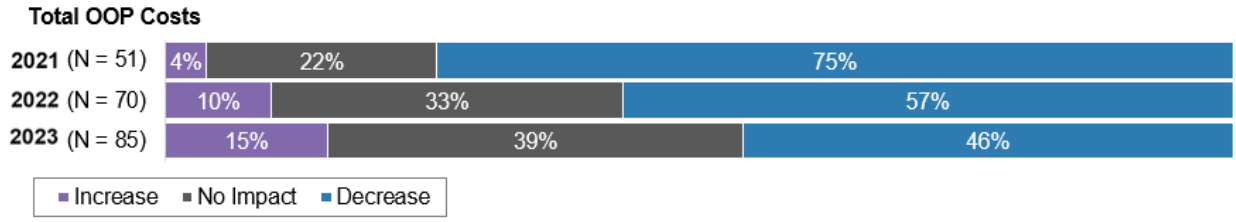
We also evaluated the impact of PDSS on total Part D costs to beneficiaries, which included 12 months' worth of the plan's premium in addition to the beneficiaries' total OOP drug costs (Figure 6.3). PDSS was associated with decreased total Part D costs to insulin users enrolled in PDSS-participating MA-PDs in each year of 2021 through 2023, though the effect size was much smaller in 2023. Specifically, we estimated that PDSS was associated with statistically significant decreases of $209, $199, and $26 in 2021 through 2023 ($p < 0.001$ for 2021 and 2022, $p = 0.03$ for 2023). These estimated effects represented decreases of about 15% in 2021 and 2022 and 2% in 2023, relative to anticipated total Part D costs in the absence of the model.

Insulin users enrolled in PDSS-participating PDPs also experienced decreases in total OOP drug costs. PDSS was associated with a $364, $426, and $69 decrease in total OOP costs in each year of the model ($p < 0.001$ for all years), representing a 20% to 22% decrease in 2021 and 2022 and a 4.3% decrease in 2023, relative to what would have been expected in the absence of the model. As with MA-PDs, the decreases in total OOP costs were driven by declines in insulin OOP costs in the first two years. PDSS was associated with a statistically significant estimated average decrease in insulin OOP costs of $368 and $384 in 2021 and 2022 ($p < 0.001$ for both years), and a much smaller and statistically insignificant decrease in insulin OOP costs in 2023 (estimated effect of –$3.09, $p = 0.84$). In contrast to the MA-PD findings, however, we also found statistically significant decreases in noninsulin OOP costs in 2022 and 2023, although we found a statistically insignificant estimated decrease in 2021 (estimated effect of –$2.28, $p = 0.63$). In 2022 and 2023, we found that PDSS was associated with a statistically significant average decrease of $45 and $74 in noninsulin OOP drug costs ($p < 0.001$ for both years). The decreases in insulin OOP costs represented a decrease of about 50% in 2021 and 2022, while the decreases in noninsulin OOP costs represented decreases of about 4% to 6% in 2022 and 2023.

After adding in 12 months of the Part D premium for each insulin user's plan, PDSS was associated with decreased total Part D costs in 2021 and 2022 for those enrolled in PDSS-participating PDPs. That is, we estimated a statistically significant decrease of $309 and $319 in 2021 and 2022 ($p < 0.001$ for both years). These decreases represented about 12% reductions in total Part D costs in those years relative to what would have been expected in the absence of the model. However, we estimated that insulin users in PDSS-participating PDPs experienced an average $85 increase in total Part D costs in 2023 ($p < 0.01$). This suggests that the premiums for those plans in which insulin users were enrolled increased for 2023, because we found that total OOP costs decreased in 2023. The increase in total Part D costs in 2023 represented a 3.5% increase relative to what would have been expected in the absence of the model.

The percentage of POs indicating a decrease in total drug costs as part of the model dropped from a high of 75% in 2021 to a low of 46% in 2023 (Figure 6.4). The drop over time may be due to POs already participating in the model indicating that their insulin copayments were already low in the prior years.

Figure 6.4. PO Survey Results on Perceived Impact of PDSS on Total OOP Drug Costs, 2021 to 2023

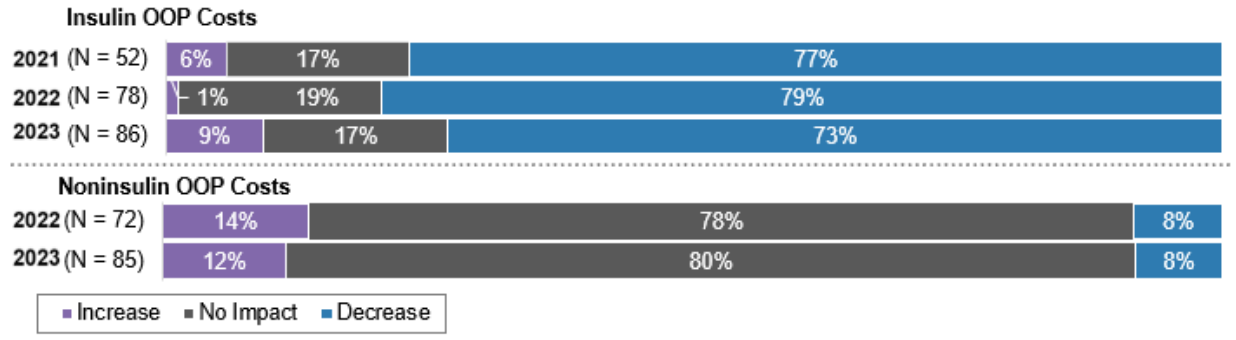


SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

The majority of POs (73%–79%, depending on the year) reported decreased insulin OOP costs, consistent with the quantitative findings (Figure 6.5). As a representative of PO A put it, "the whole reason [PDSS] was undertaken is [because] insulin is expensive. To be able to offer it at $0 through the first three phases of the benefit for beneficiaries, that certainly has an impact." According to a PO H representative, lower insulin copayments in the coverage gap were particularly effective in reducing beneficiary OOP costs and improving insulin adherence:

> In 2019, what we saw is that when the member hit the coverage gap, the average copay had increased from $44 to $110. And at that time, the adherence had gone down. Basically, this dip in adherence, we've effectively eliminated that, and then had flat, predictable copays from members all year long, no matter what phase they were in.

Figure 6.5. PO Survey Results on Perceived Impact of PDSS on Insulin OOP and Noninsulin OOP Costs, 2021 to 2023



SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

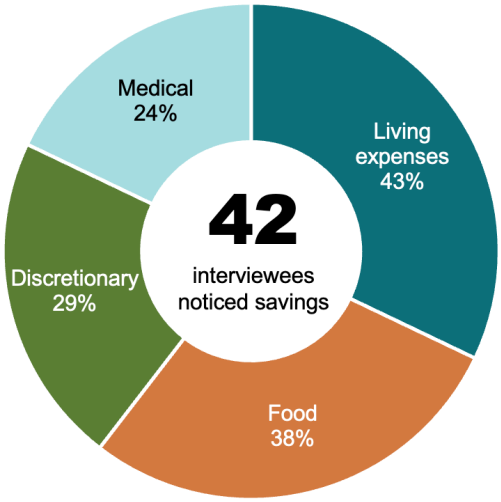
PO Y representatives agreed that PDSS was especially helpful in keeping copayments consistent in the coverage gap phase to reduce member confusion:

> Members have a hard time understanding the gap and then understanding when they're hitting the gap . . . especially if they're new to that and haven't hit [the coverage gap phase] before . . . that's always been a confusing part. So being able to have those lower costs and have some coverage through the gap is helpful.

While the quantitative findings showed increases in noninsulin OOP costs for MA-PDs and decreases for PDPs, most POs (between 78% and 80%) did not think PDSS had an impact on beneficiary noninsulin OOP costs (Figure 6.5).

Beneficiary interview results (Figure 6.6) corroborate these findings: 42% of interviewees said that they noticed that they had additional funds to spend on other items after their insulin copayments decreased.

Figure 6.6. Beneficiary Perspectives on Perceived Impact of PDSS on Personal Financial Outcomes



Of the 42 beneficiaries who noticed savings, most reported spending the extra money on living expenses, such as utilities, clothes, and paying off debt (43%); food (38%); discretionary items, such as hobbies, treats, and gifts (29%); and medical expenses, including prescription drugs, copayments for specialist visits, vitamins and supplements, and Medigap premiums (24%). As one beneficiary said, "I was able to afford the additional medication when I got into the donut hole." The remaining 58% of interviewees reported not noticing that they had extra money to spend after their insulin copayments decreased; several beneficiaries mentioned that inflation or rising medical costs were eating up any savings from lower insulin costs.

Benefit Phases

Beneficiary Cost Outcomes	Hypothesized Effect of PDSS	Anticipated 2023 IRA Impact
Benefit Phases	**Decrease** in the amount of time spent in the initial coverage phase	Decreased insulin copayments for those in nonparticipating plans might increase utilization and move beneficiaries through the initial coverage phase faster, thereby **reducing or eliminating** the estimated impact of the model
	Uncertain impact on time spent in coverage gap and catastrophic phases and the likelihood of ending the year in those phases	**Uncertain impact** on the coverage gap and catastrophic phases, given manufacturer and CMS payments in those phases

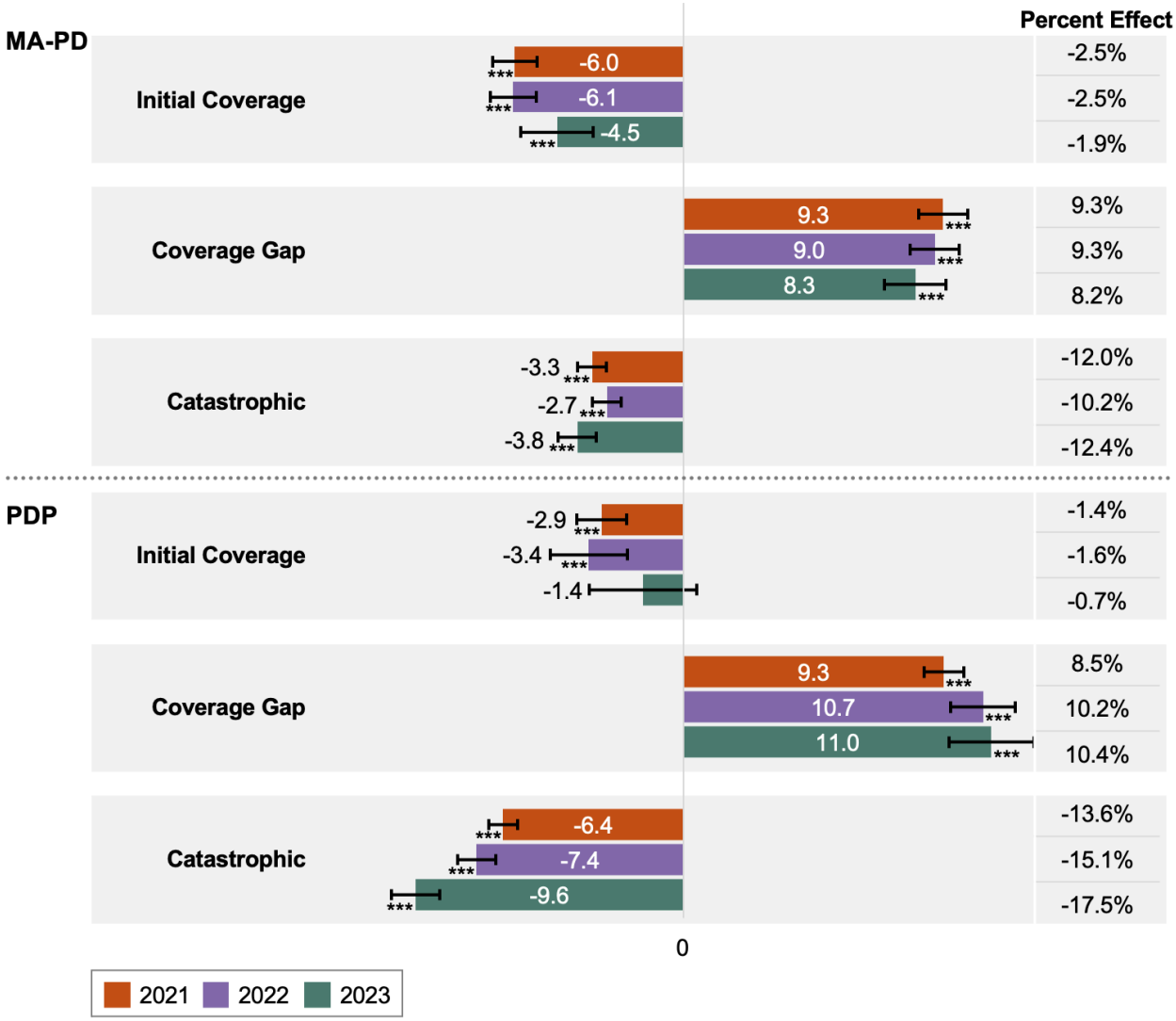
Time Spent in Each Benefit Phase

PDSS was associated with shifts in the amount of time beneficiaries spent in each phase of the Part D benefit for insulin users in PDSS-participating plans (Figure 6.7).

Insulin users in PDSS-participating MA-PDs spent on average 4.5 to 6.1 fewer days in the initial coverage phase in each year of the model ($p < 0.001$ for all years), corresponding to decreases of 1.9% to 2.5% in the amount of time spent in that phase relative to what would have been expected in the absence of the model. Conversely, we found increases in the time spent in the coverage gap, ranging from 8.3 to 9.3 more days ($p < 0.001$ for all years). These corresponded to average increases of 8.2% to 9.3% in the number of days spent in the coverage gap in each year. Finally, insulin users enrolled in PDSS-participating MA-PDs spent less time in the catastrophic phase, although the magnitude of these effects was smaller (ranging from 2.7 to 3.8 fewer days, $p < 0.001$ for all years), with percent impacts of 10.2% to 12.4%.

For insulin users enrolled in PDSS-participating PDPs, PDSS was associated with an average decrease of 2.9 days and 3.4 days in the initial coverage phase in 2021 and 2022, respectively ($p < 0.001$ for both years), corresponding to average decreases of 0.7% to 1.4%. We did not find a statistically significant association of PDSS with the number of days in the initial coverage phase for PDSS-participating PDPs in 2023.

Figure 6.7. Estimated Effect of PDSS on Days Spent in Part D Benefit Phases, by Plan Type and Year



SOURCE: Authors' analysis of Part D event and other data. See Table A.1 in Appendix A for the complete list of data sources.

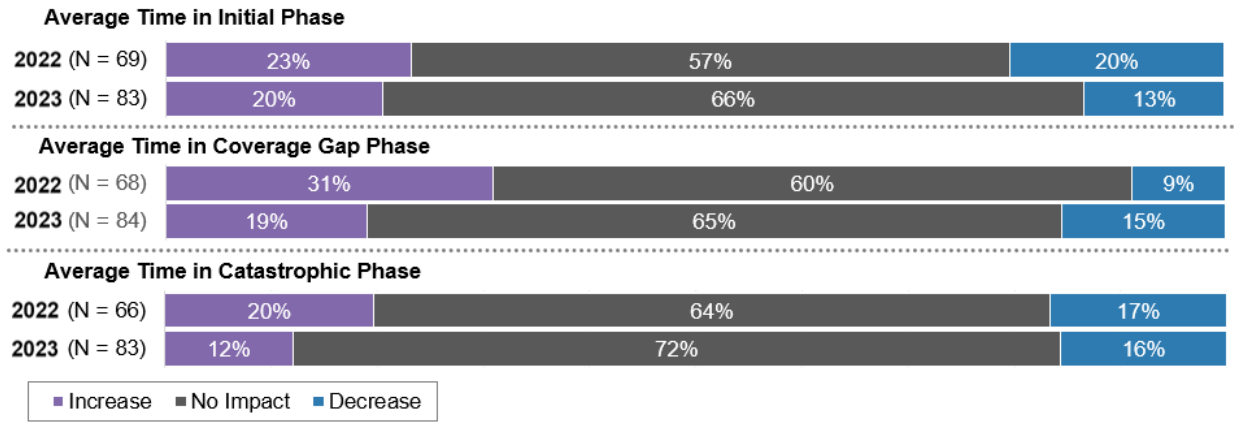
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the beneficiary-level DD regression models for each year of the model. The comparison groups consisted of insulin users enrolled in nonparticipating plans. The column labeled "Percent Effect" indicates the percentage by which the estimated effect is lower (or higher) compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

For the coverage gap and catastrophic phases, we found consistently statistically significant effects across all years. For the coverage gap, we found a consistent increase in the number of days spent in the gap, ranging from 9.3 to 11.0 additional days in each year ($p < 0.001$ for all years). We found a consistent statistically significant impact of PDSS on time spent in the catastrophic phase, with the effect estimates ranging from 6.4 to 9.6 fewer days ($p < 0.001$ for all years). The effect sizes represent about a 10% increase in time in the coverage gap in each year,

and a 13.6% to 17.5% decrease in time in the catastrophic phase, relative to what we would have expected without the model.

Nonetheless, most POs that responded to our survey reported no change in the average amount of time beneficiaries using insulins spent in each benefit phase (Figure 6.8), in contrast to the quantitative findings that show beneficiaries spent more time in the coverage gap and less time in the catastrophic phase.

Figure 6.8. PO Survey Results on Perceived Impact of PDSS on Average Time Spent in Different Part D Benefit Phases, 2022 to 2023



SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

While insulin users may be expected to spend longer in the coverage gap due to the model, only 31% of POs reported that beneficiaries actually spent more time in the coverage gap phase in 2022. The share of POs reporting an increase dropped to 19% in 2023. The majority of POs in both years reported no impact on the average time spent in the coverage gap. Indeed, representatives of some POs, such as POs A and BW, noted that the lower copayments from insulin may not have been enough to keep beneficiaries from moving into the catastrophic phase at the same rate, given the number and mix of drugs they take:

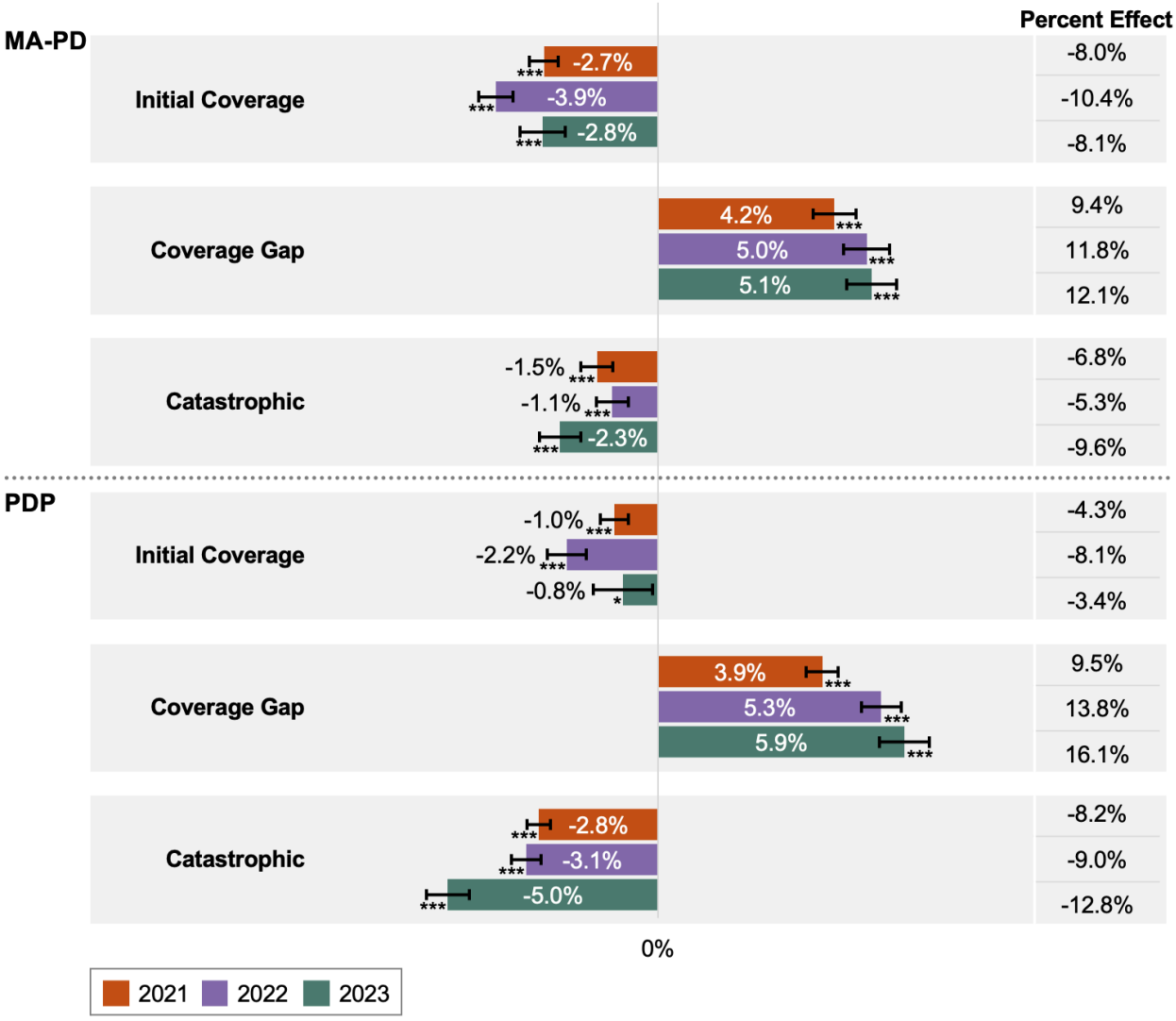
> All of the other drugs that those members are taking are the reason that the members still progress through the phases. In and of itself, the diabetic or the insulin copay would slow the member, but because that member is still taking all of the other drugs, they're still progressing through the phase. . . . It is somewhat slowed but isn't entirely mitigated. (PO A)

If the lower insulin OOP costs result in slower movement through the benefit phases, the average time spent in catastrophic may also decrease. However, most POs reported no changes in this outcome; the percentage of POs reporting no impact on the average time spent in the catastrophic phase increased from 64% in 2022 to 72% in 2023.

Probability of Ending the Year in the Coverage Gap or Catastrophic Phases

PDSS was associated with an increase in the probability that insulin users ended the year in the coverage gap and a decrease in the likelihood of ending the year in the catastrophic phase, for insulin users enrolled in both MA-PDs and PDPs (Figure 6.9).

Figure 6.9. Estimated Effect of PDSS on Likelihood of Ending the Year in Different Benefit Phases, by Plan Type and Year



SOURCE: Authors' analysis of Part D event and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the beneficiary-level DD regression models for each year of the model. The comparison groups consisted of insulin users enrolled in nonparticipating plans. The column labeled "Percent Effect" indicates the percentage by which the estimated effect is lower (or higher) compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

The probability of ending the year in the coverage gap increased for those enrolled in PDSS-participating MA-PDs by an estimated 4.2% to 5.1% in each year ($p < 0.001$), representing a 9.4% to 12.1% increase relative to what we would have expected without the model. Insulin users in PDPs were 3.9% to 5.9% more likely to end the year in the coverage gap ($p < 0.001$), representing a 9.5% to 16.1% increase.

The decreased likelihood of ending the year in the catastrophic phase was smaller in magnitude than the effect for the coverage gap but was statistically significant for both MA-PDs and PDPs. For insulin users in PDSS-participating MA-PDs, PDSS was associated with a decrease in the probability of ending the year in the catastrophic phase of between 1.1% and 2.3% ($p < 0.001$ in all years), representing a 5.3% to 9.6% decrease relative to what we would have expected without the model. For those in PDSS-participating PDPs, we estimated a statistically significant decrease of 2.8% to 5.0% in the probability of ending the year in the catastrophic phase ($p < 0.001$ for all years), representing an 8.2% to 12.8% decrease across the years.

Summary

PDSS was not associated with statistically significant changes to the total Part D premium in any year for PDSS-participating MA-PDs; nonetheless, there was a statistically significant estimated average increase in the premium in one year for PDSS-participating PDPs. Although most POs reported no impact on Part D premiums, some noted small premium increases due to the model's lower insulin copayments that were passed onto beneficiaries as part of the supplemental Part D premium. PDSS was associated with decreases in OOP drug costs for insulin users in both PDSS-participating MA-PDs and PDPs, driven by decreases in insulin OOP costs in 2021 and 2022. These estimated declines were broadly consistent for both plan types and across years of the model when we added in the total annual cost of the insulin users' monthly plan premiums, except for PDSS-participating PDPs in 2023. The 2023 finding of a statistically significant average increase in total Part D costs suggests that PDSS-participating PDP premium increases for insulin users outweighed the benefit of the lower insulin copayments, resulting in an average increase in total Part D costs for that year. More than two-fifths of interviewed insulin users noticed financial savings from the model and reported using the extra money to pay for living expenses, food, and medical expenses, among others. Lower insulin copayments provided as part of the model were also associated with insulin users spending more time in the coverage gap phase and less time in the catastrophic phase.

Chapter 7. Part D Financial and Medical Spending Outcomes

CHAPTER KEY TAKEAWAYS
• PDSS was associated with increased **gross drug costs** (payments to the pharmacy) for insulin users in both plan types and in all years. • POs indicated that gross drug costs were also affected by increases in the use of noninsulin diabetes medications and costs for drugs used to treat co-occurring conditions.
• **Part D bids** increased for participating MA-PDs and decreased for participating PDPs. POs cited increased insulin spending as the most common reason for increased Part D bids.
• PDSS was associated with average increases in PMPM **gap discount payments** and **manufacturer drug rebates**, paid by manufacturers to plans, in all years of the model.
• **Part D costs to CMS** decreased in all years of the model for both plan types. • **Reinsurance payments** made by CMS to plans for prescriptions filled in the catastrophic phase decreased in all years for PDPs but only in 2023 for MA-PDs.
• The model was not associated with changes in **medical spending** for MA-PDs. • However, for insulin users enrolled in PDSS-participating PDPs, PDSS was associated with higher average **annual medical spending** in 2021 and 2022 and with lower spending in 2023.

This chapter presents the results of our evaluation of the impact of PDSS on a set of financial outcomes, including gross drug costs, Part D bids and administrative costs, manufacturer payments, and Part D costs to Medicare. We hypothesized that PDSS would shift payments among the various stakeholders. First and foremost, we anticipated that PDSS would increase *gross spending*, defined as the total amount paid to the pharmacy for the insulin dispensed to an insulin user, on insulins for beneficiaries taking insulins and enrolled in PDSS-participating plans. This anticipated spending increase could be due either to increased utilization of insulins or changes to the total costs of insulins. Second, by design, the reduced beneficiary OOP costs for insulin increased manufacturer discount payments in the coverage gap. In addition, PDSS-participating plans may have altered their bids if they expected that the overall cost of the benefit would change as a result of the model—for example, because insulin users changed their drug utilization patterns. We hypothesized that the effect on Part D costs to Medicare was uncertain and depended on whether insulin users were less likely to enter the catastrophic phase (where Medicare pays a higher proportion of the costs as reinsurance) and the extent to which the narrower first risk corridors were triggered.

Table 7.1 lists the measures addressed in this chapter.

Table 7.1. Financial Outcome Measures

Measure	Analysis Level	Description
Gross drug costs, including: • Total • Insulin	Beneficiary	The price paid at the pharmacy for all drugs filled by a beneficiary in the year, as a total and also for insulin drugs, separately. The gross drug cost is split among beneficiaries, plans, manufacturers, and CMS, depending on the benefit phase for the fill.
Part D bids	Plan	The standardized bid for Part D coverage submitted by Part D plans as a PMPM cost. The bid reflects the projected cost to the plan of providing standard coverage, as well as a portion of the plan's administrative expenses and gain or loss margin.
Cost of Part D supplemental benefits	Plan	The cost to provide Part D supplemental benefits, such as lower copays, broader formularies, or coverage of drugs not covered under the standard Part D benefit, calculated as a PMPM amount
Part D administrative costs	Plan	The estimated costs of administering the Part D benefit, submitted as a PMPM cost as part of the overall bid
Manufacturer rebates	Plan	The amount of DIR received by plans from manufacturers for drugs covered by Part D, calculated as a PMPM amount
Manufacturer gap discount payments	Plan	The amount of coverage gap discount payments received by plans from manufacturers for drugs dispensed while beneficiaries were in the coverage gap phase, calculated as a PMPM amount
Reinsurance costs	Plan	The amount paid by CMS for the cost of prescription drugs filled in the catastrophic phase of the benefit, calculated as a PMPM amount
Part D costs to CMS	Plan	The final costs to CMS for Part D coverage provided by a given plan, calculated as a PMPM amount
Medical spending	Plan	For MA-PDs, retrospective PMPM beneficiary medical spending submitted as part of the annual bid.
	Beneficiary	For PDPs, annual total insulin user FFS medical spending.

NOTE: See Appendix B for more details on measure selection and construction.

We estimated DD regression models using nonparticipating plans as the primary comparison group. We supplemented the results of quantitative analyses with insights from our PO surveys and interviews with both POs and beneficiaries. We do not discuss all components of costs to CMS separately in this report; instead, we focus on those components deemed (in consultation with CMS) to be most directly affected by PDSS.

The cost to CMS for providing Part D coverage reflects four major components:

- risk-adjusted monthly capitation payments (known as the *direct subsidy*) determined by a competitive bidding process
- LIS payments to reduce premiums and cost sharing for beneficiaries
- reinsurance payments covering 80% of gross drug costs in the catastrophic phase
- risk corridor payments through which a portion of profits and losses—after accounting for manufacturer rebates and other DIR—are shared with CMS.

To interpret our findings, it is necessary to account for the timing of plan payments. Many components of plan payments (including reinsurance payments, which we examine here) are paid on a prospective basis during the contract year but are subject to adjustments through a

reconciliation process after the contract year ends. We examined the *final* amounts of reinsurance, DIR, and total costs to CMS, accounting for reconciliation. These final amounts may have been affected by implementation of the IRA insulin provision in 2023.

Plan bids and administrative costs, in contrast, are the amounts chosen by the plans that strongly influence payments (but are not themselves payments). There is no distinction between prospective and final amounts for plan bids or administrative costs (a portion of which are built into the plan bid), and our measures of these variables reflect bidding decisions made by the plans before the contract year. These prospectively established amounts would not have been influenced by the implementation of the IRA in 2023 because they were submitted by plans to CMS in June 2022 and finalized by September 2022 for the 2023 contract year.

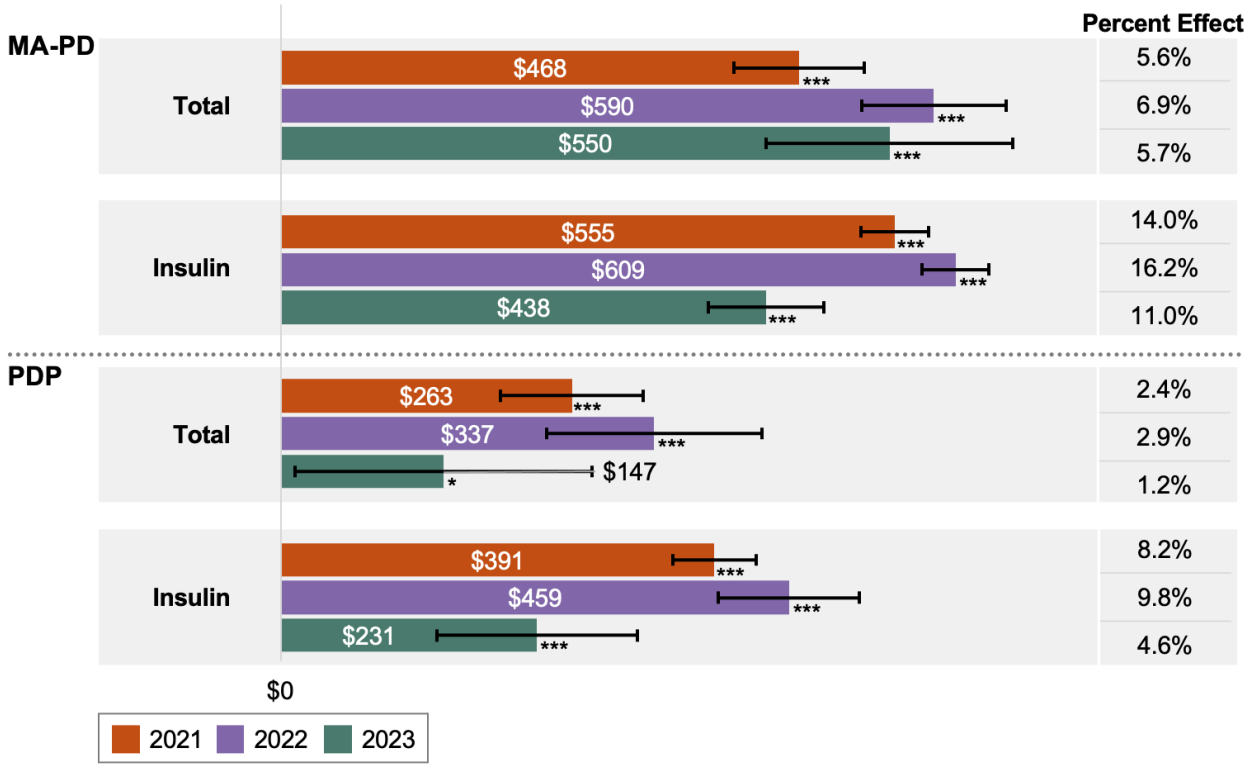
Gross Drug Costs

Financial Outcomes	Hypothesized Effect of PDSS	Anticipated 2023 IRA Impact
Gross Drug Costs	**Increase** in the gross drug costs for insulin users enrolled in PDSS-participating plans, with effects largely driven by insulin costs	Utilization of insulins in nonparticipating plans expected to increase, thereby **reducing or eliminating** the estimated impact of the model

PDSS was associated with increased average gross drug costs for insulin users in both PDSS-participating MA-PDs and PDPs, largely driven by increased insulin costs (Figure 7.1). For PDSS-participating MA-PDs, we estimated a statistically significant increase of $468, $590, and $550 in each year ($p < 0.001$ in all years), which represented a 5.6% to 6.9% increase from what would have been expected in the absence of the model. Insulin costs for MA-PDs also increased by a statistically significant amount in each year, although the effect attenuated somewhat in 2023. Specifically, we estimated increased average insulin costs of $555 in 2021, $609 in 2022, and $438 in 2023 ($p < 0.001$ for all years). These increased effects represented gross insulin costs that were about 11% to 16% higher compared with what would have been expected in the absence of the model.

We also estimated an increase in gross drug costs associated with the model for PDSS-participating PDPs, again largely due to increased insulin costs. The estimated increase in gross drug costs increased from $263 in 2021 to $337 in 2022, then decreased to $147 in 2023 ($p < 0.001$ for all years). Estimated effects for insulin costs were larger in all three years compared with the gross drug costs estimates, suggesting that noninsulin gross costs declined (results not shown). Specifically, we estimated that PDSS was associated with a $391, $459, and $231 increase in gross insulin costs in each year of the model ($p < 0.001$). The effects on gross drug costs overall represent a relatively small 1% to about 3% increase in costs above what would have been expected in the absence of the model. Estimated insulin cost effects were larger, however, ranging from 4.6% (2023) to 9.8% larger than what would have been expected.

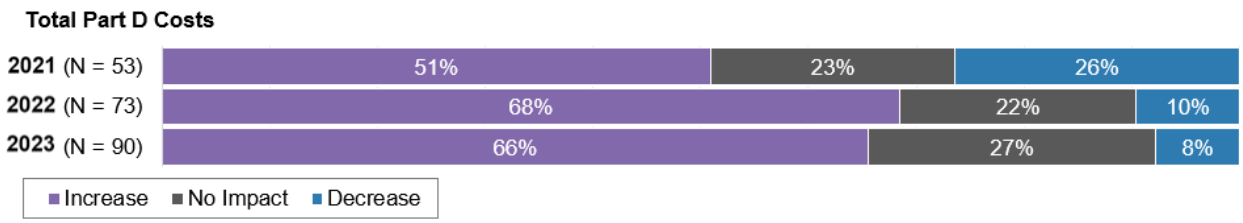
Figure 7.1. Estimated Effect of PDSS on Gross Drug Costs, by Plan Type and Year



SOURCE: Authors' analysis of Part D event and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the beneficiary-level DD regression models for each year of the model. The comparison groups consisted of insulin users enrolled in nonparticipating plans. The column labeled "Percent Effect" indicates the percentage by which the estimated effect is lower (or higher) compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

On the survey, most POs in all three years also reported that PDSS increased their total Part D costs (Figure 7.2). The percentage of POs reporting increased total Part D costs changed from 51% in 2021 to 68% in 2022 and to 66% in 2023. Meanwhile, the percentage of POs reporting decreases in total Part D costs attributable to the model decreased from 26% to 8% over the same period.

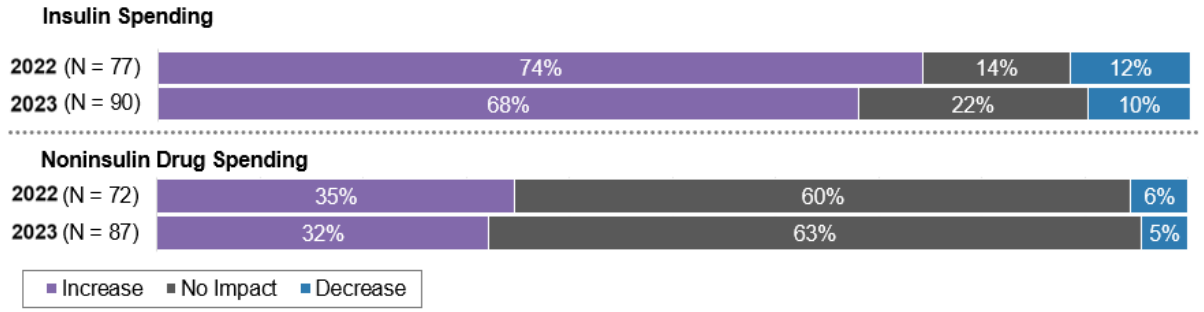
Figure 7.2. PO Survey Results on Perceived Impact of PDSS on Total Part D Costs, 2021 to 2023



SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

PO survey results also suggest that increases in total Part D costs were likely to be driven by increased insulin spending. Indeed, most POs reported increases in insulin spending and no impact on their noninsulin drug spending for both 2022 and 2023 (Figure 7.3; these questions were not included on the first wave of the PO survey). While the percentage of POs reporting increased insulin spending decreased from 74% to 68%, the percentage reporting no impact on noninsulin drug spending increased from 60% to 63% during the same period. It is worth noting that the percentage of POs reporting no impact on insulin spending increased from 14% to 22%, and the percentage of POs reporting increased noninsulin drug spending decreased from 35% to 32%.

Figure 7.3. PO Survey Results on Perceived Impact of PDSS on Insulin and Noninsulin Spending, 2022 to 2023



SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

In interviews, POs reporting increases in insulin spending said that it was an expected outcome of the model: "We want [insulin users] to take their insulin the way it's prescribed and the way they should be taking it, but that does come with increased drug costs" to the plan, said a PO A representative. PO AM representatives also said that increased enrollment of insulin users increased their plans' insulin and noninsulin drug spending: "The PDSS plans sort of attracted more insulin users who just generally have a little bit larger drug basket compared to the average beneficiary. . . The insulin copay being capped [also] helps [with drug] affordability" (PO AM). Finally, PO AO representatives noted that in addition to increased drug utilization, plans were faced with increasing drug prices:

> It's going to be a combination of new users, users that become more adherent, and then you have increases in prices. So, when you combine all of those things, right, it's difficult to say exactly what was driving the increase the most; but overall, it was a small increase.

Those POs that reported no impact on their insulin and noninsulin drug spending said that other drug classes have a larger effect on their drug spending:

> At the end of the day, the total spend in Part D is so big and really more impactful [than in] other areas, like specialty drugs, oncology, and other areas.

> But in the big scheme of the whole totality of the dollars, I guess [PDSS] didn't move the needle as much as [we had] thought. (PO AO)

About one-third of POs reported increases in noninsulin drug spending (Figure 7.3), citing changes in treatment guidelines for diabetes that led to increased utilization of GLP-1 and SGLT2 agents:

> For drug spending for noninsulin, as an example, we're not sure that that's [necessarily] attributed to the PDSS Model. We could say that . . . maybe patients had a little bit extra money so they could afford some of the other noninsulin therapies better, but also guidelines changed during this time. We've seen [utilization of] SGLT2s and GLP-1s increase, but the guidelines are now recommending them more than insulin, so it's hard to say. (PO CD)

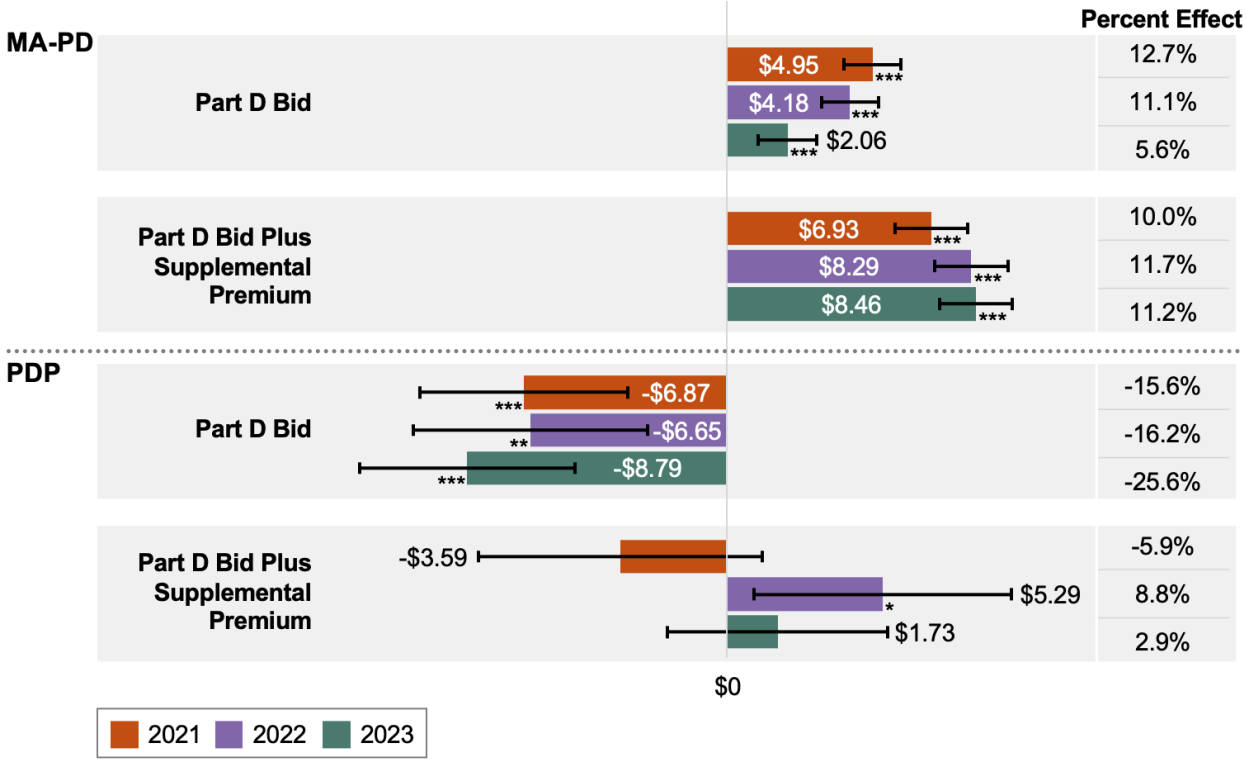
Plan Bids and Administrative Costs

Financial Outcomes	Hypothesized Effect of PDSS	Anticipated 2023 IRA Impact
Plan Bids and Administrative Costs	**No change** in Part D plan bids for basic coverage, because PDSS costs are by design supplemental Part D benefits not included in the basic Part D bid	Part D bids were due to CMS before the IRA was enacted, so the IRA is **not anticipated to impact** the bid results

We examined both the basic Part D bid, as well as the sum of the basic bid and supplemental Part D benefit costs. The cost of PDSS is intended to be built into the supplemental benefit cost, while examining the basic bid alone could reveal broader impacts of the model on projected costs for prescription drug benefits in Part D.

Among MA-PDs, we found that PDSS had a positive and significant effect on the basic Part D bid in all three years, with the magnitude of the effect decreasing over time (Figure 7.4). In particular, PDSS was associated with an average increase in the PMPM plan bid of $4.95 in 2021, $4.18 in 2022, and $2.06 in 2023 (all $p < 0.001$). These translated to increases in the bids of 12.7%, 11.1%, and 5.6%, compared with what would have been observed in the absence of the model. Examining the impact of PDSS on the sum of the basic bid plus the supplemental premium, we found a similar effect; the model was associated with increases of 10.0%, 11.7%, and 11.2% (all $p < 0.001$).

Figure 7.4. Estimated Effect of PDSS on Part D Plan Bids, by Plan Type and Year



SOURCE: Authors' analysis of Part D bid and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the plan-level DD regression models for each year of the model. The comparison groups consisted of nonparticipating plans. The column labeled "Percent Effect" indicates the percentage by which the estimated effect is lower (or higher) compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

Among PDPs, we observed the opposite estimated effect: PDSS was associated with decreases in PMPM Part D bids of $6.87 in 2021 ($p < 0.001$), $6.65 in 2022 ($p = 0.001$), and $8.79 in 2023 ($p < 0.001$). This translated to decreases of 15.6%, 16.2%, and 25.6%, respectively, among PDSS-participating plans compared with what would have been expected in the absence of the model. In the case of PDPs, we observed a different effect when considering the sum of the basic Part D bid and the supplemental premium. The effect was not significant in 2021 and 2023, and in 2022, the model was associated with a $5.29 PMPM, or 8.8% *increase* in the sum of the basic bid and the supplemental premium ($p = 0.018$).

In support of the quantitative results for Part D bids for the PDSS-participating MA-PDs, most POs reported increased Part D bids in all three years of the model. The percentage of POs reporting increases in bids grew from 44% in 2021 to 60% in 2023 (Figure 7.5). The percentage indicating that their bids stayed the same varied, ranging from a high of 40% in 2021 to a low of 33% in 2022. The percentage of POs reporting that their Part D bids decreased dropped steadily from 16% at the beginning of the model period to 2% during its last year.

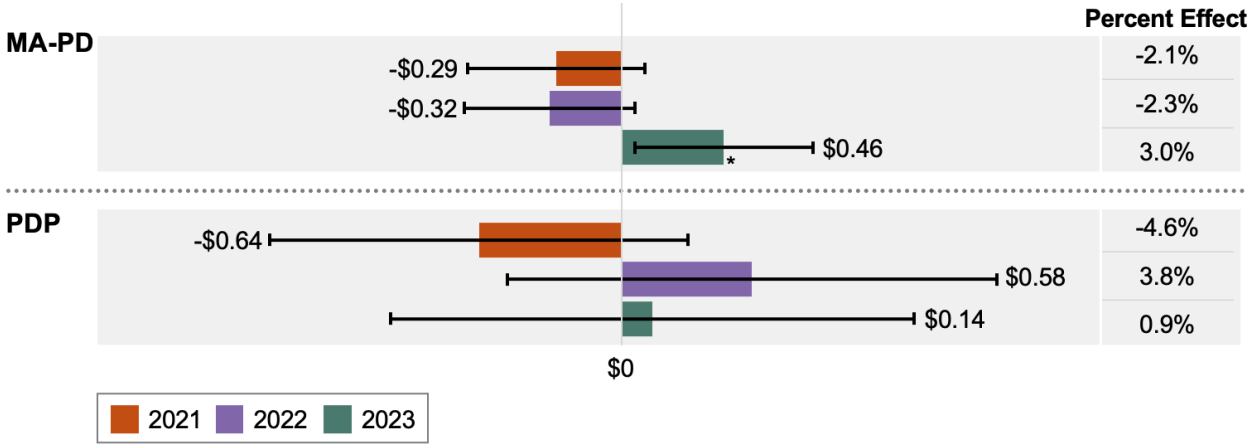
Figure 7.5. PO Survey Results on Perceived Impact of PDSS on Part D Bids, 2021 to 2023

SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

Increased insulin spending was the most common reason for increased Part D bids: "With the PDSS, we expected higher overall claims for each plan. Thus, it increased the bid" (PO E). A general increase in Part D spending was another reason for Part D bid increases: "We saw increase in our Part D spend. It wasn't just from insulin, it was, I think, from a number of things, including drug mix, inflation, things like that," said PO DH representatives.

Among both MA-PDs and PDPs, we did not observe statistically significant effects of PDSS on plan administrative costs, with the exception of PDSS-participating MA-PDs in 2023 (Figure 7.6). The estimated effect was $0.46 for MA-PDs in 2023 ($p = 0.024$), which was an increase of 3.0% over expected administrative costs in the absence of the model.

Figure 7.6. Estimated Effect of PDSS on Projected Part D Administrative Costs, by Plan Type and Year



SOURCE: Authors' analysis of Part D bid and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the plan-level DD regression models for each year of the model. The comparison groups consisted of nonparticipating plans. The column labeled "Percent Effect" indicates the percentage by which the estimated effect is lower (or higher) compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

Our PO survey results generally support the results of our data modeling: More than three-fifths of all POs in all three years of the model did not assess that PDSS affected their

administrative costs. Nonetheless, one-third or more of POs each year reported increased administrative costs attributable to the model (Figure 7.7).

Figure 7.7. PO Survey Results on Perceived Impact of PDSS on Administrative Costs, 2021 to 2023

SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

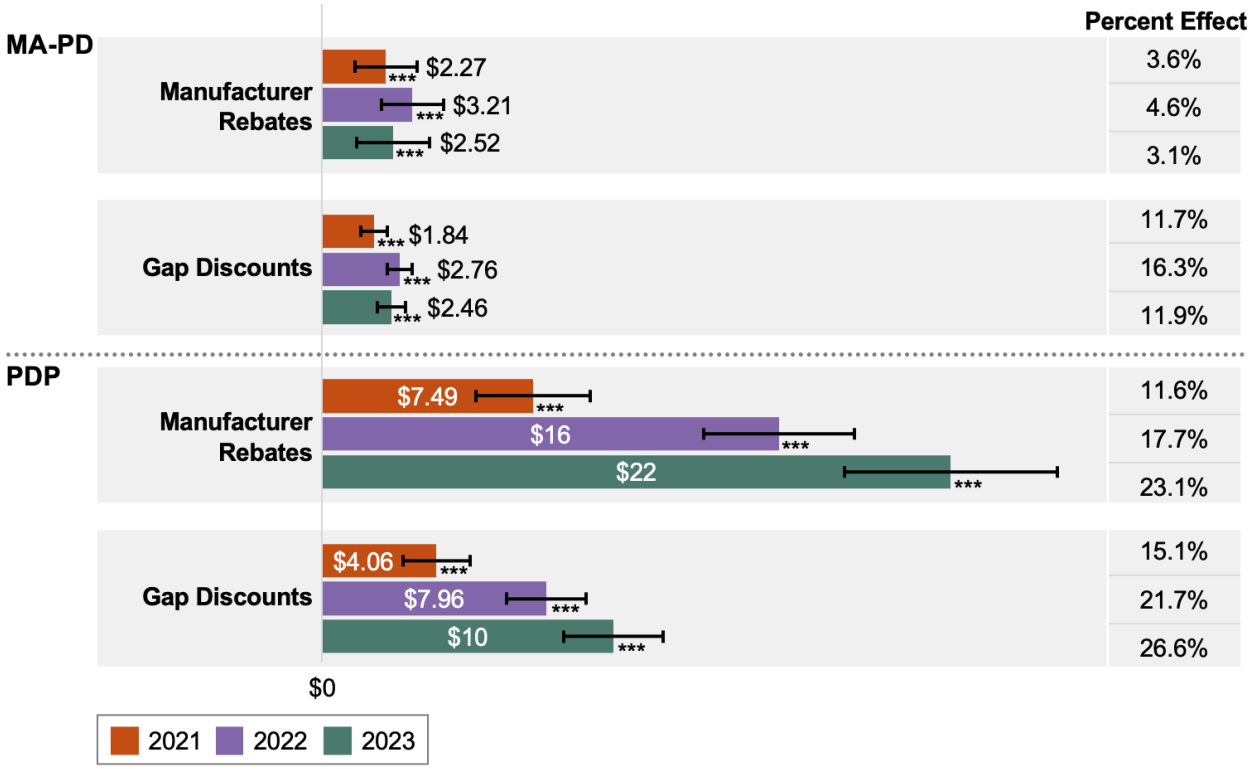
R&I program administration may be one of the reasons for increased administrative costs. Six of the ten POs with R&I programs responding to the survey in 2023 reported increased Part D administrative costs. Some POs, such as PO EC, considered increased administrative costs not only a disadvantage of model participation but also the most notable outcome of their model participation, saying that their "administrative costs to implement, code, and test the PDSS requirements," as well as "audits and monitoring," have been very time-consuming. Others, such as PO CA, noted that their "plan paid more money for the program and more admin costs to administer, with no benefit except a better member experience because insulin costs were capped." In addition, several POs noted a burdensome model application process and limited time to prepare their applications as a disadvantage of model participation, which might have resulted in a perception of increased administrative costs.

Manufacturer Payments

Financial Outcomes	Hypothesized Effect of PDSS	Anticipated 2023 IRA Impact
Manufacturer Payments	**Increase** in manufacturer discount payments for insulin coverage due to the increased contribution in the coverage gap, but **uncertain impact** on manufacturer rebates negotiated with Part D plans	Manufacturers did not contribute additional costs for insulins filled by beneficiaries in nonparticipating plans, so **no impact** on manufacturer payments

PDSS was associated with increased coverage gap discount payments for both MA-PDs and PDPs (Figure 7.8). Among MA-PDs, PDSS was associated with increases of $1.84, $2.76, and $2.46 (all $p < 0.001$) from 2021 through 2023. These increases amounted to 11.7% in 2021, 16.3% in 2022, and 11.9% in 2023. For PDPs, the PDSS effect was similar; the model was associated with increases in the PMPM gap discount payment of $4.06 in 2021, $7.96 in 2022, and $10 in 2023 (all $p < 0.001$). The PDSS effect translated to increases of 15.1% in 2021, 21.7% in 2022, and 26.6% in 2023.

Figure 7.8. Estimated Effect of PDSS on Manufacturer Payments, by Plan Type and Year



SOURCE: Authors' analysis of Part D bid and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the plan-level DD regression models for each year of the model. The comparison groups consisted of nonparticipating plans. The column labeled "Percent Effect" indicates the percentage by which the estimated effect is lower (or higher) compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

Manufacturers' coverage gap discount payments could increase as part of the model if beneficiaries filled more insulin prescriptions while in the coverage gap phase. The IRA eliminated the coverage gap as part of the standard benefit design starting in 2023. Prior to this change, PDSS was the only way for plans to offer lower copayments in the coverage gap without losing manufacturer discounts. Therefore, some POs reported increases in coverage gap discounts:

> The important part about the IRA, it was very expensive to . . . offer any gap discount [before the IRA implementation]. And the Senior Savings Model helped make it more manageable for members and for plans to offer it. So, yes, we most certainly saw a difference in the manufacturer discount payments. (PO AH)

We also found evidence that PDSS increased manufacturer rebates for both MA-PDs and PDPs (Figure 7.8). For PDSS-participating MA-PDs, we found that PMPM manufacturer rebates increased by $2.27 in 2021, $3.21 in 2022, and $2.52 in 2023 (all $p < 0.001$). This reflects increases of 3.6%, 4.6%, and 3.1%, respectively, relative to expected rebates in the absence of the model. For PDPs, PDSS resulted in manufacturer rebates that were higher by $7.49 in 2021,

$16 in 2022, and $22 in 2023 (all $p < 0.001$). This translates to manufacturer rebates that were higher by 11.6% in 2021, 17.7% in 2022, and 23.1% in 2023.

Although the majority of POs reported no impact of PDSS on manufacturer rebates in 2022 and 2023, the percentage of POs reporting increases in rebates decreased from 26% to 21%, while the percentage reporting decreases in manufacturer rebates went up from 7% to 16% over the same period (Figure 7.9).

Figure 7.9. PO Survey Results on Perceived Impact of PDSS on Manufacturer Insulin Rebates, 2022 to 2023

SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

Increases in total manufacturer rebates for insulin can stem from either an increase in the number of insulin fills, an increase in the per-fill rebate, or both factors. While most POs citing an increase in manufacturer rebates attributed it to an increasing number of insulin fills by existing insulin users and for new insulin users who joined their plans during the model period, PO E representatives argued that increased per-fill rebates also played a key role: "I think the point that needs to be made is [that] there was partnership with the manufacturers. They saw value in this, and so that was reflected in how we negotiated to help to create more affordability and fund the cost sharing reduction."

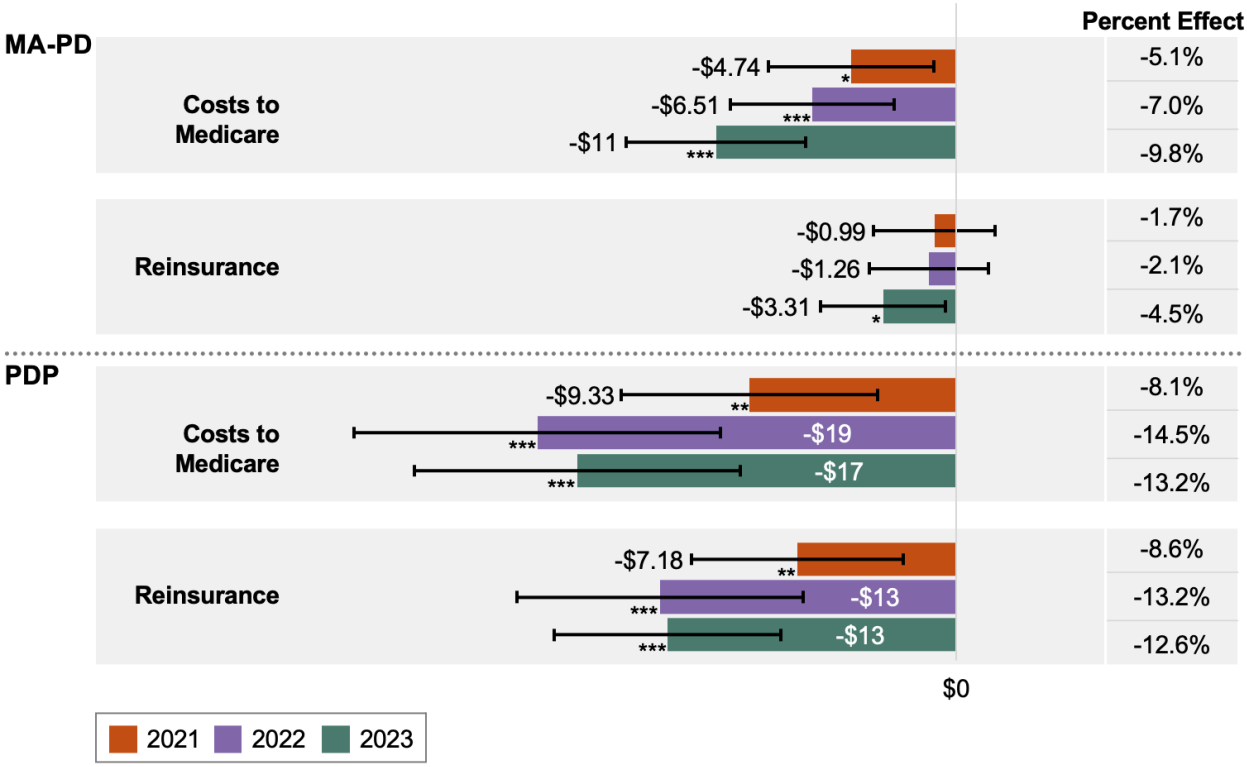
Part D Costs to Medicare

Financial Outcomes	Hypothesized Effect of PDSS	Anticipated 2023 IRA Impact
Part D Costs to CMS	**Uncertain** impact on costs to Medicare as PDSS is a supplemental benefit not paid for by CMS, but CMS may pay lower reinsurance payments if fewer beneficiaries spend time in the catastrophic phase and higher risk corridor payments due to the narrower first risk corridor option	CMS subsidized the difference in cost sharing between the new $35 maximum per month copayment and the nonparticipating plans' original cost share, so costs to Medicare might **increase** overall, but would **decrease** for PDSS-participating plans relative to nonparticipants

PDSS was associated with significantly decreased Part D costs to Medicare among PDSS-participating MA-PDs in 2021, 2022, and 2023 (Figure 7.10). We found that PDSS was associated with decreased Part D costs to Medicare among MA-PDs of $4.74 in 2021 ($p = 0.013$), $6.51 in 2022 ($p < 0.001$), and $11 in 2023 ($p < 0.001$). These effects translated to

decreases of 5.1%, 7.0%, and 9.8%, respectively. Among PDPs, PDSS was also associated with decreased Part D costs to Medicare in all three years; costs were lower by $9.33 in 2021 ($p$ = 0.002), $19 in 2022 ($p < 0.001$), and $17 ($p < 0.001$). These effects amounted to decreases of 8.1% in 2021, 14.5% in 2022, and 13.2% in 2023, relative to estimated Part D costs to Medicare in the absence of the model.

Figure 7.10. Estimated Effect of PDSS on Part D Costs to Medicare and Reinsurance Payments, by Plan Type and Year



SOURCE: Authors' analysis of Part D bid and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the plan-level DD regression models for each year of the model. The comparison groups consisted of nonparticipating plans. The column labeled "Percent Effect" indicates the percentage by which the estimated effect is lower (or higher) compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

The estimated 2023 reduction in Part D costs to Medicare solely reflects the impact of PDSS and does not include IRA impacts. This is because our analysis did not incorporate the 2023 subsidy that CMS paid to all Part D plans to reduce the OOP payment to $35 per one-month supply of insulins covered by plans not included in the model. Given this subsidy would have disproportionately increased Part D costs to Medicare for nonparticipating plans in that year, Part D costs to Medicare for PDSS-participating plans would be even lower than our estimates suggest.

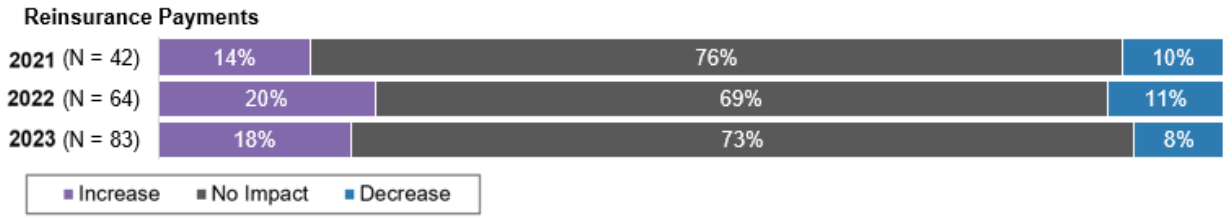
We also examined the impact of the model on PMPM reinsurance payments to plans. While there was no significant impact of PDSS on reinsurance payments to PDSS-participating MA-PDs in 2021 and 2022, we found that PDSS was associated with decreased average estimated reinsurance payments of $3.31 ($p = 0.020$), or 4.5%, in 2023. Among PDSS-participating PDPs, we found that the model led to decreases in reinsurance payments in all three years by $7.18 ($p = 0.003$), $13 ($p < 0.001$), and $13 ($p < 0.001$) in 2021, 2022, and 2023. These estimates translated to decreases of 8.6%, 13.2%, and 12.6% relative to what would have been expected in the absence of the model.

We also examined whether Part C costs to Medicare increased, because we estimated that the model was associated with increased Part C risk scores (as described in Chapter 5), which in turn affected MA payments to plans by Medicare. However, we did not find a statistically significant association between PDSS and increased Part C costs to Medicare (results not shown).

Most POs (between 69% and 76%, depending on the year) reported that PDSS had not affected their reinsurance payments (Figure 7.11). Although some POs, such as POs AY and BW, anticipated that PDSS would slow down beneficiaries in reaching the catastrophic phase, they did not experience material changes in reinsurance costs:

> If the plan is picking up a larger portion of the cost share of the drug, members are going to proceed through the coverage gap and into the catastrophic phase at a slower rate than they would've prior to PDSS. So, it's not incredibly material, but we would see members kind of stay in the coverage gap phase for an extended period of time. (PO AY)

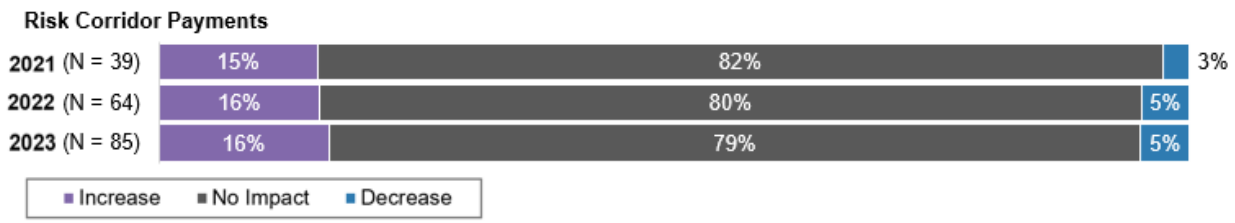
Figure 7.11. PO Survey Results on Perceived Impact of PDSS on Reinsurance Payments, 2021 to 2023



SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

We also asked POs about whether they experienced any changes to risk corridor payments as a result of the model. The majority of POs did not report changes in risk corridor payments as a result of their participation in the model (Figure 7.12). The proportion of POs reporting no impact on risk corridor payments was relatively stable across all three years at about 80%.

Figure 7.12. PO Survey Results on Perceived Impact of PDSS on Risk Corridor Payments, 2021 to 2023



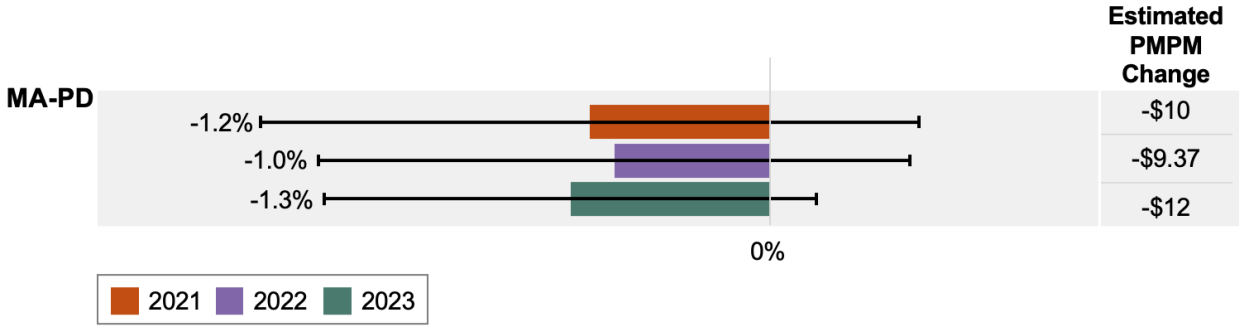
SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

Medical Spending

Financial Outcomes	Hypothesized Effect of PDSS	Anticipated 2023 IRA Impact
Medical Spending	**Uncertain** impact on medical spending in PDSS-participating plans	Utilization of insulins in nonparticipating plans expected to increase, thereby **reducing or eliminating** the estimated impact of the model

PDSS was associated with changes to medical spending, but only for insulin users in PDSS-participating PDPs. We used a different measure of medical spending for PDSS-participating MA-PDs than for PDSS-participating PDPs because relevant data for these analyses varied in availability. In particular, we note that encounter data to assess medical spending among MA-PD enrollees at the beneficiary level were not available for these analyses. Therefore, for MA-PDs, we used a plan-level measure of plan-reported retrospective PMPM medical spending included as part of the MA-PD bids submitted to CMS each year. These medical spending amounts are averaged across all beneficiaries enrolled in the plan and are submitted with a contract year bid as retrospective data in support of the new bid. For the regression analyses, we used the natural log of this measure as the dependent variable. For PDSS-participating MA-PDs, PDSS was not associated with significant changes in average PMPM medical spending in any of the three model years (Figure 7.13).

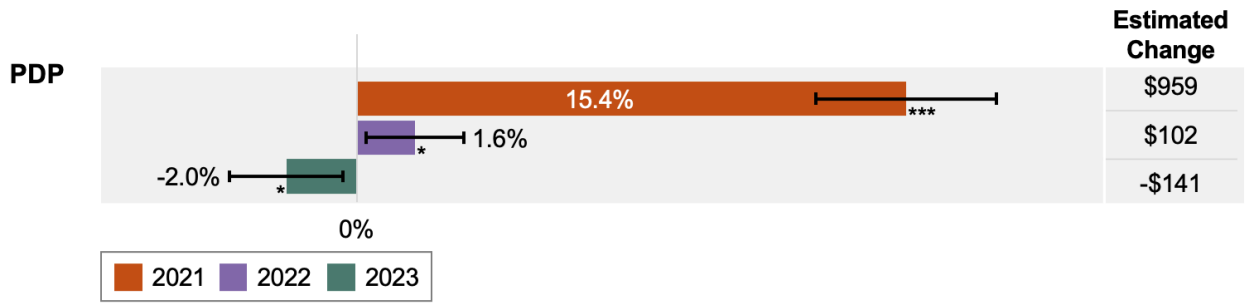
Figure 7.13. Estimated Effect of PDSS on PMPM Medical Spending by MA-PDs, by Year



SOURCE: Authors' analysis of Part D bid and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the plan-level DD regression models for each year of the model. The comparison groups consisted of nonparticipating plans. The column labeled "Estimated PMPM Change" indicates the amount by which the estimated change is lower (or higher) compared with what would have been expected in the absence of the model. Estimated change is based on geometric mean (costs). Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

For PDPs, we calculated medical spending as a beneficiary-level measure of the log of average total medical spending for insulin users. We constructed this measure using FFS claims data by summing the total FFS Medicare amount that would be paid for each claim for a beneficiary within each year, then taking the natural log. We found the largest effect in 2021, where we estimated that PDSS resulted in medical spending that was on average $959, or 15.4% higher ($p < 0.001$) than what would have been expected in the absence of the model (Figure 7.14). For 2022, estimated annual medical spending for insulin users enrolled in PDSS-participating PDPs was statistically significantly higher by $102, or 1.6% ($p < 0.05$), while in 2023, PDSS was associated with significantly *lower* spending by $141, or 2.0% ($p < 0.05$).

Figure 7.14. Estimated Effect of PDSS on Annual Medical Spending by Insulin Users Enrolled in PDPs, by Year

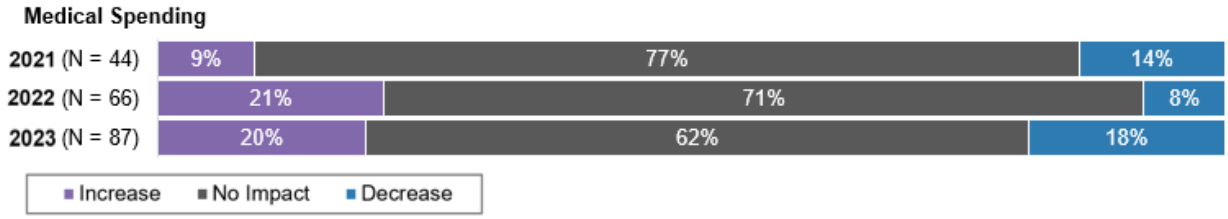


SOURCE: Authors' analysis of Part D event and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the beneficiary-level DD regression models for each year of the model. The comparison groups consisted of insulin users enrolled in nonparticipating plans. The column labeled "Estimated Change" indicates the amount by which the estimated change is lower (or higher) compared with what would have been expected in the absence of the model. Estimated change is based on geometric mean (costs). Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

It is likely that the 2021 findings, in particular, reflect the decreased use of most types of medical care during the height of the COVID-19 pandemic in 2020, with spending rebounding in 2021. Although the DD framework that we use for these analyses should "difference out" these pandemic-driven effects, it is possible that the magnitude of the effect was larger among PDSS-participating plans relative to the comparison nonparticipating plans.

While most POs answering the survey reported that PDSS had no impact on medical spending, the share of POs reporting no impact declined from 77% in 2021 to 62% in 2023. Moreover, by 2023, the percentage of POs reporting increases or decreases in medical costs became more similar (20% and 18%, respectively).

Figure 7.15. PO Survey Results on Perceived Impact of PDSS on Medical Spending, 2021 to 2023



SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

POs had different perspectives on whether the improved adherence to insulin attributable to lower insulin cost sharing would affect downstream medical spending in MA-PDs. For example, some POs did not see a change in medical spending: "We did take a look after 2021 to see if there was any difference in medical spend, medical outcomes, and it was inconclusive, because [it was] too early to really see the benefits of insulin adherence on medical outcomes at that

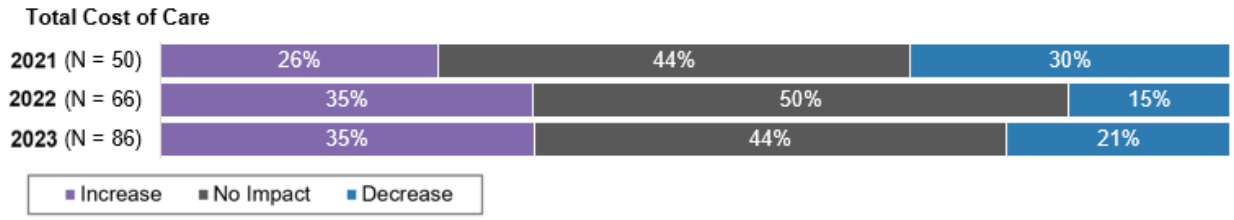
point" (PO AH). In contrast, PO E representatives said that their early evaluation of the program suggested decreased medical spending:

> We also saw a decrease in preventable diabetes admissions and [ED] visits, and then, ultimately, a decrease in medical costs that we attributed to this program. So, we were very kind of excited to see those results and really feel like it was for the benefit of our membership's health.

Most POs, however, said they could not assess the impact of PDSS on medical spending. PO C representatives, for example, thought their plan's population of insulin users was too small to measure downstream impacts: "Based on our experience of other work, usually it takes a lot more population to really isolate the impact of insulin to determine if there's an impact to medical claims." In addition, PO U representatives said that pent-up demand from the COVID-19 pandemic was still influencing medical care utilization: "[Medical care is still] being heavily influenced by the utilization patterns that were emerging, and our overall medical expense was suffering."

The *total cost of care* combines medical and drug spending, and POs also had different perspectives on how PDSS affected the total cost of care (Figure 7.16). Although most POs reported no impact on total cost of care in all three years of the model, the percentage of POs reporting increases in the total cost of care went up from 26% in 2021 to 35% in subsequent years. This change may be due to the variety of factors mentioned in earlier sections regarding higher overall Part D spending, which is also reflected in the quantitative results.

Figure 7.16. PO Survey Results on Perceived Impact of PDSS on Total Cost of Care, 2021 to 2023



SOURCE: Authors' analysis of survey response data from PDSS-participating POs.

Summary

PDSS was associated with statistically significant increases in basic Part D bids among PDSS-participating MA-PDs but decreased bids for PDSS-participating PDPs. In general, participating in the model did not significantly affect projected Part D administrative costs for MA-PDs or PDPs, but some PO representatives cited the costs of implementing R&I programs and complying with the model's monitoring and auditing requirements. Gap discount payments and rebates paid by manufacturers increased in both PDSS-participating MA-PDs and PDPs. POs generally attributed increased manufacturer rebates to increases in the number of insulin fills by existing or new insulin users or to increases in per-fill rebates. The model was also

associated with significant decreases in Part D costs to Medicare in all years for both PDSS-participating MA-PDs and PDPs. PDSS was also associated with significant decreases in reinsurance payments for PDSS-participating MA-PDs only in 2023 and for PDPs in all three years. Finally, PDSS was not associated with changes in PMPM medical spending for MA-PDs in any year of the model, but it was associated with statistically significant increases in average annual medical spending among insulin users in PDSS-participating PDPs in 2021 and 2022 and average decreases in medical spending in 2023. Although most POs completing our surveys did not report an impact of the model on medical spending or total cost of care, perspectives differed on whether increased insulin utilization and adherence associated with reduced beneficiary OOP insulin costs could affect downstream medical spending.

Chapter 8. Spillover Effects of the Model Test

CHAPTER KEY TAKEAWAYS

- PDSS was associated with increases in **noninsulin user enrollment** in both plan types across all three years.
- While the model was associated with increased **dual- and LIS-eligible enrollment** in MA-PDs, we did not find an association for PDPs.

- Noninsulin users enrolled in participating MA-PDs experienced **Part D OOP drug cost** increases in each model year, while those in participating PDPs experienced average decreases.
- After adding in the cost of premiums, the model was associated with increases in **total Part D costs** for noninsulin users in both plan types, although the effect was smaller and not statistically significant for MA-PDs in 2023.

- PDSS was associated with small increases in the number of days spent in the **coverage gap** for noninsulin users in both plan types.

PDSS may have resulted in spillover effects on beneficiaries not eligible for the model or not taking insulin. Beneficiaries eligible for the Part D LIS were not eligible for the model because they generally already had low copayments for their medications, and noninsulin users did not receive the benefits of the model because they did not use the drug targeted by the model. This chapter presents the results of our quantitative evaluation of the impacts of the model on noninsulin users and beneficiaries eligible for the LIS, including those dually eligible for Medicare and Medicaid.

The hypothesized effect of the model on enrollment by these groups was unclear. On the one hand, if premiums and other benefit design characteristics change for all plan enrollees because of model participation, enrollees not taking insulin or not eligible for the model may leave the plan. On the other hand, Part D plans may maintain their noninsulin benefit designs to attract or retain noninsulin users and/or LIS-eligible beneficiaries. The hypothesized effects of the model on noninsulin users' Part D OOP drug costs are uncertain, depending on whether the PDSS-participating plans altered their benefit designs in response to model participation and, by extension, whether noninsulin users responded to any changes in benefit design by altering their utilization of prescription drugs. Similar to the hypothesized effects for insulin users, though, we hypothesized an increase in total Part D costs after the premium costs for the year were added to the Part D OOP costs, especially for those enrolled in PDSS-participating PDPs who would likely face an increase in the supplemental premium because of PDSS.

Table 8.1 shows the outcome measures analyzed in this chapter, including enrollment, Part D OOP drug costs and total Part D costs, and progression through the benefit phases.

Table 8.1. Spillover Outcome Measures

Measure	Analysis Level	Description
Plan enrollment by subgroups: • Noninsulin users • Dual eligible • LIS eligible	Plan	Number of noninsulin users, dual-eligible and LIS-eligible beneficiaries enrolled in the plan as of July 1st of the year
Total OOP drug costs	Beneficiary	The total OOP amount that beneficiaries were responsible for paying for all of their drug fills in a year
Total Part D costs	Beneficiary	The sum of total OOP drug costs plus 12 months of the Part D premium for the plan
Time spent in benefit phases: • Initial coverage • Coverage gap • Catastrophic	Beneficiary	The number of 30-day periods that beneficiaries spent in each of the Part D benefit phases (converted to days for the purpose of reporting DD model effects)

NOTE: See Appendix B for more details on measure selection and construction.

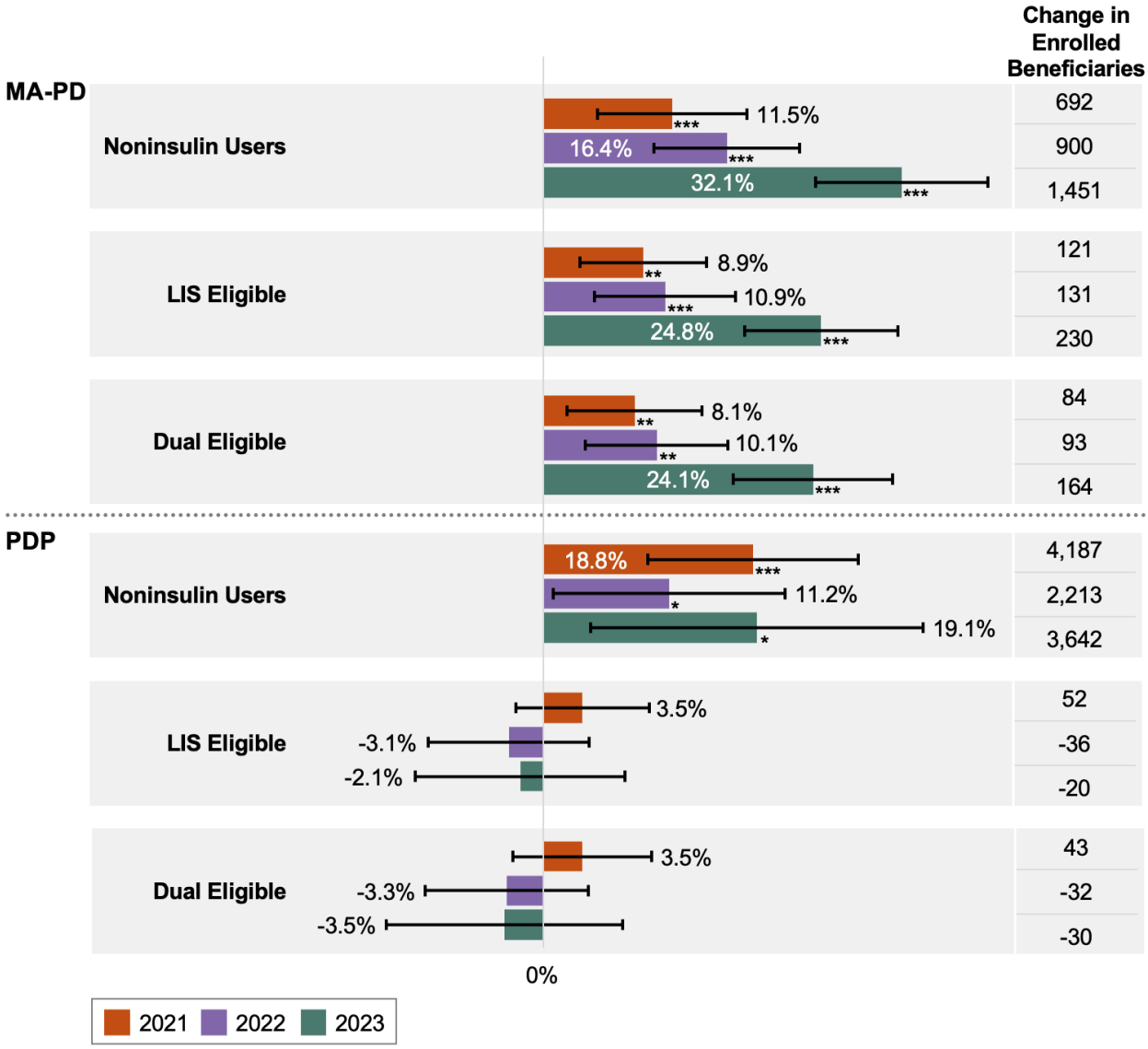
For the plan-level enrollment analyses, we ran DD regression models using nonparticipating plans as the comparison group. For the beneficiary-level analyses, we ran DD regression models using noninsulin users enrolled in nonparticipating plans as the primary comparison group. We did not specifically ask about spillover effects during our qualitative data collection activities; therefore, this chapter focuses solely on quantitative outcome estimates.

Plan Enrollment by Subgroups

Plan Enrollment	Hypothesized Effect of PDSS	Anticipated 2023 IRA Impact
Subgroups	**Decrease** in the number of noninsulin users enrolled in PDSS-participating plans. **Uncertain** impact on enrollment of dually eligible and LIS-eligible beneficiaries in PDSS-participating plans	Because cost sharing and formularies for noninsulin drugs were established before the IRA was enacted, enrollment responses in 2023 are expected to be **similar** to those in earlier model years

PDSS was associated with statistically significant increases in enrollment of noninsulin users in both PDSS-participating MA-PDs and PDPs. In PDSS-participating MA-PDs, enrollment of noninsulin users increased by an estimated average of 11.5% in 2021 ($p = 0.001$), 16.4% in 2022 ($p < 0.001$), and 32.1% in 2023 ($p < 0.001$) relative to expected enrollment in the absence of PDSS. We estimated that these effects translated to average enrollment increases of 692 noninsulin users in 2021, 900 in 2022, and 1,452 in 2023. Among PDSS-participating PDPs, enrollment of noninsulin users increased by an average of 18.8% in 2021 ($p < 0.001$), 11.2% in 2022 ($p = 0.03$), and 19.1% in 2023 ($p = 0.01$) relative to what would have been expected in the absence of the model. This translated to enrollment increases of 4,187 noninsulin users in 2021; 2,213 noninsulin users in 2022; and 3,642 noninsulin users in 2023.

Figure 8.1. Estimated Effect of PDSS on Enrollment by Subgroups, by Plan Type and Year



SOURCE: Authors' analysis of Part D enrollment and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the plan-level DD regression models for each year of the model. The comparison groups consisted of nonparticipating plans. The column labeled "Change in Enrolled Beneficiaries" indicates the number by which the estimated effect is lower (or higher) compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

Among PDSS-participating MA-PDs, we found increased enrollment even among LIS-eligible and dual-eligible beneficiaries. Enrollment of LIS-eligible beneficiaries increased by an estimated average 8.9% in 2021 ($p = 0.002$), 10.9% in 2022 ($p < 0.001$), and 24.8% in 2023 ($p < 0.001$) because of PDSS. The estimated effect of the model translates to higher enrollment of LIS-eligible beneficiaries into PDSS-participating MA-PDs by an average of 121 enrollees in

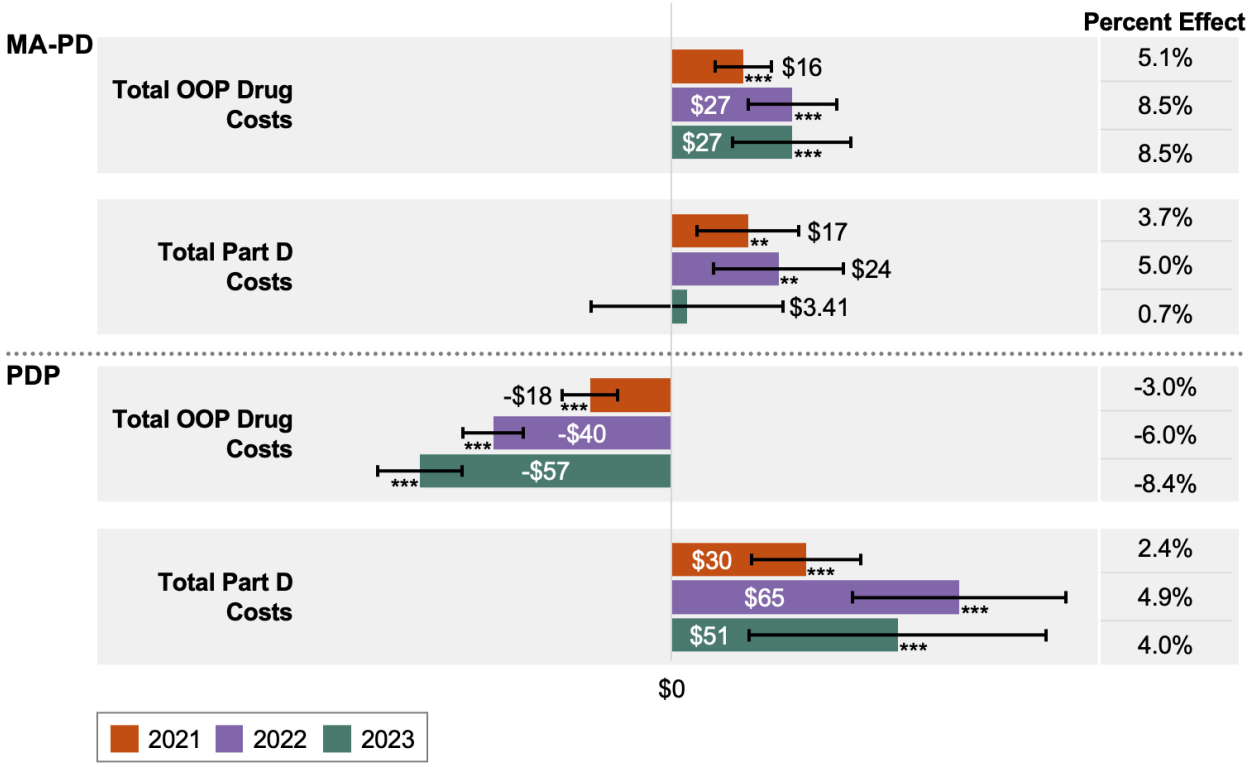
2021, 131 in 2022, and 230 in 2023. However, we did not estimate any statistically significant effects of PDSS on enrollment of LIS-eligible beneficiaries into PDSS-participating PDPs. Similarly, we observed increased enrollment of dual-eligible beneficiaries in PDSS-participating MA-PDs; enrollment increased by 8.1% in 2021 ($p = 0.007$), 10.1% in 2022 ($p = 0.002$), and 24.1% in 2023 ($p < 0.001$). The PDSS estimated effect translated to an additional average 84 dual-eligible beneficiaries in 2021, 93 in 2022, and 164 in 2023. We did not find statistically significant estimates of the impact of PDSS on dual-eligible beneficiary enrollment in PDSS-participating PDPs, which is similar to the effect on LIS-eligible beneficiary enrollment.

Noninsulin User Costs

Beneficiary Cost Outcomes	Hypothesized Effect of PDSS	Anticipated 2023 IRA Impact
Noninsulin User OOP Costs	**Uncertain** impact on OOP drug costs and **increased** total Part D costs for noninsulin users in PDSS-participating plans	Because cost sharing and formularies for noninsulin drugs were established before the IRA was enacted, OOP drug costs and total Part D costs in 2023 are expected to be **similar** to those in earlier model years

Noninsulin users enrolled in PDSS-participating MA-PDs experienced statistically significant average increases of $16, $27, and $27 in their total OOP drug costs in each year of the model ($p < 0.001$ for each year). These impacts represented 5.1% (2021) and 8.5% (2022 and 2023) increases in OOP drug costs in each year, compared with what we would have expected without the model. However, noninsulin users enrolled in PDSS-participating PDPs experienced statistically significant decreases in their total OOP drug costs in all years, with an estimated $18, $40, and $57 average decrease in each year ($p < 0.001$ in all years). These effects represented 3.0%, 6.0% and 8.4% decreases in OOP drug costs in each year.

Figure 8.2. Estimated Effect of PDSS on Noninsulin User Part D Costs, by Plan Type and Year



SOURCE: Authors' analysis of Part D event and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the beneficiary-level DD regression models for each year of the model. The comparison groups consisted of noninsulin users enrolled in nonparticipating plans. The column labeled "Percent Effect" indicates the percentage by which the estimated effect is lower (or higher) compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

We also found statistically significant impacts of PDSS on total Part D costs for noninsulin users, for both PDSS-participating MA-PDs and PDPs. PDSS was associated with a statistically significant $17 and $24 increase in total Part D costs in 2021 and 2022 ($p < 0.01$ for both years), but we did not find a statistically significant association in 2023 (estimated effect of –$3.41, $p = 0.76$). We found a positive and statistically significant association of PDSS with noninsulin user total Part D costs in PDSS-participating PDPs in all years. PDSS was associated with increases in average total Part D costs of $30, $65, and $51 in each of the three years ($p < 0.001$ for 2021 and 2022, $p = 0.003$ for 2023). These effects corresponded to estimated 2.4%, 4.9%, and 4.0% increases in total Part D costs for noninsulin users relative to what would have been expected in the absence of the model. The flip in sign for the estimated effects for PDP noninsulin user OOP costs compared with total Part D costs suggests that premium increases for the plans in which beneficiaries were enrolled played an important role in mitigating any impacts of cost reductions for this group of beneficiaries.

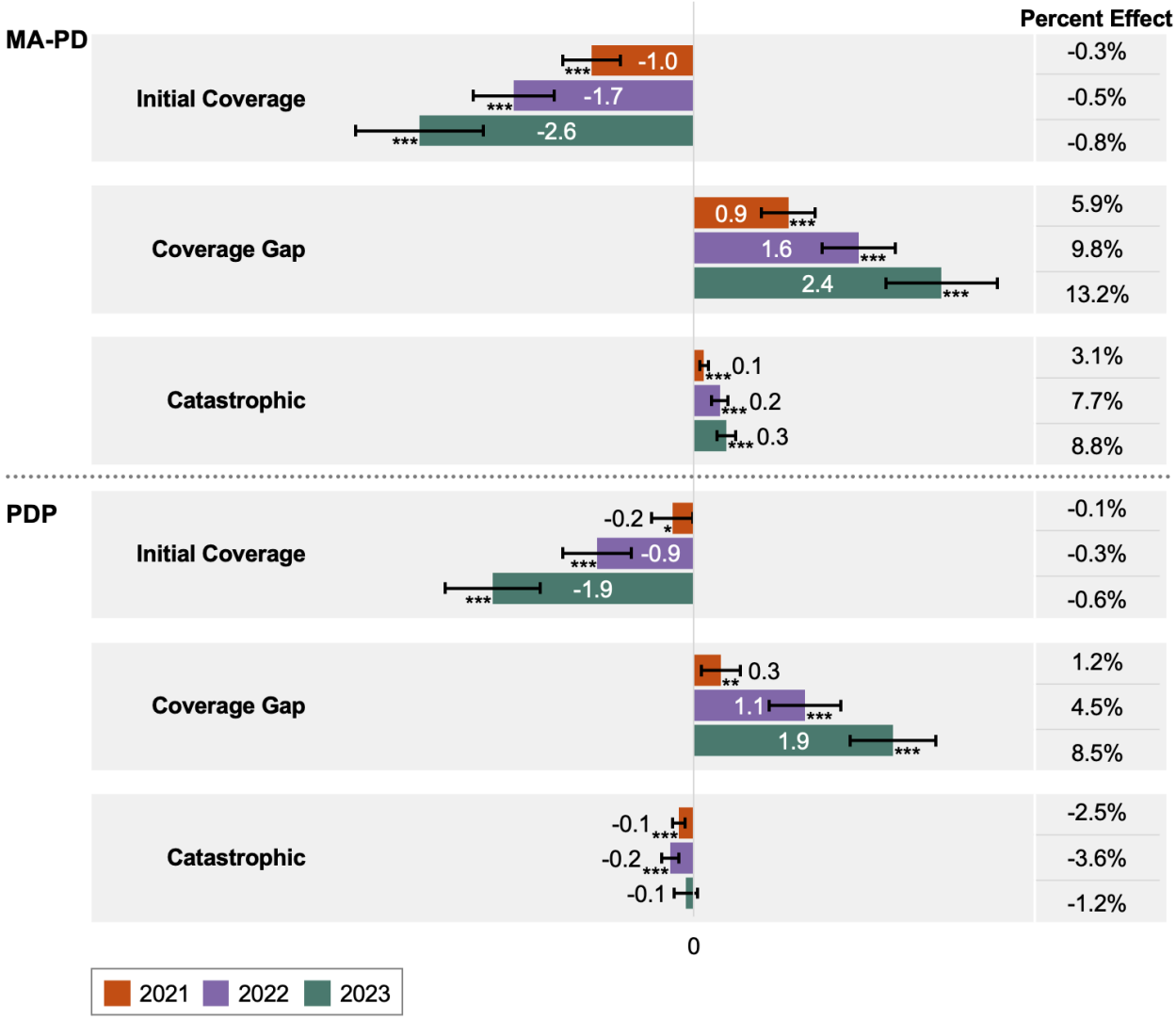
Time Spent in Each Benefit Phase by Noninsulin Users

Beneficiary Cost Outcomes	Hypothesized Effect of PDSS	Anticipated 2023 IRA Impact
Benefit Phases, Noninsulin Users	**No change** in the time spent in the different benefit phases by noninsulin users because of the model	Because cost sharing and formularies for noninsulin drugs were established before the IRA was enacted, the time spent in each benefit phase in 2023 is expected to be **similar** to those in earlier model years

PDSS was associated with statistically significant impacts on the time that noninsulin users spent in the different benefit phases (Figure 8.3). We estimated that PDSS was associated with small increases in the number of days spent in the coverage gap and catastrophic phases of the benefit for noninsulin users enrolled in PDSS-participating MA-PDs. Specifically, noninsulin users spent on average 0.9 to 2.4 additional days in the coverage gap ($p < 0.001$ for all years) and 0.1 to 0.3 additional days in the catastrophic phase ($p < 0.001$ for all years). These effects corresponded to 3.1% to 13.2% additional days relative to what would have been expected in the absence of the model. However, we estimated that noninsulin users in PDSS-participating MA-PDs spent on average 1.0 to 2.6 fewer days in the initial coverage phase ($p < 0.001$ for all years), reflecting 0.3% to 0.8% fewer days.

PDSS was associated with increased time spent in the coverage gap phase of the benefit for noninsulin users in PDSS-participating PDPs, but time spent in the initial coverage and catastrophic phases decreased. These effects were not statistically significant for all years. We estimated a decrease of 0.2 to 1.9 days in the initial coverage phase ($p = 0.039$ for 2021, $p < 0.001$ for 2022 and 2023). These impacts reflected a 0.1% to 0.6% decrease in the time spent in the phase. We estimated an increase of 0.3 to 1.9 days in the coverage gap for noninsulin users in PDSS-participating PDPs ($p = 0.007$ for 2021, $p < 0.001$ for 2022 and 2023), corresponding to a 1.2% to 8.5% increase in the number of days in the coverage gap for those years. Finally, we estimated that PDSS was associated with a 0.1 to 0.2 decrease in the number of days spent in the catastrophic phase in 2021 and 2022 ($p < 0.001$), but we estimated no statistically significant impact for 2023 (effect size of –0.1, $p = 0.17$). For 2021 and 2022, these estimates corresponded to 2.5% and 3.6% decreases in the number of days spent in the catastrophic phase.

Figure 8.3. Estimated Effect of PDSS on Time Spent by Noninsulin Users in Part D Benefit Phases, by Plan Type and Year



SOURCE: Authors' analysis of Part D event and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$. This figure shows average coefficients on the PDSS implementation indicator from the beneficiary-level DD regression models for each year of the model. The comparison groups consisted of noninsulin users enrolled in nonparticipating plans. The column labeled "Percent Effect" indicates the percentage by which the estimated effect is lower (or higher) compared with what would have been expected in the absence of the model. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

Summary

PDSS was associated with statistically significant increases in enrollment by noninsulin users in both PDSS-participating MA-PDs and PDPs. We also found that PDSS was associated with increases in total Part D costs for noninsulin users enrolled in PDSS-participating MA-PDs and PDPs, although the estimate was not statistically significant for PDSS-participating MA-PDs in

2023. For MA-PDs, we also found increases in enrollment of dual-eligible and LIS-eligible beneficiaries but did not find statistically significant changes in enrollment for these two groups in PDSS-participating PDPs. These findings suggest that PDSS-participating MA-PDs may have improved benefit design or other plan features to attract or retain beneficiaries who would not directly benefit from PDSS. Noninsulin users enrolled in PDSS-participating MA-PDs experienced increases in total OOP drug costs and total Part D costs and spent less time in the initial coverage phase and more time in the coverage gap and catastrophic phases. On the other hand, PDSS was associated with a decrease in total OOP drug costs but an increase in total Part D costs for noninsulin users in PDSS-participating PDPs, and noninsulin users spent less time in the initial coverage phase and more time in the coverage gap phase, but slightly less time in the catastrophic phase. The OOP drug cost and benefit phase findings complement each other for the MA-PD results in that increased OOP drug costs may suggest that noninsulin users spent less time in the earlier phases of the benefit. However, the findings for PDPs suggest that OOP drug costs may have declined but that gross drug costs increased for noninsulin users, which would translate to less time in the initial coverage phase because gross drug costs determine when beneficiaries exit that phase. Taken together, these findings suggest that PDSS had some impact on beneficiaries not targeted by the model.

Chapter 9. Conclusions

The mixed-methods evaluation of all three years of PDSS yielded important insights into the impact of reducing beneficiary Part D cost sharing for insulins on a variety of outcomes, including costs, utilization, adherence, and health. This chapter summarizes our findings by stakeholder group (insulin users, Part D payers, and nontargeted beneficiaries), compares the estimated effects with our hypothesized outcomes, presents evaluation limitations, and concludes with some lessons learned for future Part D–focused model tests.

Insulin Users

PDSS broadly reached its goals for insulin users, who were directly targeted by the model. The hypothesized effects of the model included increased utilization of and adherence to insulins and lower OOP costs overall; our evaluation findings suggest that these effects materialized. Premium increases were not expected—or observed—among MA-PDs because of their ability to use MA rebate dollars to "buy down" the Part D supplemental premiums that went up because of the increased cost of the coverage for model drugs. Among PDPs, premium increases were expected because these plans cannot use MA rebate dollars in the same way. Yet it appears that PDSS-participating PDPs were generally able to keep average premium increases low; we estimated an average increase in Part D premiums only in 2022. Lower insulin costs also drove decreased overall OOP drug costs for insulin users, another expected outcome of the model. These lower OOP drug costs held even in 2023 during the simultaneous implementation of the IRA insulin copayment provision, although the decreases were attenuated that year. Estimated declines in overall Part D costs for insulin users were broadly similar for MA-PDs and PDPs and for most years of the model, suggesting that most increases in plan premiums for insulin users were outweighed by lower insulin copayments. However, we found that PDSS was associated with increased Part D costs for insulin users enrolled in PDSS-participating PDPs in 2023, suggesting that the increased premiums for PDPs in that year outweighed the relatively smaller decrease in total OOP drug costs. The model's lower insulin copayments appeared to have an impact on the time that insulin users spent in the latter two Part D benefit phases. Specifically, we found that they spent more time in the coverage gap phase and less time in the catastrophic phase.

Nonetheless, PDSS seems to have increased MA and Part D risk scores among insulin users in both PDSS-participating MA-PDs and PDPs, particularly in the earlier years of the model. Higher risk scores lead to higher payments from Medicare to MA and Part D plans as compensation for providing coverage to apparently higher-risk enrollees, although we did not find that the estimated higher risk scores for insulin users were associated with higher costs to

Medicare. The risk score finding was unexpected; improved adherence to insulin was hypothesized to slow the development of short-term diabetes complications and potentially other diagnoses that could increase the risk score. However, less than half of interviewed POs and only 6% of interviewed insulin users noted improvements in health status because of the model, suggesting that the time frame of PDSS might have been too short to demonstrate improvements in health outcomes. Although about one-quarter of interviewed insulin users said that their doctors had detected improvements in their blood sugar levels, no statistically significant evidence surfaced in our data modeling of an effect of PDSS on blood sugar control for those enrolled in PDSS-participating MA-PDs. Blood sugar control is an immediate goal of insulin prescribing, and we expected to see improved control even within the relatively short time frame of the model. However, data limitations likely reduced our ability to detect such changes in two important ways: (1) The outcome is measured only for a small sample of beneficiaries in each year, and (2) we cannot track the same beneficiaries' blood sugar levels over multiple years of the model. Our statistical approach also had some limitations and was not able to leverage within-beneficiary changes for this outcome.

The effect of the model on outcomes considered to be short-term diabetes complications was mixed among MA-PDs and PDPs. For insulin users' inpatient stays and ED visits for diabetes-related complications, we found decreases among PDSS-participating MA-PDs in 2023 but a statistically significant increase in inpatient stays among insulin users enrolled in PDSS-participating PDPs in 2022. We expected to see decreased complications, so the increase in inpatient stays for those enrolled in PDSS-participating PDPs was surprising. Nonetheless, the small effect size translates to an increase of 1.5 inpatient stays per 1,000 beneficiaries in a given year. In addition, none of the interviewed insulin users reported changes in inpatient hospital stays or ED visits.

Payers

The anticipated effects of the model on Part D payers—plans, manufacturers, and CMS—varied and were uncertain in some cases. Our analysis covered multiple potential financial effects on payers, including changes to Part D bids and administrative costs, manufacturer rebates and gap discount payments, reinsurance costs and PMPM Part D coverage costs to Medicare, and overall medical spending.

For **plans**, PDSS was not expected to affect Part D basic bids, but we did observe a statistically significant average increase among MA-PDs and decreases among PDPs. PDPs have increasingly submitted negative Part D basic bids over time, so we also included the supplemental Part D premium in our analysis and found a positive, significant effect of PDSS on the bid plus supplemental benefit costs for PDSS-participating PDPs, but only for 2022. We were uncertain about how PDSS would affect administrative costs, and we generally found no significant effect on these costs for MA-PDs or PDPs. The model's anticipated effect on overall

medical spending was also unclear. Medical spending among insulin users in PDPs increased in 2021 and 2022, but decreased in 2023; it is possible that the 2022 estimated increase in inpatient stays due to diabetes-related complications might partially explain these findings. We found no estimated effect of PDSS on PMPM average medical spending for PDSS-participating MA-PDs in any year, however.

For **manufacturers**, we found that PMPM gap discount payments and total drug rebates increased to both MA-PDs and PDPs. Gap discount payments were expected to rise because PDSS changed the structure of the Part D benefit contributions such that manufacturers' contributions increased. The anticipated impact of PDSS on manufacturer rebates was uncertain. Because the model generally reduced beneficiary OOP costs for insulin users, our findings suggest that these reductions were paid for, at least in part, by increased manufacturer payments.

The anticipated financial effects of the model on **CMS** were uncertain, especially given the implementation of the IRA insulin provision in 2023. We found significant decreases in Part D costs to Medicare for both MA-PDs and PDPs in all three years. Although there were significant decreases in reinsurance payments to MA-PDs only in 2023, we found decreases to PDPs in all three years. The reductions in reinsurance payments are consistent with the finding that insulin users were less likely to end the year in the catastrophic phase during which reinsurance payments are made.

Spillover Effects

Although we did not expect to see enrollment changes for noninsulin users in participating plans, we did see average increases among both MA-PDs and PDPs. However, only MA-PDs experienced average increases in enrollment by dual-eligible and LIS-eligible beneficiaries, suggesting that these beneficiaries may have been attracted by other benefits offered by these plans.

Noninsulin users in MA-PDs also experienced statistically significant increases in total OOP drug costs, but we estimated average increases in total Part D costs for most years for both MA-PDs and PDPs (except for a not statistically significant result for MA-PDs in 2023). These increases were expected in part because noninsulin users might pay more for their Part D OOP drug costs and total Part D costs if their plans adjusted other benefits in response to participation in PDSS.

Impact of the Inflation Reduction Act in 2023

The implementation of the IRA insulin copayment provisions in 2023, the last year of the model, altered expectations of the impact of the model in that year because it enabled all insulin users in Part D plans to access the maximum $35 copayment for a one-month supply of insulin. As expected, the estimated effect of PDSS was generally smaller—but still present—in 2023 compared with effects in the previous two years of the model. A couple of factors may have

influenced this outcome, including the time needed to help make beneficiaries aware of the availability of the lower insulin copayments and the lag in implementation of the $35 maximum copayments at the pharmacy counter (CMS, 2023a), which may have led to fewer beneficiaries in nonparticipating plans filling their insulin prescriptions in the early part of 2023 and contributed to the statistically significant effects that we estimated with regard to insulin utilization, adherence, and OOP drug costs for insulin users in PDSS-participating plans in that year.

Limitations

Although comprehensive, our analytic approach has some limitations. First, we focused our analyses on beneficiaries who were continuously enrolled in the same plan (PDSS-participating plans or comparison plans) for at least two consecutive years. Therefore, our results do not reflect the effects of the model on beneficiaries who elected to enroll in a PDSS-participating plan after that plan joined the model. However, our results do provide insights into how outcomes changed for both insulin and noninsulin users enrolled in the same plan for a continuous period, thereby better isolating the impacts of changes to benefit design due to PDSS from other changes to benefit design experienced due to a beneficiary's switching plans.

Second, the strength of our findings is improved by entropy balancing weights derived at the plan and beneficiary levels for each analysis to align the participating and comparison groups in terms of key characteristics and pre-trends in the outcome being assessed, which we expect to improve the likelihood of meeting the key DD assumption of parallel trends. Fortunately, the balancing results for all analyses generally indicated that we were able to achieve good balance. In cases where we found it difficult to achieve good balance, which was usually isolated to one or two characteristics, we maintained the characteristic in the balancing algorithm and included it as a control variable in the DD regression step.

Third, requiring insulin utilization in the pre-period for beneficiaries to be included in our insulin user cohort omits from our analyses those beneficiaries who may have delayed or not taken insulin before PDSS began because of costs and those beneficiaries who began to take insulin because of the model. We include additional analyses in this report showing the characteristics of beneficiaries who switched into a PDSS-participating plan after it joined the model and then started using insulin to provide insights into this group of beneficiaries.

Fourth, although we invited all PDSS-participating POs to complete our annual surveys, not all POs participated in every survey or answered all of the questions. Moreover, our PO, beneficiary, SHIP counselor, and insurance agent interview samples were relatively small and thus not representative.

Finally, although our qualitative data analyses generally supported the results of our data modeling, there were instances where self-reported data from POs did not align with the results of our quantitative model estimates. This is not surprising because POs often entered multiple

plans and even both plan types into the model. While our regression models estimated impacts separately for MA-PDs and PDPs by comparing trends in key outcomes before and after the model started and relative to nonparticipating plans, PO representatives generally focused on changes in outcomes over time. Additionally, social desirability bias may have influenced their responses to our survey and interview questions; that is, PO representatives might have provided responses that they believed were expected or favorable, rather than fully accurate.

Lessons Learned from the Model

Looking forward, there are several lessons to be learned from the PDSS evaluation that may inform future Part D drug–focused models. First, given the close association between high beneficiary OOP drug costs and low utilization, models that reduce Part D drug costs as a barrier to access can increase utilization of the targeted drug(s), but these models may also want to offer components that more directly address nonfinancial sources of medication nonadherence to increase their impact (Petroski et al., 2024). Second, more distal outcomes, including health outcomes, may be less likely to manifest during a relatively short model test time frame. Thus, longer evaluation periods may be need for prescription drug model tests. Third, aside from the optional R&I component, PDSS featured a relatively straightforward design that minimized POs' administrative costs, a feature that model participants valued. The need to design the R&I program might have contributed to the low uptake of this component. Model designs that do not require participating plans to develop their own interventions may be easier to implement and evaluate, increasing the likelihood of identifying effects attributable to the model itself and explaining the mechanisms of action. Finally, working within the parameters of the Part D benefit design to test adjustments to cost sharing and other barriers to access may further improve beneficiary access to and utilization of medications, especially with the additional IRA Part D benefit design changes that were in effect after the end of PDSS in December 2023.

Appendix A. Data Sources and Quantitative Methods

This appendix provides more detail on the data sources used to construct the quantitative outcome measures and the quantitative methods used for the analyses presented in this report.

Data Sources

Table A.1 summarizes the location and unit of observation for secondary data sources that we used for the quantitative analyses presented in this report.

Table A.1. Secondary Data Sources

Data Source	Location	Data Considered Final	Unit of Observation
PDE	IDR	Summer of following year	Beneficiary
MA encounter	IDR	13 months after end of plan year	Beneficiary
FFS claims	IDR	12 months after end of year	Beneficiary
Enrollment and disenrollment files	IDR	Second week of every month	Beneficiary
Medicare beneficiary summary file	IDR	June of the following year	Beneficiary
Medicare Bayesian-Improved Surname Geocoding 2.0	RAND	Fall of following year	Beneficiary
Risk scores (HCCs and RxHCCs)	IDR	Fall of the following year	Beneficiary
HEDIS	CMS	Every fall prior to open enrollment	Beneficiary
Plan bids	OACT	September of year prior to plan offering	Plan
HPMS plan information	CMS	Continuous	Plan
Summary DIR reports	HPMS	June of the following year	Plan
PRS	HPMS	September of the following year	Plan
CMS Star Ratings	Public	Every fall prior to open enrollment	Contract
PDSS application data	CMS Innovation Center	Fall (for upcoming plan year)	PDSS-participating plans and manufacturers
Model-eligible insulin list	CMS Innovation Center	Fall (for upcoming model year)	PDSS-participating manufacturers
Area Health Resources File	HRSA	NA	County

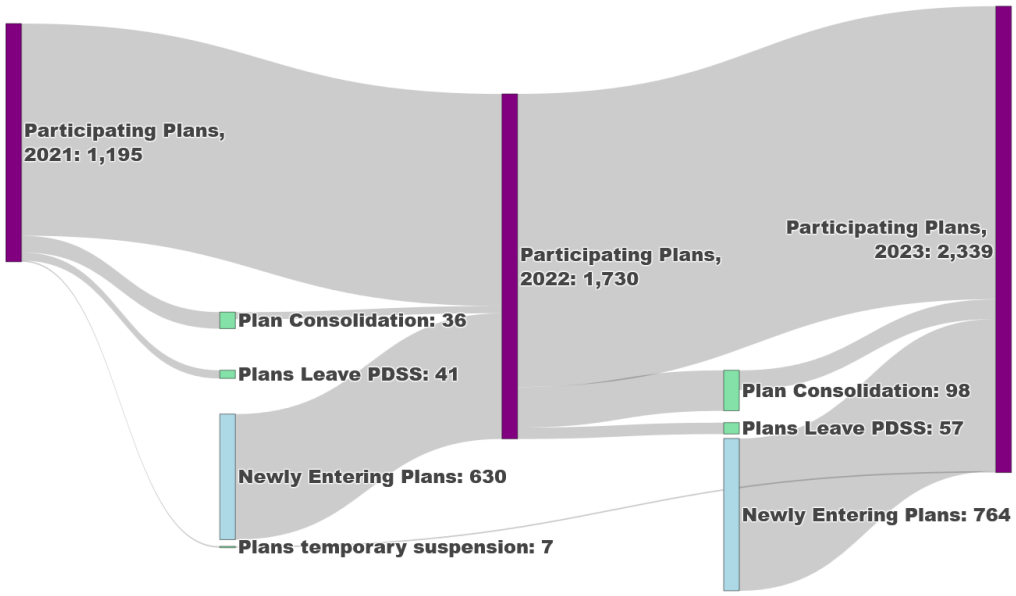
NOTE: HCC = Hierarchical Condition Category; HRSA = Health Resources and Services Administration; IDR = Integrated Data Repository; NA = not applicable; OACT = CMS Office of the Actuary; RxHCC = Prescription Drug Hierarchical Condition Code.

Identification of Participating and Comparison Plans

Participating Plans

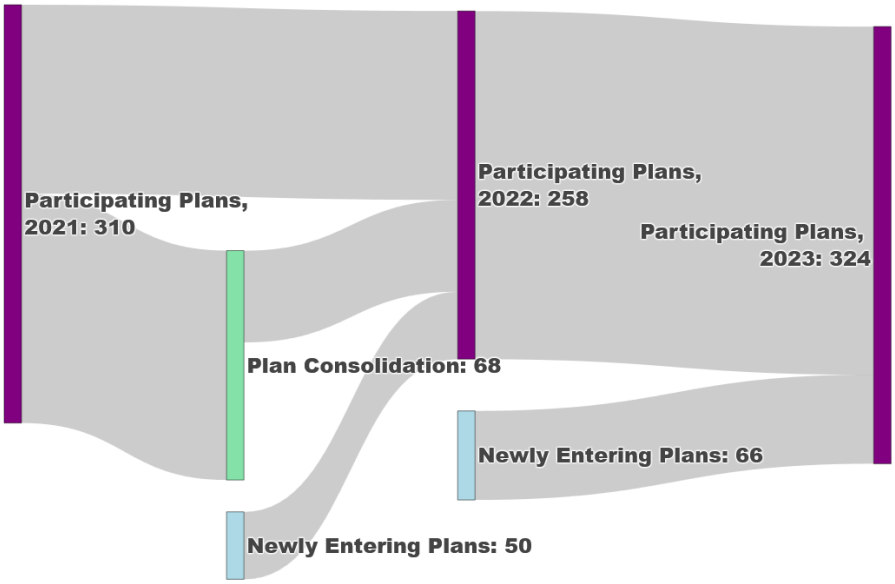
We defined *participating plans* as those that participated in at least one year of the model—that is, in 2021, 2022, and/or 2023. We included plans in the participating group only for those years in which they participated in the model. Figures A.1 and A.2 show the participation patterns for plans across the three model years for MA-PDs and PDPs, respectively. The majority of participating MA-PDs in 2021 continued to participate in 2022, and similarly, the majority of participating MA-PDs in 2022 continued to participate in 2023. In 2022, more than 600 MA-PDs newly entered the model, and in 2023, more than 700 MA-PD plans newly entered. In both 2021 and 2022, a small number of plans either terminated or declined to continue in the model. A similar pattern was observed for PDPs, although no PDPs terminated or declined to continue in the model.

Figure A.1. PDSS-Participating MA-PD Patterns, 2021 to 2023



SOURCE: Authors' analysis of PDSS-participating plan data.
NOTE: "Plans Leave PDSS" includes those that terminated entirely (left the MA Program) and those that continued offering MA coverage but left the model.

Figure A.2. PDSS-Participating PDP Patterns, 2021 to 2023



SOURCE: Authors' analysis of PDSS-participating plan data.

We included PDSS-participating MA-PDs and PDPs in the regression analyses described later in this appendix if they had at least one year of pre-period data before joining the model (e.g., they did not join the model in their first year of existence). We also excluded plans with no enrollment as of July 2023 and removed plans that left the model after 2021 and rejoined it in 2023, because very few plans were in this participation pattern and the entropy balancing approach would likely not have converged with so few plans. Finally, we excluded one plan from the plan-level cost and bid outcome analyses because there were no bid data for that plan. As explained in Appendix B, we included plans (MA-PDs only) in the analysis of medical spending only if we were able to clearly crosswalk their medical spending year data to the bid data year (medical spending data are from two years prior to the bid data year). The number of PDSS-participating plans included in the different regression analyses is shown in Table A.2.

Table A.2. Number of PDSS Participating Plans Included in Regression Analyses, by Plan Type

Description	MA-PDs	PDPs
Participating plans in 2023 HPMS data	2,339	324
Removed plans with no enrollment in July 2023	2,331	324
Removed plans that were part of small participation patterns: • Left and rejoined the model • Did not have pre-period data	1,698	317
Number of plans included in analyses of cost and bid outcomes (excludes one plan missing bid data)	1,697	317
Number of plans included in analysis of MA-PD medical spending	1,152	NA

SOURCE: Authors' analysis of HPMS and other CMS administrative data.
NOTE: NA = not applicable.

Comparison Plans

We defined *comparison plans* as those plans that did not participate in PDSS in any of the three years of the model. For the second evaluation report (Taylor et al., 2023), we used eligible nonparticipating MA-PDs and PDPs (e.g., those enhanced Part D plans that did not participate in the model) as our main comparison groups to make them as similar as possible to the PDSS-participating plan groups. However, as PDSS participation increased in each subsequent year of the model, the number of eligible but nonparticipating PDPs, in particular, declined substantially, raising concerns about the validity of findings with a smaller comparison group. Therefore, for this evaluation, we used the "all nonparticipating" plans group as the main comparison group to ensure a sufficient sample size of plans, especially for the PDPs.

As with our earlier evaluation (Taylor et al., 2023), we excluded from the comparison group 1876 Cost, 1833 Cost, Employer/Union Only Direct Contract PDP, Medicare-Medicaid Plan HMO, National Pace, Private Fee-for-Service, dual-eligible Special Needs Plans, and Point-of-Sale Contractor plans because they had different targeted populations or Part D benefit structures compared with Part D plans available to the general Medicare population.

Table A.3 shows the characteristics of PDSS-participating MA-PDs in each year of the model, 2021 through 2023, along with the characteristics of nonparticipating plans for 2023. A more detailed discussion of differences across model years and of the nonparticipating plans in 2023 is provided in Chapter 2.

Table A.3. Characteristics of PDSS-Participating MA-PDs, 2021 to 2023

Plan Characteristic	2021 PDSS Participants: MY 2021	2022 PDSS Participants: MY 2022	2023 PDSS Participants: MY 2023	Nonparticipants in All Years: MY 2023
N	1,195	1,730	2,339	1,698
Mean number of enrollees	7,112.4	6,414.1	6,013.1	3,393.4
Mean age	72.3	72.5	72.4	72.1
Original reason for Medicare entitlement				
Age	75.7%	76.6%	75.9%	72.3%
Disability	24.1%	23.2%	23.7%	26.8%
ESRD	0.2%	0.2%	0.3%	0.6%
Percentage of insulin users	8.6%	8.2%	7.8%	7.1%
Mean number of 30-day insulin fills among insulin users	10.6	10.5	10.4	10.2
Percentage of noninsulin antidiabetic medication users	22.5%	23.4%	24.3%	22.6%
Percentage of beneficiaries in benefit phase by the end of year				
Deductible	1.0%	0.8%	0.6%	1.6%
Initial coverage	70.4%	70.9%	70.0%	68.0%
Coverage gap	15.4%	15.3%	15.9%	14.0%
Catastrophic	5.6%	5.4%	6.3%	8.2%
Mean Part D risk score	0.93	0.92	0.94	1.02
Median household income	$67,242	$67,959	$67,892	$70,020
Urbanicity	1.8	1.8	1.8	1.8
Drug benefit type				
Actuarially Equivalent	0.0%	0.0%	0.0%	0.0%
Basic Alternative	0.0%	0.0%	0.0%	3.4%
Defined Standard	0.0%	0.0%	0.0%	8.2%
Enhanced Alternative	100.0%	100.0%	100.0%	88.5%
Offer non-zero Part D deductible	45.4%	36.7%	25.7%	45.7%
Mean plan deductible	$102.73	$82.10	$63.89	$153.26
Star Rating: Getting Needed Drugs	3.47	3.82	3.57	3.01
Star Rating: Diabetes Medication Adherence	3.96	3.89	3.20	3.01
Full gap coverage—generics only	29.0%	54.7%	59.5%	56.7%
Full gap coverage not offered	71.0%	45.2%	40.4%	43.3%
Partial gap coverage—brands only	1.3%	0.6%	0.9%	0.0%
Partial gap coverage—generics only	0.1%	2.4%	0.6%	8.8%
Partial gap coverage not offered	97.0%	94.6%	93.3%	87.2%
For profit	80.7%	77.5%	80.9%	81.9%
Offer non-zero Part D total premium	39.1%	37.1%	31.8%	38.3%
Part C premium	$11.57	$10.08	$7.47	$8.23
Part D buydown	$54.49	$62.86	$71.25	$50.09

SOURCE: Authors' analysis of CMS and other data. Please see Appendix Table A.1 for details on data sources.
NOTE: MY = measurement year.

Table A.4 presents the descriptive statistics for PDSS-participating PDPs in 2021 through 2023, along with descriptive statistics for nonparticipating plans in 2023.

Table A.4. Characteristics of PDSS-Participating PDPs, 2021 to 2023

Plan Characteristic	2021 PDSS Participants: MY 2021	2022 PDSS Participants: MY 2022	2023 PDSS Participants: MY 2023	Nonparticipants in All Years: MY 2023
N	310	258	324	490
Mean number of enrollees	17,406.2	23,455.7	24,334.6	21,558.6
Mean age	74.0	74.8	74.5	70.6
Original reason for Medicare entitlement				
Age	86.7%	87.4%	88.7%	75.4%
Disability	12.8%	12.2%	11.0%	23.9%
ESRD	0.3%	0.3%	0.3%	0.6%
Percentage of insulin users	8.7%	9.6%	7.7%	5.6%
Mean number of 30-day insulin fills among insulin users	11.3	11.2	11.2	10.4
Percentage of noninsulin antidiabetic medication users	21.0%	22.2%	21.2%	18.9%
Percentage of beneficiaries in benefit phase by the end of year				
Deductible	0.7%	0.6%	1.4%	15.4%
Initial coverage	69.8%	66.9%	66.8%	52.1%
Coverage gap	18.3%	20.7%	19.3%	14.5%
Catastrophic	7.4%	8.3%	8.2%	10.5%
Mean Part D risk score	0.85	0.87	0.86	0.97
Median household income	$68,837	$68,993	$68,903	$68,109
Urbanicity	1.6	1.6	1.6	1.6
Drug benefit type				
Actuarially Equivalent	0.0%	0.0%	0.0%	51.2%
Basic Alternative	0.0%	0.0%	0.0%	12.5%
Defined Standard	0.0%	0.0%	0.0%	0.0%
Enhanced Alternative	100.0%	100.0%	100.0%	36.3%
Offer non-zero Part D deductible	77.1%	53.5%	63.0%	97.4%
Mean plan deductible	$248.27	$205.19	$253.63	$479.74
Star Rating: Getting Needed Drugs	3.10	3.18	2.98	2.92
Star Rating: Diabetes Medication Adherence	3.65	3.56	2.67	2.42
Full gap coverage—generics only	22.3%	27.1%	42.9%	2.7%
Full gap coverage not offered	77.7%	72.9%	57.1%	97.4%
Partial gap coverage—brands only	0.0%	0.0%	0.0%	0.0%
Partial gap coverage—generics only	0.0%	0.0%	0.0%	0.0%
Partial gap coverage not offered	100.0%	100.0%	100.0%	100.0%
For profit	100.0%	99.6%	99.7%	95.7%
Offer non-zero Part D total premium	100.0%	100.0%	100.0%	100.0%

SOURCE: Authors' analysis of CMS and other data. Please see Table A.1 for details on data sources.
NOTE: MY = measurement year.

MA-PDs and PDPs can change their plan IDs over time and crosswalk beneficiaries from the previous plan ID to the new ID. To account for plan ID changes over time and ensure that we appropriately assigned beneficiaries to plans, we used the Service Area Crosswalk from HPMS

for MA-PDs to identify changes to MA-PDs, segments, and service areas over time.[7] We used the publicly available plan crosswalk for PDPs to crosswalk PDPs to new plan IDs. Because the vast majority of plan ID changes over time were due to consolidations, we made the final model year (2023) the reference year in our analysis and rolled up plan-level data to the reference year by either summing variables that can be added (such as enrollment) or by weighting a variable by the enrollment of the plans that consolidated.

Identification of Insulin Users and Noninsulin Users

As described in the second evaluation report (Taylor et al., 2023), which was focused solely on 2021 outcomes, we conducted analyses separately for two groups of beneficiaries that may be affected by the model. The first group consists of *insulin users*, defined as those beneficiaries who filled at least one 2021 model-eligible insulin in 2020 (before the model began). The second group consists of *noninsulin users*, identified as enrollees of the plan who were not in the insulin user group (that is, those who did not fill at least one 2021 model-eligible insulin in 2020). Beneficiaries who were eligible for the LIS were not eligible to participate in the model and, therefore, were not included in either analytic sample.

For this third evaluation report, we extended the original cohort approach to allow for more beneficiaries to enter the sample as their plans joined PDSS in later years of the model (2022 and 2023). Therefore, we included beneficiaries in our insulin user or noninsulin user groups if they were enrolled for the full year before their plans joined PDSS (or in the same plans if they were in comparison plans) and continued to be enrolled in those plans for at least one full year after their plans joined PDSS. Insulin users were included in the sample if they met the enrollment criteria and also used at least one model-eligible insulin in the year before their plans joined the model. Noninsulin users were those otherwise eligible for the sample but who did not use insulin in that pre-period year. Table A.5 shows the number of beneficiaries in our insulin user and noninsulin user cohorts who met these criteria, regardless of how many years of post-PDSS data they might have contributed. We included as many years of post-PDSS-participation data in the analyses as possible, although we included only those years in which beneficiaries were enrolled in the same plans.

[7] We calculated plan-level measures for those plans that had multiple segments by rolling up county- or segment-level data to the plan level.

Table A.5. Number of Insulin Users and Noninsulin Users in Cohorts, by Plan Type

Plan Type	2021 Insulin Users	2022 Insulin Users	2023 Insulin Users	2021 Noninsulin Users	2022 Noninsulin Users	2023 Noninsulin Users
MA-PDs						
PDSS-participating	362,578	320,276	262,029	5,651,985	5,140,617	4,393,483
Comparison	169,261	164,147	136,889	3,056,319	3,201,959	2,736,700
PDPs						
PDSS-participating	287,921	255,537	214,311	4,694,399	4,644,854	4,112,643
Comparison	264,022	232,493	189,151	5,233,316	5,140,121	4,285,726

SOUCE: Authors' analysis of CMS administrative and other data. Please see Table A.1 for additional information on data sources.
NOTE: Numbers of distinct beneficiaries have been added within each PDSS participation year, taking into account when a beneficiary's plan joined PDSS in determining the first model year and the pre-period for that beneficiary. For example, if a beneficiary's plan joined PDSS in 2022 and the beneficiary were enrolled in that plan for both 2021 and 2022, the beneficiary's pre-period would be 2021 and their first model year would be 2022.

Overview of Regression Models

In this report, we present our analyses of data from multiple post-PDSS years, in contrast to the single year of post-PDSS data considered in the first evaluation report. Accordingly, we used a staggered DD approach to estimate effects. A large literature has developed recently that highlights the shortcomings of using the classical two-way fixed effects approach to estimating DD models when treatment adoption is staggered over time (e.g., Callaway and Sant'Anna, 2021). Our approach was designed to accommodate the insight that using already-treated study units as comparisons to understand the impact of changing into a participating plan can bias effect estimates.

An additional difficulty in our setting is the fact that—as we analyzed more years of data—fewer and fewer plans and beneficiaries were "stable" across the full study period. For example, beneficiaries could switch plans, disenroll, or pass away. Similarly, plans could appear mid-study or disappear. For this reason, we adopted a "relaxed stable cohort" approach, which requires that—for beneficiary-level analyses—beneficiaries have at least one pre-PDSS year and one post-PDSS year of data in the same plan to be eligible for inclusion as a participating beneficiary. As shown in Table A.5 above, this approach results in fewer beneficiaries being included in the later cohorts of the model because fewer plans newly joined the model in those later years. For plan-level analyses, plans have to have at least one year of data before and one year of data after joining PDSS. Taking this relaxed stable cohort approach allowed us to make use of pre-to-post-period changes within a plan or for a beneficiary while preserving much more of the sample than would have been possible if we had required observations in all study years to be included in the analytic sample. We implemented a bootstrapping approach to appropriately estimate CIs so as to allow, for example, a control beneficiary with observations in all study

years to serve as a control for all treated observations, regardless of which years of data were available.

The second key change from the previous evaluation report is our handling of the parallel trends assumption for DD models. In that earlier analysis, we evaluated the sensitivity of results to violations of parallel trends as measured relative to the deviation from parallel trends observed in the pre-period (Rambachan and Roth, 2023). For these analyses, we used entropy balancing (Hainmueller, 2012) to weight pre-period trends to be equivalent in the PDSS-participating and comparison groups. Entropy balancing is a tool that can be used to re-weight the observations so that the mean values of potentially confounding variables are equal between the participating and comparison samples. The benefit of this approach is that it is expected to produce estimates that display less bias due to the violation of parallel trends than the approach described in the second evaluation report (Taylor et al., 2023), although it is more difficult to assess the impact of deviations from parallel trends in the post-period. This approach has been used successfully in the MA Value-Based Insurance Design model test evaluation (Eibner et al., 2023), and lessons learned in that study guided our analytical approach for evaluating PDSS. In cases where we only had a single year of pre-PDSS data, we were unable to calculate pre-period trends and, therefore, did not balance on that characteristic. In sensitivity analyses, we assessed the robustness of results to including only observations with at least two pre-period years. Dropping observations with a single pre-period year generally resulted in small changes, so different treatment of this modeling choice would not have substantially affected the evaluation's overall findings.

The plan- and beneficiary-level analyses were the same in most respects; however, the plan-level analyses were weighted on the pre-period trends of the given outcome measure being assessed, as well as a selected set of demographic characteristics, whereas the beneficiary-level analyses were weighted on more characteristics. Because the sample size was much smaller for plans compared with beneficiaries, it could be difficult to balance on many characteristics for the plan-level models. Therefore, we elected to achieve close balance for the pre-period trends rather than include additional variables and potentially achieve a looser balance for pre-period trends to better balance other characteristics. Please see Appendix D for detailed statistics on how well balancing did for each outcome.

More formally, our models took the form of $y_{t,i} = \alpha_i + \eta_{p,t} + \beta_{p,t} \cdot DD_{p,t} + \delta_t X_{p,t,i} + \varepsilon_{p,t,i}$. In this formulation, *t* indexes the year, *i* indexes beneficiaries, *p* indexes patterns of years for which partially stable observations are available, α is a beneficiary-level fixed effect (or plan-level fixed effect for the plan-level outcomes), η is the year fixed effect, β estimates the DD treatment effect for pattern *p* at time *t*, *X* contains covariates, and ε is an error term. These models are also weighted using the entropy balancing weights. Our final effect estimates average $\beta_{p,t}$ across patterns, so that we have a single year-specific average treatment effect estimate. Standard errors are bootstrapped to account for the fact that control observations may be used for more than one pattern.

The one beneficiary-level analysis that does not follow this approach is the blood sugar control measure, because very few beneficiaries with data for this measure satisfied the requirements of our relaxed stable cohort approach. This is because we observed responses for a sample of beneficiaries in each year, and the sampling proportion was such that very few beneficiaries were sampled more than once. Therefore, we took a modified approach that was also used successfully in the MA Value-Based Insurance Design model test evaluation (Eibner et al., 2023)—specifically, for outcomes related to end of life where we typically cannot observe outcomes for a beneficiary in more than one time period. This approach weighted all combinations of participating and nonparticipating beneficiaries in the sample by year to match the means of a single year/participation group. Thus, we reduced differences in the composition of the analytic sample from year to year, both within and across participation status classifications. This is a weaker research design than our primary models, because lacking the ability to use beneficiary-level fixed effects to infer the DD treatment effect substantially increased our reliance on making the groups similar, but our standard approach with observations for a given beneficiary at multiple time periods was not feasible.

The beneficiary-level characteristics are largely the same as those used as covariates in the earlier analyses presented in the second evaluation report (Taylor et al., 2023), although we added county-level characteristics for this evaluation.

Table A.6 presents pre-period descriptive statistics for insulin users in our cohorts before we applied balancing weights.

Table A.6. Selected Pre-Period Descriptive Statistics for Insulin User Cohorts Before Balancing, by Plan Type

Variable	PDSS-Participating MA-PDs	Comparison MA-PDs	PDSS-Participating PDPs	Comparison PDPs
Beneficiary demographics				
Age	72.0	72.0	74.0	72.8
Originally entitled due to age	71.2%	75.4%	82.6%	81.8%
Originally entitled due to disability	28.6%	24.0%	16.8%	17.2%
Beneficiary chronic conditions				
RxHCC flag for kidney disease	0.8%	0.7%	0.8%	0.7%
RxHCC flag for high cholesterol	58.9%	54.6%	57.5%	55.8%
RxHCC flag for CHF	25.6%	20.8%	23.6%	22.1%
RxHCC flag for hypertension	63.8%	63.6%	65.1%	64.8%
Part C risk score (HCC)	1.76	1.58	1.64	1.58
Part D risk score (RxHCC)	1.41	1.33	1.38	1.35
Beneficiary insulin utilization				
Number of 30-day insulin fills	7.3	8.2	8.1	7.9
Any fill of intermediate-acting insulin	3.8%	21.2%	2.9%	3.0%
Any fill of long-acting insulin	57.1%	44.3%	60.9%	59.5%
Any fill of rapid-acting insulin	23.6%	21.5%	29.7%	28.4%
Any fill of insulin pen	54.5%	48.3%	60.3%	60.9%
Any fill of insulin vial	23.3%	33.3%	18.6%	16.3%

Variable	PDSS-Participating MA-PDs	Comparison MA-PDs	PDSS-Participating PDPs	Comparison PDPs
Prescription drug and health care utilization				
Any use of noninsulin antidiabetic medication	71.5%	71.8%	68.5%	69.1%
Number of Part D drug fills per year	43.1	40.2	46.9	46.5
Number of ED visits	0.6	0.6	0.4	0.4
Number of hospitalizations	0.3	0.2	0.3	0.4
County-level characteristics				
Median income for service area	$30,031	$32,805	$31,246	$31,228
Rural	2.9%	2.8%	8.6%	9.6%
Suburban	10.4%	7.0%	15.4%	15.8%
Urban	86.8%	90.5%	76.0%	75.3%
Health professional shortage area:				
No designation	7.6%	5.3%	10.3%	10.0%
Whole county designation	5.7%	3.2%	7.8%	8.2%
Partial county designation	86.8%	91.8%	82.0%	82.5%
Percentage of population over 65	16.5%	15.7%	17.0%	16.9%
Social Deprivation Index	150.84	137.17	137.33	136.89
Original Medicare costs per capita	$10,523	$10,194	$10,205	$10,190

SOURCE: Authors' analysis of CMS administrative and other data. Please see Table A.1 for additional information on data sources.
NOTE: CHF = congestive heart failure; HCC = Hierarchical Condition Category; RxHCC = Prescription Drug Hierarchical Condition Code.

Appendix B. Outcome Measures

This appendix describes our quantitative data collection and analytic methods. We analyzed secondary data on plan- and beneficiary-level outcomes across several domains, such as access to insulins, plan enrollment, time spent by beneficiaries in different phases of the Part D benefit, OOP costs, and costs to plans, manufacturers, and Medicare.

Access Measures

We operationalized *access* as utilization and adherence for the purposes of this evaluation. There are several difficulties with measuring insulin adherence, which informed our selection of adherence measures. The *days supplied* variable associated with prescription data is a key input to many of the adherence metrics, and for injectable medications like insulin, the dosing can vary considerably across patients (Stolpe et al., 2016). As a result of this variation in dosing, we used several measures of insulin utilization and adherence, ranging from simplistic to complex, which we describe in this section.

Covered Insulins

We calculated the average number of covered insulins on participating plan formularies, which we analyzed descriptively only, because covered insulins would affect beneficiary use.

Number of 30-Day Fills

We then measured the number of 30-day insulin fills as an overall metric to capture changes in use across all insulin types, because many beneficiaries could use more than one type of insulin. We think this measure is likely the most sensitive to changes in cost sharing for insulin.

Persistence to Basal Insulin

The most complex measure that we used is the Pharmacy Quality Alliance's Persistence to Basal Insulin (PST-INS) measure (Pharmacy Quality Alliance, 2022). The PST-INS focuses on intermediate- and long-acting insulins only, because these types of insulins are the most commonly used on a regular basis. The measure is designed to capture continued use without large gaps between insulin fills. In contrast to our other measures, the PST-INS excludes beneficiaries with gestational diabetes, who are in hospice, who have ESRD, and who use mixed or concentrated insulins. We classified beneficiaries into two categories—persistent or not persistent—within each calendar year where they have at least one fill of a basal insulin.

Medication Possession Ratio

We calculated an MPR measure for rapid/short-acting insulin types, which were the most commonly used after basal insulin. The MPR calculates the total number of days of insulin supplied and divides that by either the calendar year (for existing users) or the time between the first fill and the end of the calendar year (for new users). Days supplied carried into the subsequent calendar year were truncated at December 31.

We used the MPR because we wanted to see whether the model influences the total number of days supplied for the type of insulin; more-conservative measures, such as a proportion of days covered, would count concurrently filled medications as one. The values for the MPR can range from zero—where a beneficiary would have the insulin for zero days of the year and where they had no days supplied of insulin for the year—to more than one if a beneficiary had more than 365 days' worth of insulin on hand. A zero MPR might also occur if the beneficiary had a fill in the previous year but no fills in the subsequent year.

We required that each beneficiary have at least two fills of a rapid/short-acting insulin to be included in the measure for each model year. We conducted a sensitivity analysis removing the two-fill requirement, and we report those results in Appendix D.

Health Outcome Measures

We accessed the MA and Part D risk scores for insulin users in our regression model sample via the CMS IDR. The risk scores for an individual beneficiary are calculated based on a beneficiary's diagnoses, sociodemographic characteristics, dual eligibility for Medicare and Medicaid, and whether or not the beneficiary resided in the community or an institution in that year. Diagnoses that contribute to a beneficiary's risk score are recorded in the year prior to the risk score being used for payment purposes. For example, for Part D plan year 2023, diagnoses from 2022 were used to adjust the 2023 payments. We used each beneficiary's final MA and Part D risk score for each year and assigned the year of record for the analyses as the year prior to the payment year reflected in the CMS data to evaluate whether PDSS was associated with changes in diagnoses reflected in the risk scores for the year in which the diagnoses were recorded. Given data runout timelines, we used midyear risk scores for the 2023 analyses included in this report.

MA-PDs are required to submit care quality data every year to CMS for use in calculating the MA Star Ratings. One of the HEDIS measures reported is "Diabetes Care—Blood Sugar Controlled (C11)" (CMS, 2023b), which measures the percentage of MA enrollees with diabetes between the ages of 18 and 75 whose most recent HbA1c level was greater than 9%, or who were not tested during that year. We accessed the beneficiary-level data submitted by MA-PDs to CMS for the Star Ratings. These data indicate whether a beneficiary was included in the denominator for the measure for the given year and, if so, whether or not their blood sugar was controlled for that year. Given that insulin is prescribed as a treatment to help control high blood sugar, understanding the extent to which PDSS may have increased the proportion of

beneficiaries with controlled blood sugar would provide important insights into the impact of the model in averting health care complications. Because of the sampling methodology used for this Star Ratings measure, we were not able to observe many beneficiaries in the dataset across multiple years. To address this issue, we implemented an alternative analytic approach that we describe in Appendix A.

Because reduced copayments for insulin might improve adherence to insulin, complications associated with poorly managed diabetes could be reduced. To measure whether PDSS reduced short-term diabetes complications, we constructed three measures of health care utilization, as follows:

1. **Prevention Quality Indicator (PQI) 01—Short-Term Diabetes Complications Admissions**. This measure counts the number of hospital discharges for patients with diabetes with short-term complications, including ketoacidosis, hyperosmolarity, or coma.
2. **PQI 14—Uncontrolled Diabetes Admissions**. This measure counts the number of hospital discharges for patients with uncontrolled diabetes who did not also have diagnoses for long- or short-term complications.
3. **Number of ED visits for short-term complications** uses the same diagnoses as in (1) but counts the number of ED visits by insulin users in a given year for short-term diabetes complications. This measure was intended to capture the occurrence of complications that were not grave enough to warrant hospital admission and, therefore, would not have been counted by PQI 01.

Table B.1 presents the diagnosis codes used to identify short-term diabetes complication hospital admissions (PQI 01) and ED visits.

Table B.1. Diagnosis Codes for Short-Term Diabetes Complication Admissions

Diagnosis Code	Description
E1010	Type 1 diabetes mellitus with ketoacidosis without coma
E1011	Type 1 diabetes mellitus with ketoacidosis with coma
E10641	Type 1 diabetes mellitus with hypoglycemia with coma
E1100	Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma
E1101	Type 2 diabetes mellitus with hyperosmolarity with coma
E1110	Type 2 diabetes mellitus with ketoacidosis without coma
E1111	Type 2 diabetes mellitus with ketoacidosis with coma
E11641	Type 2 diabetes mellitus with hypoglycemia with coma
E1300	Other specified diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma
E1301	Other specified diabetes mellitus with hyperosmolarity with coma
E1310	Other specified diabetes mellitus with ketoacidosis without coma
E1311	Other specified diabetes mellitus with ketoacidosis with coma
E13641	Other specified diabetes mellitus with hypoglycemia with coma

SOURCE: Adapted from Agency for Healthcare Research and Quality, 2023.

Table B.2 presents the diagnosis codes used to identify inpatient stays for uncontrolled diabetes admissions (PQI 14).

Table B.2. Diagnosis Codes for Uncontrolled Diabetes Admissions

Diagnosis Code	Description
E10649	Type 1 diabetes mellitus with hypoglycemia without coma
E1065	Type 1 diabetes mellitus with hyperglycemia
E11649	Type 2 diabetes mellitus with hypoglycemia without coma
E1165	Type 2 diabetes mellitus with hyperglycemia
E13649	Other specified diabetes mellitus with hypoglycemia without coma
E1365	Other specified diabetes mellitus with hyperglycemia

SOURCE: Adapted from Agency for Healthcare Research and Quality, 2023.

We looked for the above short-term diabetes complications and uncontrolled diabetes in the MA encounter and FFS claims data for ED visits and inpatient stays for beneficiaries in our insulin user sample.

Enrollment Measures

We assessed the effect of the model on a plan's total enrollment and on *new plan enrollment*, defined as the number of beneficiaries newly enrolling in the plan. We also assessed changes in enrollment by insulin users. We calculated our enrollment measures using enrollment as of July 1 of the given calendar year, because enrollment generally stabilizes at this point in the year. We identified beneficiaries enrolled in each plan on that date and then determined whether each beneficiary met our criteria for insulin user enrollment, defined within each calendar year, separately from our beneficiary-level regression model samples, because we wished to identify insulin use within the calendar year itself and not only in the pre-period year, as we did for the beneficiary samples. We defined *new plan enrollment* as beneficiaries enrolled on July 1 who were enrolled in a different plan as of December 1 of the preceding year.

Beneficiary Cost Measures

We analyzed annual beneficiary OOP spending on prescription drugs, as well as total beneficiary spending inclusive of Part D premiums. Our analysis of OOP spending measures focuses on beneficiaries who were continuously enrolled in their plans for a minimum of 24 months. We excluded LIS-eligible beneficiaries from our analysis of OOP costs because they were not eligible for PDSS.

Premiums

In addition to cost sharing on prescriptions, beneficiaries must pay premiums for Part D coverage. We analyzed plan-level data on Part D premiums extracted from HPMS. In enhanced alternative PDPs and MA-PDs, the Part D premium reflects the sum of a basic premium that pays for standard Part D coverage (which is derived from the plan's Part D bids) and a supplemental premium that pays for enhanced coverage, which can be expressed as follows:

$$\text{Total Part D premium} = \text{Basic Part D Premium} + \text{Supplemental Part D Premium}.$$

We analyzed total premiums, basic premiums, and supplemental premiums as separate outcomes. Many MA-PDs use their MA rebates to reduce (or buy down) the Part D premium. Rebates can be used to buy down both the basic and the supplemental premiums. We analyzed Part D premiums for MA-PDs after rebates had been applied. This premium measure captures the premium amount that beneficiaries who are ineligible for LIS must pay. We did not incorporate premium reductions due to LIS because LIS-eligible beneficiaries were not targeted by PDSS.

Out-of-Pocket Costs

We calculated OOP spending on prescription drugs by aggregating OOP amounts reported in the PDE data to the beneficiary-year level. We constructed three measures of OOP costs: total OOP (including OOP costs for all covered prescriptions filled by a beneficiary in a year), OOP costs for model-eligible insulins, and OOP costs for all noninsulin drugs.

We also constructed a measure of total beneficiary spending by adding 12 times the total monthly Part D premium to total beneficiary OOP spending on prescription drugs. The plan-level premium measure that we used (as described above) accounts for MA-PDs that applied the MA rebate to lower their Part D premiums.

Benefit Phase Progression

We also evaluated the effect of PDSS on beneficiary progression through the different phases of the Part D benefit: deductible, initial coverage, coverage gap, and catastrophic. We determined beneficiary progression through the benefit phases using different cost measures for each phase. Beneficiary spending determines when a beneficiary exits the deductible phase. *Gross drug spending* (that is, the total drug cost before the application of manufacturer rebates) determines when a beneficiary exits the initial coverage phase, moving into the coverage gap phase. Beneficiary OOP spending plus manufacturer gap discount payments determine when a beneficiary exits the coverage gap phase and moves into the catastrophic phase. Once a beneficiary has entered the catastrophic phase, costs for each fill are split among the beneficiary, plans, and CMS.

Reducing beneficiary OOP costs for insulins through the first three benefit phases may increase the utilization of insulins, as well as possibly other prescription drugs. Increased utilization may move beneficiaries into the coverage gap faster, based on gross drug spending. Once in the gap, beneficiaries pay lower OOP costs for insulin, which likely increases the amount of time beneficiaries spend in the gap and may reduce the amount of time that they spend in the catastrophic phase. Changes in the time spent in each benefit phase have cost implications for beneficiaries, plans, manufacturers, and CMS.

The PDE data provide information on which benefit phase beneficiaries were in at the beginning of a fill and in which benefit phase beneficiaries were in after accounting for the costs of specific fills. We identified the beginning and ending fills for each benefit phase for each beneficiary in order to identify the point in time during the year when they entered each of the phases of the benefit. We then calculated a measure of the number of 30-day periods each beneficiary spent in each phase. We counted all days for PDEs that started in one benefit phase and ended in another phase. We grouped time spent in the deductible phase with time spent in the initial coverage phase, because not all plans offered a deductible. Beneficiaries with no fills spent zero 30-day periods in each benefit phase. Beneficiaries who had PDEs in benefit phases that were out of order were excluded from the analyses, because this pattern should be infeasible (this occurred for a very small number of all beneficiaries). In addition to evaluating the amount of time spent in the benefit phases, we also constructed separate measures of whether each beneficiary ended the year in the initial coverage, coverage gap, or catastrophic phase. A decrease in the likelihood of spending the year in the catastrophic phase implies a reduction in reinsurance costs, which are incurred in the catastrophic phase, for CMS.

Part D Financial and Medical Spending Measures

Gross Drug Costs

In addition to beneficiary OOP spending, we examined *gross drug costs*, which we defined as total annual spending on Part D–covered prescription drugs before receiving manufacturer rebates or federal reinsurance. Gross drug costs are paid for by different stakeholders, depending on where the beneficiary is in the Part D benefit for a given fill. We analyzed gross drug costs at the beneficiary-year level for the same continuously enrolled cohort that we used to examine PDSS impacts on OOP spending.

PDSS operates, in part, by changing how gross drug costs are split among stakeholders in the coverage gap so that plans can offer beneficiaries more predictable and affordable cost sharing throughout the noncatastrophic benefit phases. By making beneficiary cost sharing for insulin more predictable and affordable, PDSS was expected to increase adherence, which, in turn, could increase the volume of insulin dispensed to beneficiaries and increase gross drug costs.

Gross drug costs for noninsulin drugs might also be affected by other, more complex mechanisms. Improved health because of better diabetes management could potentially reduce the need for some other drugs, which might tend to reduce gross drug costs. However, reductions in beneficiary insulin cost sharing might leave beneficiaries with more financial resources to afford cost sharing on other drugs, which might tend to increase gross drug costs. These utilization responses could also be shaped by changes in plans' benefit design made in response to PDSS, while negotiations with manufacturers over discounts, rebates, and formulary placement of noninsulin drugs could also potentially be affected by the model.

We derived gross drug costs from the PDE data. We aggregated gross drug costs below the catastrophic phase (GDCB) and gross drug costs above the catastrophic phase (GDCA) over all prescriptions for each beneficiary in our sample.

Plan Bids and Administrative Costs

OACT provided data on plan bids. We extracted bids and other related variables from the Part D Bid Pricing Tool, an Microsoft Excel workbook that plans submit to CMS with detailed information on inputs contributing to the derivation of their bids. The standardized Part D bid is reported directly in these data.

The Part D bid submitted by a plan is required to reflect the projected cost to the plan of providing the basic Part D benefit, including net plan spending on drugs, administrative costs (known as "nonbenefit expenses"), and the plan's gain/loss (that is, profit) margin. For enhanced alternative PDPs and MA-PDs, which can offer supplemental benefits and otherwise deviate from the basic Part D benefit, the plan's total nonbenefit expenses and gain/loss margin are allocated between standard coverage and supplemental benefits: Only the portions allocated to basic coverage are added to the Part D bid.

Part D bids for basic coverage can be negative as a result of decreasing plan liability over time. This can happen due to many factors, including very high DIR relative to total Part D costs, narrow formularies that attract healthy people with low risk scores, and generous benefit designs that lead to high supplemental premiums. We found that the incidence of negative basic Part D bids increased over time, representing fewer than ten MA-PD bids per year from 2019 to 2021, 41 bids in 2022 (0.8%), and 97 bids in 2023 (1.7%). There was a similar number of negative PDP bids from 2019 to 2021. This number rose to 87 in 2022 (11.2%) and 138 in 2023 (17.0%). We note, however, that the sum of the basic bid and the supplemental premium before the MA-PD buys it down with MA rebate dollars is always non-negative. Therefore, we present regression results for both the PDSS effect on the basic Part D bid alone, as well as for the effect on the sum of the basic bid and the supplemental Part D premium.

To capture PDSS impacts on plans' total administrative costs, we defined our administrative cost measure to include both the portion allocated to basic coverage and the portion allocated to supplemental benefits. These administrative costs were measured as a PMPM amount.

Manufacturer Payments

Manufacturer Rebates

Manufacturer rebates are payments from drug manufacturers to plans to offset a portion of gross drug spending. Rebates provide plans with resources that can be used to offer lower bids and beneficiary premiums to attract more enrollees. Rebates might be provided to plans for a variety of reasons. For example, a rebate might be triggered when sales of a drug reach a specified volume or market-share threshold, or a rebate might be provided in exchange for more favorable formulary placement or other actions by plans that would offer manufacturers higher sale volumes and revenues.

Rebates have grown rapidly in recent years, contributing to a divergence between the negotiated *list price* of drugs (which is the price reflected in gross drug spending) and the net price paid by the plan. However, as some analysts have observed (Trish, Kaiser, and Joyce, 2020), rising list prices have increased the cost sharing for patients in coinsurance benefit designs, where patients pay a percentage of the cost of the drug as opposed to a fixed amount (as copayments). Rising list prices have also contributed to the growing importance of CMS spending on reinsurance, which undermines incentives for plans to control overall prescription drug spending, because the plans pay only 15% of drug costs once beneficiaries enter the catastrophic phase. While these larger questions about the role of rebates in Part D are beyond the scope of this evaluation, the impact of PDSS on manufacturer rebates is thus an outcome of interest for our evaluation.

The likely impact of PDSS on rebates for noninsulin drugs sold by PDSS-participating manufacturers, or on rebates from other manufacturers, is unclear, because the utilization impacts of PDSS on noninsulin drugs are ambiguous a priori.

We derived manufacturer rebates from summary DIR data reported to CMS by plans, which CMS shared with the study team for the purpose of this evaluation. Plans are required to report all DIR received from manufacturers so that plans' prescription drug spending net of rebates and other DIR can be accounted for in calculating final CMS reinsurance payments and in calculating plans' profits or losses for the purpose of calculating any risk corridor payments.

The summary DIR data that we analyzed were reported at the plan level and, thus, reflect the total amount of DIR received by a plan in a given coverage year. The data did not provide detail on the amounts of rebates and other DIR allocated to specific drugs. We therefore analyzed the total amount of manufacturer rebates received in a given year rather than rebates specifically tied to insulins or other drugs. We defined our measure of manufacturer rebates as the sum of two categories: "rebates expected but not yet received" and "all other rebates." As with other plan-level cost outcomes, we constructed manufacturer rebates as a PMPM average.

Manufacturer Gap Discount Payments

Manufacturers of brand-name drugs pay 70% of the cost of those drugs filled when the beneficiary is in the coverage gap phase of the Part D benefit. The model directly targeted the gap discount payments by applying the 70% payment before the application of any supplemental benefits offered by the plan. Therefore, manufacturers of insulins participating in the model continued to pay 70% of insulin costs in the coverage gap while beneficiary OOP costs were capped at $35 per one-month supply. PDSS could increase the number of insulin fills in the coverage gap and could also increase the amount of time a beneficiary spends in the coverage gap, which would, in turn, increase manufacturer gap discount payments.

We assessed the impact of PDSS on total manufacturer gap discount payments by summing the total gap discount payment variables in the PDE data for each plan, then dividing the total by the number of member-months to obtain a PMPM amount. We ran DD regressions at the plan level comparing PDSS-participating MA-PDs and PDPs (separately) with all nonparticipating plans.

Part D Costs to CMS

The final cost to CMS of providing Part D coverage reflects both prospective payments made during the coverage year and reconciliation payments made after the coverage year ended. The final cost to CMS also includes risk corridor payments (which can flow from plans to CMS or from CMS to plans) that serve to share any excess profits or losses between plans and CMS.

Some of the outcome variables discussed above have mechanical impacts on important components of final Part D costs to CMS. Monthly capitation payments to plans are determined in large part by the plan bid, reinsurance payments to plans (defined above) are directly affected by gross drug spending in the catastrophic phase, and manufacturer rebates are shared with CMS through adjustments to reinsurance and through risk corridor payments. The direction of PDSS impacts on several of these components is theoretically ambiguous, and the relative magnitudes of any such impacts are also unclear, so we do not have a firm hypothesis about the direction of PDSS impacts on Part D costs to CMS.

We defined our outcome measure as the PMPM cost to CMS of final plan payments for Part D. Some components of final costs (for instance, the direct subsidy) are readily calculated at the PMPM level, others can be aggregated from individual-level data to the plan level, and others (such as DIR and risk corridor payments) are defined only at the level of the entire plan. We used PRS data, which provide the final payments made by CMS to the plans across the various components, to obtain the PMPM values of most of the components described below. We constructed PMPM final costs by deriving plan-level final costs and then dividing by the number of enrollee member-months in the plan for the coverage year. At a high level—and abstracting

from the distinction between prospective payments and reconciliation amounts—the final Part D cost to CMS for a plan can be defined as the sum of four components:[8]

- risk-adjusted direct federal subsidy payments
- federal reinsurance payments
- low-income cost sharing and premium subsidy payments
- risk corridor payments.

The risk-adjusted direct federal subsidy payment is the monthly risk-adjusted capitation payment corresponding to the cost of the basic Part D benefit projected in the plan's bid, excluding the portion of costs for basic coverage that is covered by the beneficiary premium (known as the *enrollee premium*). We used direct subsidy payment amounts reported in the PRS data in our analysis.

Federal reinsurance payments from CMS to plans provide reimbursement for 80% of gross drug costs in the catastrophic phase, with an adjustment for a proportion of DIR received by the plans (details of the reinsurance calculation are presented above). We used the final reinsurance payment amounts from the PRS data, calculated as a plan-level measure of PMPM reinsurance rates. Thus, we calculated final reinsurance payments to plans as 80% of plan-level gross drug spending in the GDCA, reduced to account for the portion of DIR allocated to drug spending in the catastrophic phase. That is,

$$\text{Reins} = 0.8*\text{GDCA} - 0.8*\text{DIR}*(\text{GDCA}/(\text{GDCA} + \text{GDCB})),$$

where *Reins* is the total reinsurance payment received by a plan (aggregated across all beneficiary-months in a plan), *DIR* is the total amount of DIR received by a plan, *GDCA* is gross drug spending above the catastrophic phase, and *GDCB* is gross drug spending below the catastrophic phase.

Low-income cost-sharing subsidy (LICS) and low-income premium subsidy (LIPS) payments from CMS to plans provide reimbursement for plans' foregone cost sharing and premium revenues associated with the LIS. LICS payments are reported in the PDE data, and we aggregated these data to the plan level to derive the LICS payment amount for each plan. We derived LIPS payments for each plan from IDR data on beneficiaries' LIS status and months of enrollment. We calculated the total number of member-months of enrollment in each plan attributable to beneficiaries at the full LIS level and each partial LIS level within the IDR. We then multiplied these counts of LIS member-months by plan-level LIPS payment amounts

[8] For 2023, CMS made subsidy payments to plans for insulins not entered into the model to make up the difference between the plans' formulary insulin cost sharing amounts included as part of plans' 2023 bids and the IRA's requirement that plans cover insulins on their formularies at a maximum $35 per one-month supply. We did not include these payments in the calculation of Part D costs to CMS. While this subsidy mainly affected nonparticipating plans, PDSS-participating plans would have received this subsidy for any insulins on their formularies that they did not include on their list of plan-selected model insulins.

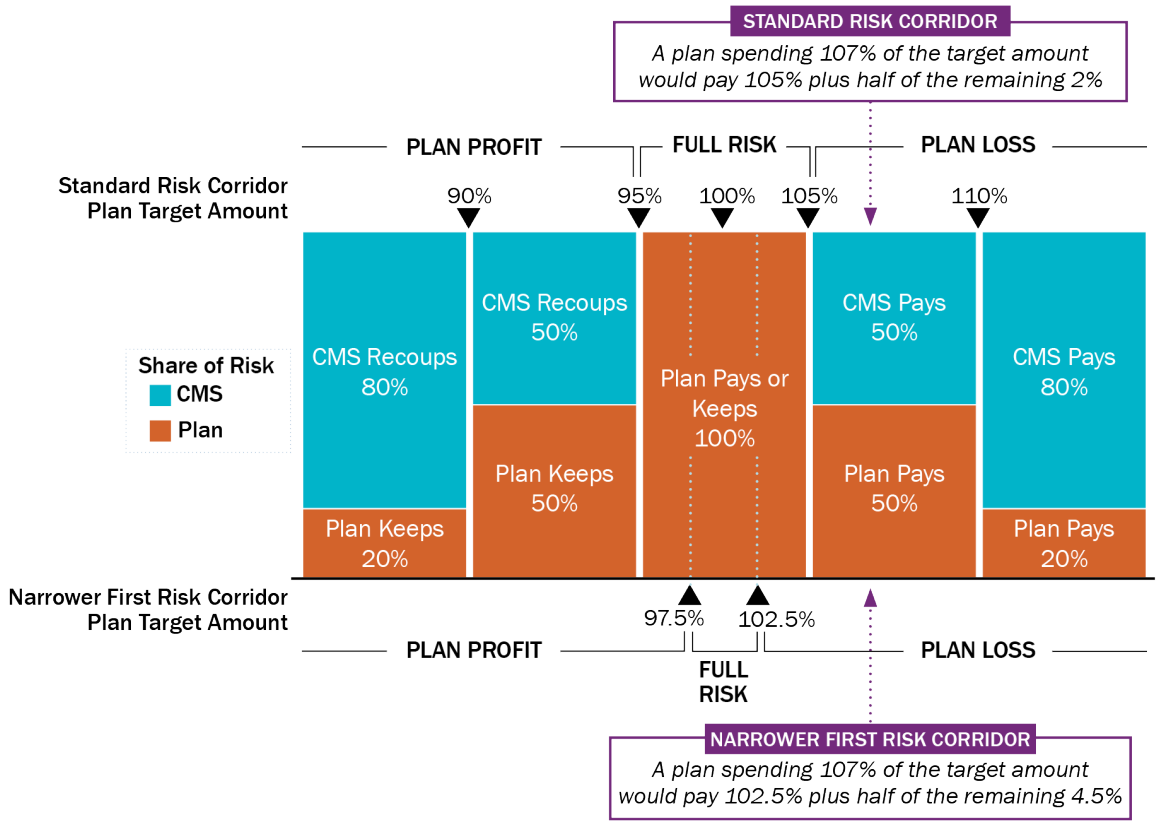
reported in HPMS and aggregated them to the plan level to obtain the total LIPS payment for each plan.

Risk corridor payments are made to share unanticipated plan profits and losses with CMS. The risk corridor involves comparison of allowed costs (drug costs paid by the plan, net of federal reinsurance and DIR, and subject to an adjustment for induced utilization) to a target amount (the risk-adjusted bid for basic Part D coverage, excluding a portion of the plan's profit margin and administrative expenses).

We used risk corridor payments reported in the PRS data in our analysis. However, the following description of how risk corridor payments are determined may be helpful to some readers.

Figure B.1, which is reproduced from our first PDSS evaluation report, illustrates the structure of the risk corridor in Part D and the optional narrower first risk corridor component of PDSS. Under the standard risk corridor in Part D (which applies to all plans except PDSS-participating plans that elected and received the narrower first risk corridor), no risk corridor payments are made if allowed costs are within 5% of the target amount. If a plan's allowed costs exceed the target amount by more than 5% (that is, the plan has excess losses), then CMS makes risk corridor payments to the plan. If allowed costs fall below the target amount by more than 5% (that is, the plan has excess profits), then the plan makes risk corridor payments to CMS.

Figure B.1. Medicare Part D Risk Corridors



SOURCE: Reproduced from Taylor et al., 2022.

PDSS-participating plans could have chosen to participate in a narrower first risk corridor threshold, whereby the first risk corridor was narrowed from 95–105% to 97.5–102.5%. This may have increased plan participation in the model by providing additional protection if losses were incurred, but plans would also share a greater amount of any unanticipated profits with CMS. Plans choosing this option only received the narrower first risk corridor payments if they enrolled a statistically significantly larger share of beneficiaries taking plan-selected model insulins, defined as enrollment that is at least one standard deviation above the mean enrollment for the plan type (CMS, 2020). As shown in Figure B.1, plans eligible for the narrower first risk corridor and spending 107% of the target amount would have paid 102.5% plus half of the remaining 4.5%.

Allowed costs are calculated using data on plans' covered drug spending and reinsurance payments derived from the PDE data, amounts of total DIR received in the summary DIR data described above, and additional adjustment factors reported in the plan bid data and provided by OACT. Specifically, allowed costs are calculated and included in the PRS data based on the following definition:

$$\text{Allowed Costs} = (\text{CPP} - \text{Reinsurance} - \text{Total DIR}) / \text{Induced Utilization Factor},$$

where *CPP* is the total amount of covered Part D plan paid amounts reported in the PDE data, *Reinsurance* is the final amount of plan-level reinsurance (as defined above), and *Total DIR* is the total amount of DIR received by plans as reported in the summary DIR data that was used to define manufacturer rebates (as discussed above). The induced utilization factor, which was reported as part of the plan bid for enhanced alternative plans and MA-PDs offering supplemental Part D benefits, was intended to capture the spillover effect of enhanced benefits on spending associated with the basic Part D benefit.

The target amount is calculated using data on plan bids, gain/loss margin, and administrative expenses reported in the bid, as well as other adjustment factors reported in the plan bid data and provided by OACT. Specifically, the PMPM target amount is calculated as the PMPM allowable cost target (which we derived from the plan's bid, nonbenefit expenses, and gain/loss margin) multiplied by the target amount adjustment (a factor reported as part of the plan bid), and then we multiplied this PMPM target amount by the number of beneficiary-months of enrollment in the plan. (Note that both allowed costs and the target amount are calculated as plan-level totals for the purpose of deriving the risk corridor payment.)

Finally, because PDSS-participating plans could elect a narrower first risk corridor (where risk sharing begins with a deviation of 2.5% from the target amount rather than 5%), the PRS data included adjustments made to the risk corridor payments based on which plans elected and received the narrower risk corridor to correctly calculate risk corridor payments for the PDSS-participating plans.

We used the above components to derive PMPM Part D costs to Medicare by summing the four components of total costs and dividing that sum by the total number of beneficiary-months in the plan:

$$\text{PMPM Part D Costs to CMS} = \frac{(Plan\ Enrollment * DirSub) + Reins + LIS + RiskCor}{Plan\ Enrollment},$$

where *DirSub* is the PMPM direct subsidy, *Reins* is the total amount of reinsurance payments, *LIS* is the total LIS amount, *RiskCor* is the total risk corridor payment, and *Plan Enrollment* is the total number of beneficiary-months in the plan.

Medical Spending

MA-PD Plan-Level Medical Spending

For MA-PDs, direct information on medical spending is not available at the beneficiary level, because these data are not a required component of MA encounter data reporting, and some plans do not pay providers on a FFS basis. Instead, we used the MA-PD bid data provided by the OACT, in which plans provided base period data from two years prior to the bid year to support their projected estimates of Part A and Part B medical spending estimates for their beneficiaries.

MA-PDs may be offered for enrollment at either the plan or segment level, where segments are offered in a subset of the plan's service area and may have different premiums and cost sharing compared with other segments in the plan. MA-PD bids for segmented plans are submitted at the segment level and are generally based on their own segment-level experience data from two years prior. There are two instances, however, in which this is not the case:

1. The plan/segment is new. In this case, we dropped this segment from the analysis presented in this report, because it has no pre-period data.
2. The segment had insufficient prior experience data to form a bid and thus used data from multiple segments to inform the bid. In this case, we also dropped the segment from our analysis, because we cannot extract the segment-level spending data.

The exclusion of segments or plans that fell into one or the other of these categories resulted in an approximately 23% smaller sample of PDSS-participating MA-PDs in 2021, 29% smaller in 2022, and 36% smaller in 2023 for these analyses; the exclusion rate for nonparticipating MA-PDs was larger at about 42%. We rolled segment-level data up to the plan level using enrollment weighting. For regression analyses, we applied a log-transformation to the outcome.

PDP Beneficiary-Level Medical Spending

For FFS beneficiaries enrolled in stand-alone PDPs, medical spending is available at the beneficiary level in the FFS claims data. Therefore, for FFS beneficiaries, we calculated annual medical spending at the beneficiary level as the sum of spending on the following categories of care: inpatient, outpatient, home health services, skilled nursing facility care, hospice care, and durable medical equipment. We dropped claim type 64, which is defined as MA claims that are paid as FFS, because they accounted for only a handful of claims. All amounts were summed at the claim header level from claims in the Integrated Data Repository (IDR) table V2_MDCR_CLM, with categories defined by the claim type code. We detail the specifics of the cost calculation in Table B.3. For regression analyses, we applied a log-transformation to the outcome.

Table B.3. Fee-for-Service Claims Medical Spending Calculations

Claim code	Claim Type	Cost Calculation	Medicare FFS Benefit Structure
10	HHA	CLM_PMT_AMT	$0 for covered HHA services
20	Non-swing bed SNF	CLM_PMT_AMT + CLM_MDCR_COINSRNC_AMT	Daily coinsurance for days 21–100 of extended care services; beneficiary pays all costs after day 100
30	Swing bed SNF	CLM_PMT_AMT + CLM_MDCR_COINSRNC_AMT	Daily coinsurance for days 21–100 of extended care services; beneficiary pays all costs after day 100
40	Outpatient	CLM_PMT_AMT + CLM_MDCR_DDCTBL_AMT + CLM_MDCR_COINSRNC_AMT	Annual deductible + 20% coinsurance
50	Hospice	CLM_PMT_AMT	$0 for covered hospice services
60	Inpatient	CLM_PMT_AMT + (CLM_MDCR_DDCTBL_AMT – CLM_MDCR_COINSRNC_AMT) + CLM_MDCR_COINSRNC_AMT	Deductible applies to days 1–60 of each benefit period; then, daily coinsurance for days 61–90; then, daily coinsurance for lifetime reserve days up to an additional 60 days
64	Medicare advantage (paid as FFS)	NA	NA
71	RIC O Local Carrier non-DMEPOS	CLM_ALOWD_CHRG_AMT	Annual deductible + 20% coinsurance
72	RIC O Local Carrier DMEPOS	CLM_ALOWD_CHRG_AMT	Annual deductible + 20% coinsurance
81	RIC M DMERC Non-DMEPOS	CLM_ALOWD_CHRG_AMT	Annual deductible + 20% coinsurance
82	RIC M DMERC DMEPOS	CLM_ALOWD_CHRG_AMT	Annual deductible + 20% coinsurance

SOURCE: Authors' analysis of publicly available Original Medicare benefit information and IDR data dictionary.
NOTE: DMEPOS = Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; HHA = Home Health Agency; NA = not applicable; RIC = Rehabilitation Impairment Category. The letters after RIC indicate the type of category.

Spillover Effect Measures

Enrollment

We assessed the effect of the model on enrollment by noninsulin users in PDSS-participating plans. Furthermore, we examined PDSS effects on enrollment for beneficiaries eligible for the Part D LIS and those enrollees who were dually eligible for Medicare and Medicaid (dual-eligible beneficiaries are also LIS-eligible).

We calculated our enrollment measures using enrollment as of July 1 of the given calendar year, because enrollment generally stabilizes at this point in the year. We identified beneficiaries

enrolled in each plan on that date and then determined whether each beneficiary met our criteria for subgroup enrollment. We defined noninsulin users within each calendar year, separately from our beneficiary-level regression model samples, because we wished to identify insulin nonuse within the calendar year itself and not only in the pre-period, as we did for the beneficiary samples. We considered beneficiaries eligible for the LIS, or dually eligible for Medicare and Medicaid, if they were LIS- or dual-eligible for at least six months of the calendar year.

Noninsulin User Costs

As described above, we calculated OOP spending on prescription drugs by aggregating OOP amounts reported in the PDE data to the beneficiary-year level. We constructed total beneficiary OOP, defined as OOP costs for all covered prescriptions filled by a beneficiary in a year. We also constructed a measure of total beneficiary spending by adding 12 times the total monthly Part D premium that a beneficiary would have paid to the plan to total beneficiary OOP spending on prescription drugs.

Benefit Phase Progression

As described above, we identified the beginning and ending fills for each benefit phase for each beneficiary in the PDE data to identify the point in time during the year when they entered each of the phases of the benefit. We then calculated a measure of the number of 30-day periods the beneficiary spent in each phase. Beneficiaries with no fills spent zero 30-day periods in each benefit phase.

Appendix C. PO Rewards and Incentives Programs

Table C.1 presents information on the R&I programs offered by PDSS-participating MA-PDs in 2021 through 2023.

Table C.1. PDSS Rewards and Incentives Programs, 2021 to 2023

Parent Organization (*N* = 16)	Number of Plans, 2021 (*N* = 32)	Number of Plans, 2022 (*N* = 76)	Number of Plans, 2023 (*N* = 85)	Targeting Criteria	Activity	Reward
Offer R&I program in 2021 only						
PO BF	2	NA	NA	Beneficiaries taking insulin	Participate in MTM and complete a CMR	• $100 gift card
Offer R&I program in 2021 and 2022						
PO DD	7	8	NA	P1: At least two fills of any diabetes medicine on at least two different days	P1: Complete CMR	• P1: $25 gift card (Walmart, Amazon, Subway) (2021) • P1: $50 gift card (specific locations/services) (2022)
				P2: At least two fills of any diabetes medicine on at least two different days	P2: Complete consultation and adhere to statin medicines (PDC > 80%)	• P2: $50 gift card (Walmart, Amazon, Subway) (2021) • P2: $50 gift card (specific locations/services) (2022)
Offer R&I program in 2021, 2022, and 2023						
PO K	2	2	2	Diabetes diagnosis and meets CMR eligibility criteria	Complete annual CMR	• $30 Target gift card (2021) • $30 gas station gift card (2022) • $30 gift card (gas/food) (2023)
PO CW	16	14	14	Diabetes diagnosis and meets CMR eligibility criteria	Complete annual CMR	• $30 Target gift card (2021) • $30 gas station gift card (2022) • $30 gift card (gas/food) (2023)

Parent Organization (*N* = 16)	Number of Plans, 2021 (*N* = 32)	Number of Plans, 2022 (*N* = 76)	Number of Plans, 2023 (*N* = 85)	Targeting Criteria	Activity	Reward
PO CZ	5	5	5	Diabetes diagnosis and beneficiary takes specific diabetes medications	• Receive consultation and adhere to diabetes medicines (at least two fills on separate days of specified medications) (2021, 2022) • Receive consultation and achieve 80% diabetes medication adherence (2023)	• $75 gift card (Mastercard, Visa) (2021) • $75 gift card (specific goods/services) (2022) • $75 gift card (Mastercard, Visa) (2023)
Offer R&I program in 2022 only						
PO AB	NA	1	NA	Eligible for Star Ratings diabetes medication adherence measure	Adhere to diabetes medication and participate in disease management program	• $10 quarterly gift card (select retailers)
Offer R&I program in 2022 and 2023						
PO U	NA	5	5	Diabetes or prediabetes based on fills of diabetes medications	Engage with MTM services provided by partner pharmacists	• $20 Benefit Card to spend on supplemental benefit services (2021, 2022) • $20 MasterCard debit card to spend on healthy services (dental, eyewear, hearing, transportation, groceries) (2023)
PO Y	NA	3	3	• P1: Diabetes based on medication fills	• P1: Enroll in rewards program, fill at least one statin (2021, 2022)	• P1: $15 gift card (2021, 2022)
				• P2: Diabetes based on medication fills	• P2: Enroll in rewards program, achieve 80% PDC (2021, 2022)	• P2: $20 gift card (2021, 2022)
				• P1: Diabetes based on medication fills (2023)	• P1: Enroll in rewards program, fill at least one	• P1: $15 gift card (2023)

Parent Organization (*N* = 16)	Number of Plans, 2021 (*N* = 32)	Number of Plans, 2022 (*N* = 76)	Number of Plans, 2023 (*N* = 85)	Targeting Criteria	Activity	Reward
					statin and complete educational activity (2023)	
				• P2: Diabetes based on medication fills enough to fill at least 80% of the time on mediation (2023)	• P2: Enroll in rewards program, fill prescription enough to cover 80% of time supposed to be on medication and complete educational activity (2023)	• P2: $20 gift card (2023)
PO AD	NA	27	23	• P1: Diabetes diagnosis and eligible for CMR (2021–2023)	• P1: Complete CMR (2021–2023)	• $25 gift card (restaurant, gas station, movie theater) (2021, 2022)
				• P2: Diabetes diagnosis and beneficiary takes statin medications (2023)	• P2: Complete consultation and start statin therapy (2023)	• $25 gift card (restaurant, gas station, movie theater, food delivery, select grocery stores) (2023)
PO AJ	NA	4	4	• P1: Diabetes or prediabetes diagnosis based on codes and drug utilization (2021, 2022)	• P1: Diabetes medication adherence of at least 84% PDC and complete CMR (2021, 2022)	• P1: $25 quarterly OTC card (2021, 2022)
				• P2: Diabetes or prediabetes diagnosis based on codes and drug utilization (2021, 2022)	• P2: Statin adherence of at least 83% and enrolled in Part D disease management program (2021, 2022)	• P2: $25 quarterly OTC card (2021, 2022)
				• P1: Diabetes diagnosis and meets CMR eligibility criteria (2023)	• P1: Diabetes medication adherence of at least 90% PDC and complete CMR (2023)	• P1: $50 trimonthly OTC card (2023)
				• P2: Diabetes diagnosis based on codes and drug utilization (2023)	• P2: Attend diabetes management class and fill statin within same quarter of attendance (2023)	• P2: $50 trimonthly OTC card (2023)
PO CA	NA	7	5	• P1: Beneficiaries eligible for Star Ratings diabetes medication adherence	• P1: Complete a CMR and adhere to diabetes medications	• P1: $100 gift card to select retailers

Parent Organization (*N* = 16)	Number of Plans, 2021 (*N* = 32)	Number of Plans, 2022 (*N* = 76)	Number of Plans, 2023 (*N* = 85)	Targeting Criteria	Activity	Reward
				measure; qualify for CMR (2021, 2022)		
				• P2: Beneficiaries eligible for Star Ratings diabetes medication adherence measure; qualify for CMR (2021, 2022)	• P2: Complete a CMR and fill a new statin prescription	• P2: $100 gift card to select retailers
				• P1: Diabetes diagnosis based on codes and eligible for CMR (2023)		
				• P2: Diabetes diagnosis based on codes, meets CMR and statin use eligibility criteria (2023)		
Offer R&I program in 2023 only						
PO AK	NA	NA	13	• Diabetes or prediabetes diagnosis	• Fill 90-day script for one of three drug classes, and complete one clinical consultation	• $30 quarterly digital wallet reward through select vendor
PO AZ	NA	NA	1	• P1: At least two fills of any diabetes medicine on at least two different days, and meets CMR eligibility criteria	• P1: Qualify for CMR and complete activity during plan year	• P1: $50 gift card (pharmacy, gas/transportation, restaurant, grocery store)
				• P2: At least two fills of any diabetes medicine on at least two different days, and meets CMR eligibility criteria	• P2: Complete educational intervention and adhere to statin medicines (PDC > 80%)	• P2: $50 gift card (pharmacy, gas/transportation, restaurant, grocery store)
PO DE	NA	NA	4	• P1: At least two fills of any diabetes medicine on at least two different days	• P1: Complete CMR	• P1: $50 gift card (pharmacy, gas/transportation, restaurant, grocery store)

Parent Organization (*N* = 16)	Number of Plans, 2021 (*N* = 32)	Number of Plans, 2022 (*N* = 76)	Number of Plans, 2023 (*N* = 85)	Targeting Criteria	Activity	Reward
				• P2: At least two fills of any diabetes medicine on at least two different days	• P2: Complete educational intervention and adhere to statin medicines (PDC > 80%)	• P2: $50 gift card (pharmacy, gas/transportation, restaurant, grocery store)
PO DJ	NA	NA	3	Diabetes diagnosis based on drug utilization and clinical based methodology	Fill prescription for any insulin and participate in diabetic education course	$10 gift card quarterly and $40 annually for groceries
PO EA	NA	NA	3	Diabetes diagnosis (Type 1 or Type 2)	Anti-diabetic drug adherence of at least 75% and participate in MTM which includes a CMR	$100 biannual gift card

SOURCE: Authors' analysis of PO R&I program participation information provided to the authors by the CMS Innovation Center.
NOTE: P1 and P2 represent program 1 and program 2, respectively. POs offering more than one R&I program offered both programs to the enrollees of the same plans. NA = not applicable; PDC = proportion of days covered.

Appendix D. Detailed Quantitative Results

This appendix presents the detailed descriptive statistics, balancing, and regression results for the quantitative outcomes presented in this report.

A key component of weighting analyses is understanding how good the resulting balance is and how much statistical power was lost due to the weighting. To assess balance, we calculated absolute standardized mean differences, which compared the means in the treated and comparison groups after dividing by the standard deviation in the treated group, with values close to zero indicating good balance. To assess the loss in statistical power, we analyzed effective sample size, which conservatively estimates the size of an unweighted sample that would be needed to produce the same statistical power as the weighted sample; effective sample sizes close to the nominal sample size indicate little loss of power due to weighting. For the sake of brevity, we do not present balance at the level of analysis where the weights are estimated. Rather, we report sample sizes, effective sample sizes, and balance metrics averaging across participation patterns and then across years, where averages are weighted by the number of treated observations in the analysis. For balance measures, we then further summarized across the covariates that were used in balancing, by taking either the unweighted mean or maximum across covariates.

Plan-Level Descriptive Statistics

In Tables D.1 and D.2, we present the plan-level descriptive statistics for the PDSS-participating MA-PDs and PDPs included in the regression results for each of the three years of the model, as well as the set of comparison plans for each year.

Table D.1. Descriptive Statistics for MA-PDs Included in Regression Analyses, by Year

	2021 PDSS Participants 2021 Measurement Year	**Nonparticipants in All Years** 2021 Measurement Year	**2022 PDSS Participants** 2022 Measurement Year	**Nonparticipants in All Years** 2022 Measurement Year	**2023 PDSS Participants** 2023 Measurement Year	**Nonparticipants in All Years** 2023 Measurement Year
Mean age	72.2	71.8	72.7	71.8	72.8	72.3
Original reason for Medicare entitlement						
Age	75.5%	70.7%	77.0%	70.9%	76.8%	72.0%
Disability	24.3%	28.6%	22.8%	28.3%	23.0%	27.1%
ESRD	0.2%	0.5%	0.2%	0.6%	0.2%	0.6%
Percentage of insulin users	8.1%	7.3%	7.6%	7.1%	7.3%	7.1%
Mean number of 30-day insulin fills among insulin users	10.6	10.0	10.5	9.9	10.5	10.2
Percentage of noninsulin antidiabetic medication users	22.0%	20.8%	22.4%	21.6%	23.6%	22.5%
Percentage of beneficiaries in each benefit phase by the end of year						
Deductible	1.0%	1.5%	0.8%	1.7%	0.5%	1.7%
Initial coverage	71.0%	68.8%	71.3%	68.4%	70.4%	67.9%
Coverage gap	14.8%	13.5%	15.1%	13.6%	16.0%	14.2%
Catastrophic	5.5%	7.6%	5.3%	7.7%	6.2%	8.3%
Mean Part D risk score	0.92	1.01	0.92	1.02	0.93	1.04
Median household income	$66,829	$70,287	$67,650	$69,830	$67,692	$69,835
Urbanicity	1.8	1.8	1.8	1.8	1.8	1.8
Drug benefit type						
Actuarially Equivalent Standard	0.0%	0.0%	0.0%	0.0%	0.0%	3.7%
Basic Alternative	0.0%	3.0%	0.0%	2.2%	2.3%	3.3%
Defined Standard	0.0%	7.2%	0.0%	7.8%	0.0%	8.1%
Enhanced Alternative	100.0%	89.8%	100.0%	90.1%	100.0%	88.2%
Offer non-zero Part D deductible	45.7%	47.9%	37.8%	46.5%	26.1%	44.2%
Mean plan deductible	$101.17	$141.67	$85.36	$150.57	$61.70	$145.73
Part D Star Rating: Getting Needed Drugs	3.49	3.53	3.86	3.58	3.58	3.00
Part D Star Rating: Diabetes Medication Adherence	3.97	3.76	3.92	3.65	3.19	3.00
Full gap coverage—generics only	26.8%	56.9%	53.6%	57.1%	59.0%	56.8%

	2021 PDSS Participants 2021 Measurement Year	**Nonparticipants in All Years** 2021 Measurement Year	**2022 PDSS Participants** 2022 Measurement Year	**Nonparticipants in All Years** 2022 Measurement Year	**2023 PDSS Participants** 2023 Measurement Year	**Nonparticipants in All Years** 2023 Measurement Year
Full gap coverage not offered	73.1%	43.1%	46.4%	42.9%	40.9%	43.2%
Partial gap coverage—brands only	1.2%	0.0%	0.6%	0.0%	1.2%	0.0%
Partial gap coverage—generics only	0.1%	2.3%	1.6%	9.1%	0.7%	9.3%
Partial gap coverage not offered	97.0%	94.3%	95.8%	87.4%	95.1%	87.3%
For profit	80.9%	82.2%	77.4%	82.3%	79.3%	82.0%
Offer non-zero Part D total premium	38.7%	45.4%	40.1%	41.5%	36.4%	39.3%
Part C premium	$11.16	$12.08	$11.57	$10.24	$9.72	$8.59
Part D buydown	$53.74	$35.93	$59.90	$42.99	$68.11	$49.70

SOURCES: Authors' analysis of CMS Part D plan, PDE, and other data.
NOTE: Means presented unless otherwise noted.

Table D.2. Descriptive Statistics for PDPs Included in Regression Analyses, by Year

	2021 PDSS Participants MY 2021	Nonparticipants in All Years MY 2021	2022 PDSS Participants MY 2022	Nonparticipants in All Years MY 2022	2023 PDSS Participants MY 2023	Nonparticipants in All Years MY 2023
Mean age	74.0	69.2	74.8	69.9	74.6	70.4
Original reason for Medicare entitlement						
Age	86.7%	69.5%	87.4%	72.0%	88.7%	72.6%
Disability	12.8%	29.5%	12.2%	27.1%	11.0%	26.6%
ESRD	0.3%	0.7%	0.3%	0.7%	0.3%	0.7%
Percentage of insulin users	8.7%	6.8%	9.6%	6.1%	7.7%	6.1%
Mean number of 30-day insulin fills among insulin users	11.3	10.6	11.3	10.4	11.2	10.6
Percentage of noninsulin antidiabetic medication users	21.0%	18.6%	22.1%	18.8%	21.3%	19.7%
Percentage of beneficiaries in each coverage phase by the end of year						
Deductible	0.7%	14.2%	0.6%	15.3%	1.4%	17.1%
Initial coverage	69.8%	51.1%	67.1%	50.3%	66.8%	48.1%
Coverage gap	18.3%	15.1%	20.5%	15.2%	19.2%	15.2%
Catastrophic	7.4%	11.1%	8.2%	11.0%	8.2%	11.6%
Mean Part D risk score	0.85	1.01	0.87	1.00	0.86	1.02
Median household income	$68,837	$67,701	$68,969	$67,983	$68,836	$68,113
Urbanicity	1.6	1.6	1.6	1.6	1.6	1.6
Drug benefit type						
Actuarially Equivalent Standard	0.0%	51.0%	0.0%	51.1%	0.0%	59.5%
Basic Alternative	0.0%	26.2%	0.0%	22.8%	0.0%	14.7%
Defined Standard	0.0%	0.2%	0.0%	0.0%	0.0%	0.0%
Enhanced Alternative	100.0%	22.5%	100.0%	26.1%	100.0%	25.8%
Offer non-zero Part D deductible	77.1%	96.9%	53.7%	96.6%	56.5%	96.9%
Mean plan deductible	$248.27	$416.63	$205.73	$445.35	$251.26	$475.18
Part D Star Rating: Getting Needed Drugs	3.10	3.04	3.18	3.24	3.00	2.91
Part D Star Rating: Diabetes Medication Adherence	3.65	3.48	3.57	3.37	2.68	2.40
Full gap coverage—generics only	22.3%	3.3%	27.1%	3.4%	43.5%	3.1%
Full gap coverage not offered	77.7%	96.7%	72.9%	96.6%	56.5%	96.9%

	2021 PDSS Participants MY 2021	Nonparticipants in All Years MY 2021	2022 PDSS Participants MY 2022	Nonparticipants in All Years MY 2022	2023 PDSS Participants MY 2023	Nonparticipants in All Years MY 2023
Partial gap coverage—brands only	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Partial gap coverage—generics only	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Partial gap coverage not offered	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
For profit	100.0%	95.4%	99.6%	94.9%	99.7%	95.2%
Offer non-zero Part D total premium	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

SOURCES: Authors' analysis of CMS Part D plan, PDE, and other data.
NOTE: Means presented unless otherwise noted. MY = measurement year.

Insulin User Descriptive Statistics

Table D.3 presents descriptive statistics for insulin users enrolled in PDSS-participating MA-PDs in 2021 through 2023, for all beneficiaries enrolled in an MA-PD who had at least one fill of insulin in each year of the model.

Table D.3. Descriptive Statistics for Insulin Users in PDSS-Participating and Nonparticipating MA-PDs, by Year

MA-PD	*N*	Age	Originally Entitled Due to Age	Originally Entitled Due to Disability
Participating				
2021	420,569	72.2	69.8%	29.8%
2022	534,115	72.5	70.7%	28.8%
2023	650,978	72.6	71.3%	28.1%
Nonparticipating				
2021	196,436	72.7	73.3%	26.0%
2022	192,380	73.0	74.6%	24.7%
2023	193,848	73.2	75.4%	23.8%

SOURCES: Authors' analysis of CMS enrollment, PDE, and other data.

Table D.4 presents descriptive statistics for insulin users enrolled in PDSS-participating PDPs in 2021 through 2023, for all beneficiaries enrolled in a PDP who had at least one fill of insulin in each year of the model.

Table D.4. Descriptive Statistics for Insulin Users in PDSS-Participating and Nonparticipating PDPs, by Year

PDP	*N*	Age	Originally Entitled Due to Age	Originally Entitled Due to Disability
Participating				
2021	314,162	74.4	83.3%	15.9%
2022	361,526	74.3	84.4%	14.8%
2023	387,431	74.3	85.2%	14.0%
Nonparticipating				
2021	238,230	73.9	81.0%	17.8%
2022	197,335	74.6	82.7%	16.2%
2023	195,266	74.8	83.3%	15.7%

SOURCES: Authors' analysis of CMS enrollment, PDE, and other data.

Enrollment Regression Results

Table D.5 presents the balance statistics for the plan enrollment regression results.

Table D.5. Balance Statistics for Plan Enrollment Regression Results, by Plan Type

Outcome Measure	Average *N*: PDSS Participating Plans	Average *N*: Comparison Plans	Average ESS	Mean ASMD	Maximum ASMD
MA-PDs					
Total enrollment	1,698	1,449	1,155	0.043	0.100
New plan enrollment	1,698	1,449	1,156	0.042	0.100
Insulin users	1,698	1,449	1,150	0.047	0.100
PDPs					
Total enrollment	317	415	98	0.050	0.109
New plan enrollment	317	415	91	0.057	0.100
Insulin users	317	415	103	0.052	0.100

SOURCES: Authors' analysis of Part D event and other data. See Appendix A for additional details on the data sources and methods used. ASMD = average standardized mean difference; ESS = effective sample size.

Table D.6 presents the detailed results for the MA-PD enrollment regressions.

Table D.6. Detailed MA-PD Enrollment Regression Results, by Year

Outcome Measure	DD Coefficient	Standard Error	*P*-Value	95% CI Low	95% CI High	Treated Mean
Total enrollment						
2021	0.109	0.029	<0.001	0.052	0.165	8,626
2022	0.139	0.029	<0.001	0.081	0.197	8,109
2023	0.269	0.029	<0.001	0.212	0.326	7,488
New plan enrollment						
2021	0.210	0.047	<0.001	0.118	0.302	1,793
2022	0.102	0.046	0.025	0.013	0.191	1,476
2023	0.407	0.046	<0.001	0.318	0.497	1,325
Insulin users						
2021	0.242	0.028	<0.001	0.187	0.297	396
2022	0.312	0.029	<0.001	0.255	0.369	364
2023	0.326	0.028	<0.001	0.271	0.380	331

SOURCES: Authors' analysis of enrollment and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: This table shows coefficients on the PDSS implementation indicator from the plan-level DD regression models. The comparison groups consisted of nonparticipating plans. 95% CIs are based on plan-clustered standard errors. Results are presented as log-transformed effects. See Appendix A for additional technical details.

Table D.7 presents the detailed results for the PDP enrollment regressions.

Table D.7. Detailed PDP Enrollment Regression Results, by Year

Outcome Measure	DD Coefficient	Standard Error	*P*-Value	95% CI Low	95% CI High	Treated Mean
Total enrollment						
2021	0.166	0.043	<0.001	0.082	0.250	29,678
2022	0.119	0.049	0.014	0.024	0.214	24,511
2023	0.027	0.127	0.830	–0.222	0.276	24,932
New plan enrollment						
2021	–0.045	0.172	0.794	–0.381	0.291	3,956
2022	–0.388	0.150	0.010	–0.682	–0.093	4,106
2023	–0.097	0.166	0.557	–0.422	0.228	3,464
Insulin users						
2021	0.558	0.059	<0.001	0.442	0.674	1,531
2022	0.653	0.061	<0.001	0.534	0.772	1,390
2023	0.694	0.068	<0.001	0.561	0.827	1,192

SOURCES: Authors' analysis of Part D enrollment and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: This table shows coefficients on the PDSS implementation indicator from the plan-level DD regression models. The comparison groups consisted of nonparticipating plans. 95% CIs are based on plan-clustered standard errors. See Appendix A for additional technical details.

Access Regression Results

Table D.8 presents the balance statistics for the beneficiary access regression results.

Table D.8. Balance Statistics for Beneficiary Access Regression Results, by Plan Type

Outcome Measure	Average *N*: PDSS Participants	Average *N*: Comparison Beneficiaries	Average ESS	Mean ASMD	Maximum ASMD
MA-PDs					
Number of 30-day fills	188,122	68,015	42,718	0.044	0.101
MPR for short/rapid-acting insulin	27,259	12,478	7,874	0.046	0.101
MPR for short/rapid-acting insulin (SA)	39,585	16,829	10,549	0.058	0.109
Persistence to basal insulin	90,793	37,914	20,631	0.041	0.135
PDPs					
Number of 30-day fills	167,378	96,203	92,443	0.030	0.100
MPR for short/rapid-acting insulin	32,711	18,715	17,855	0.030	0.100
MPR for short/rapid-acting insulin (SA)	46,361	25,481	24,380	0.041	0.161
Persistence to basal insulin	89,074	50,308	47,950	0.028	0.100

SOURCES: Authors' analysis of Part D event and other data. See Appendix A for additional details on the data sources and methods used.
NOTE: "MPR for short/rapid-acting insulin (SA)" rows show balance statistics for the sensitivity analysis (SA) mentioned in Chapter 4. ASMD = average standardized mean difference; ESS = effective sample size.

Table D.9 presents the detailed results for the MA-PD access regressions.

Table D.9. Detailed MA-PD Access Regression Results, by Year

Outcome Measure	DD Coefficient	Standard Error	*P*-Value	95% CI Low	95% CI High	Treated Mean
Number of 30-day fills						
2021	0.852	0.029	<0.001	0.794	0.909	10.356
2022	0.744	0.033	<0.001	0.679	0.810	9.868
2023	0.388	0.035	<0.001	0.320	0.455	9.811
MPR for short/rapid-acting insulin						
2021	0.026	0.002	<0.001	0.021	0.030	0.656
2022	0.027	0.002	<0.001	0.023	0.032	0.655
2023	0.011	0.003	<0.001	0.006	0.017	0.653
MPR for short/rapid-acting insulin (SA)						
2021	0.033	0.002	<0.001	0.028	0.037	0.585
2022	0.031	0.002	<0.001	0.026	0.035	0.581
2023	0.010	0.003	<0.001	0.004	0.016	0.577
Persistence to basal insulin						
2021	0.016	0.003	<0.001	0.011	0.021	0.675
2022	0.012	0.003	<0.001	0.005	0.018	0.662
2023	0.001	0.004	0.683	–0.006	0.008	0.646

SOURCES: Authors' analysis of PDE and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: This table shows coefficients from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in nonparticipating plans. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details. "MPR for Short/Rapid-Acting Insulin (SA)" rows show results from the sensitivity analysis (SA) mentioned in Chapter 4.

Table D.10 presents the detailed results for the PDP access regressions.

Table D.10. Detailed PDP Access Regression Results, by Year

Outcome Measure	DD Coefficient	Standard Error	*P*-Value	95% CI Low	95% CI High	Treated Mean
Number of 30-day fills						
2021	0.821	0.026	<0.001	0.769	0.873	11.253
2022	1.051	0.036	<0.001	0.980	1.121	10.900
2023	0.586	0.040	<0.001	0.507	0.665	10.818
MPR for short/rapid-acting insulin						
2021	0.028	0.002	<0.001	0.024	0.032	0.658
2022	0.029	0.002	<0.001	0.024	0.033	0.655
2023	0.008	0.003	0.002	0.003	0.014	0.652

Outcome Measure	DD Coefficient	Standard Error	*P*-Value	95% CI Low	95% CI High	Treated Mean
MPR for short/rapid-acting insulin (SA)						
2021	0.027	0.002	<0.001	0.024	0.031	0.588
2022	0.030	0.002	<0.001	0.026	0.034	0.586
2023	0.006	0.003	0.037	0.000	0.012	0.583
Persistence to basal insulin						
2021	0.007	0.002	<0.001	0.003	0.012	0.695
2022	0.008	0.003	0.002	0.003	0.013	0.690
2023	0.007	0.003	0.031	0.001	0.013	0.668

SOURCES: Authors' analysis of PDE and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: This table shows coefficients from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in nonparticipating plans. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details. "MPR for Short/Rapid-Acting Insulin (SA)" rows show results from the sensitivity analysis (SA) mentioned in Chapter 4.

Health Outcome Regression Results

Table D.11 presents the balance statistics for the beneficiary health outcome regression results.

Table D.11. Balance Statistics for Beneficiary Health Outcome Regression Results, by Plan Type

Outcome Measure	Average *N*: PDSS Participants	Average *N*: Comparison Beneficiaries	Average ESS	Mean ASMD	Maximum ASMD
MA-PDs					
MA risk score	188,122	68,015	42,719	0.043	0.101
Part D risk score	188,122	68,015	42,719	0.043	0.101
Blood sugar controlled	7,099	11,580	2,393	0.064	0.104
Inpatient stays—short-term complications	188,122	68,015	42,719	0.042	0.101
ED visits—short-term complications	187,907	67,959	42,656	0.043	0.101
Inpatient stays—uncontrolled diabetes	188,122	68,015	42,719	0.043	0.101
PDPs					
MA risk score	167,378	96,203	92,443	0.029	0.100
Part D risk score	167,378	96,203	92,443	0.029	0.100
Inpatient stays—short-term complications	167,378	96,203	92,443	0.029	0.100
ED visits—short-term complications	167,295	96,105	92,338	0.028	0.100
Inpatient stays—uncontrolled diabetes	167,378	96,203	92,443	0.028	0.100

SOURCES: Authors' analysis of Part D event and other data. See Appendix A for additional details on the data sources and methods used.
NOTE: ASMD = average standardized mean difference; ESS = effective sample size.

Table D.12 presents the detailed results for the MA-PD health outcome regressions.

Table D.12. Detailed MA-PD Health Outcome Regression Results, by Year

Outcome Measure	DD Coefficient	Standard Error	*P*-Value	95% CI Low	95% CI High	Treated Mean
MA risk score						
2021	0.088	0.006	<0.001	0.076	0.099	1.880
2022	0.074	0.007	<0.001	0.061	0.088	1.904
2023	0.043	0.007	<0.001	0.029	0.057	1.821
Part D risk score						
2021	0.052	0.004	<0.001	0.043	0.060	1.520
2022	0.044	0.005	<0.001	0.035	0.054	1.469
2023	0.039	0.005	<0.001	0.028	0.049	1.446
Blood sugar controlled						
2021	0.016	0.019	0.391	–0.021	0.053	0.236
2022	–0.006	0.018	0.722	–0.041	0.029	0.228
2023	0.028	0.019	0.149	–0.010	0.066	0.183
Inpatient stays—short-term complications						
2021	–0.001	0.000	0.007	–0.002	0.000	0.005
2022	0.000	0.000	0.518	–0.001	0.001	0.005
2023	–0.001	0.000	0.060	–0.002	0.000	0.006
Inpatient stays—uncontrolled diabetes						
2021	0.000	0.000	0.888	–0.001	0.001	0.005
2022	0.000	0.000	0.721	–0.001	0.000	0.005
2023	–0.001	0.000	0.007	–0.002	0.000	0.005
ED visits—short-term complications						
2021	–0.001	0.001	0.452	–0.003	0.001	0.035
2022	–0.002	0.001	0.094	–0.004	0.000	0.037
2023	–0.003	0.001	0.007	–0.006	–0.001	0.039

SOURCES: Authors' analysis of PDE and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: This table shows coefficients from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in nonparticipating plans. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Table D.13 presents the detailed results for the PDP health outcome regressions.

Table D.13. Detailed PDP Health Outcome Regression Results, by Year

Outcome Measure	DD Coefficient	Standard Error	*P*-Value	95% CI Low	95% CI High	Treated Mean
MA risk score						
2021	0.038	0.005	<0.001	0.028	0.049	1.700
2022	0.044	0.005	<0.001	0.034	0.054	1.735
2023	0.007	0.005	0.181	–0.003	0.018	1.777
Part D risk score						
2021	0.019	0.003	<0.001	0.013	0.024	1.442
2022	0.017	0.004	<0.001	0.010	0.024	1.432
2023	–0.002	0.004	0.678	–0.010	0.007	1.445
Inpatient stays—short-term complications						
2021	0.000	0.000	0.183	0.000	0.001	0.005
2022	0.000	0.000	0.629	0.000	0.001	0.005
2023	0.000	0.000	0.874	–0.001	0.001	0.006
Inpatient stays—uncontrolled diabetes						
2021	0.000	0.000	0.265	0.000	0.001	0.006
2022	0.001	0.000	<0.001	0.001	0.002	0.007
2023	0.000	0.000	0.518	–0.001	0.001	0.008
ED visits—short-term complications						
2021	–0.001	0.001	0.086	–0.002	0.000	0.023
2022	0.001	0.001	0.213	0.000	0.002	0.025
2023	–0.001	0.001	0.233	–0.003	0.001	0.027

SOURCES: Authors' analysis of PDE and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: This table shows coefficients from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in nonparticipating plans. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Beneficiary Cost and Benefit Phase Regression Results

Table D.14 presents the balance statistics for the cost and benefit phase regression results.

Table D.14. Balance Statistics for Cost and Benefit Phase Regression Results, by Plan Type

Outcome Measure	Average *N*: PDSS Participants/ Participating Plans	Average *N*: Comparison Beneficiaries/ Plans	Average ESS	Mean ASMD	Maximum ASMD
MA-PDs					
Plan level					
Total Part D premium	1,698	1,449	1,152	0.047	0.100
Basic Part D premium	1,698	1,449	1,148	0.047	0.100
Supplemental Part D premium	1,698	1,449	1,152	0.041	0.100

Outcome Measure	Average *N*: PDSS Participants/ Participating Plans	Average *N*: Comparison Beneficiaries/ Plans	Average ESS	Mean ASMD	Maximum ASMD
Beneficiary level					
Total OOP costs	188,122	68,015	42,554	0.044	0.102
Insulin OOP costs	188,122	68,015	42,690	0.044	0.102
Noninsulin OOP costs	188,122	68,015	42,663	0.044	0.102
Total Part D costs	188,122	68,015	42,442	0.044	0.102
Number of days—initial coverage	187,698	67,771	42,610	0.044	0.101
Number of days—coverage gap	188,122	68,015	42,721	0.044	0.101
Number of days—catastrophic	188,122	68,015	42,719	0.043	0.101
Probability of ending year in initial phase	188,122	68,015	42,718	0.044	0.101
Probability of ending year in gap	188,122	68,015	42,719	0.043	0.101
Probability of ending year in catastrophic	188,122	68,015	42,720	0.043	0.101
PDPs					
Plan level					
Total Part D premium	317	415	77	0.056	0.100
Basic Part D premium	317	415	68	0.073	0.240
Supplemental Part D premium	317	415	46	0.114	0.532
Beneficiary level					
Total OOP costs	167,378	96,203	91,944	0.029	0.100
Insulin OOP costs	167,378	96,203	90,681	0.029	0.100
Noninsulin OOP costs	167,378	96,203	92,331	0.029	0.100
Total Part D costs	167,378	96,203	92,181	0.028	0.100
Number of days—initial coverage	166,985	96,029	92,299	0.029	0.100
Number of days—coverage gap	167,378	96,203	92,442	0.030	0.100
Number of days—catastrophic	167,378	96,203	92,443	0.029	0.100
Probability of ending year in initial phase	167,378	96,203	92,441	0.030	0.100
Probability of ending year in gap	167,378	96,203	92,443	0.030	0.100
Probability of ending year in catastrophic	167,378	96,203	92,443	0.029	0.100

SOURCES: Authors' analysis of Part D event and other data. See Appendix A for additional details on the data sources and methods used.
NOTE: ASMD = average standardized mean difference; ESS = effective sample size.

Table D.15 presents the detailed results for the MA-PD cost and benefit phase regressions.

Table D.15. Detailed MA-PD Cost and Benefit Phase Regression Results, by Year

Outcome Measure	DD Coefficient	Standard Error	*P*-Value	95% CI Low	95% CI High	Treated Mean
Total Part D premium						
2021	0.34	0.41	0.41	–0.47	1.14	13.09
2022	0.09	0.37	0.82	–0.64	0.81	14.35
2023	–0.13	0.39	0.73	–0.89	0.62	13.82
Basic Part D premium						
2021	0.62	0.36	0.09	–0.10	1.33	12.39
2022	0.30	0.36	0.41	–0.41	1.00	13.36
2023	–0.36	0.37	0.33	–1.10	0.37	12.40
Supplemental Part D premium						
2021	–0.39	0.19	0.04	–0.76	–0.02	0.70
2022	–0.32	0.18	0.08	–0.68	0.04	0.99
2023	0.16	0.20	0.41	–0.22	0.54	1.42
Total OOP costs						
2021	–213.74	8.15	<0.001	–229.72	–197.76	994.27
2022	–197.66	9.93	<0.001	–217.12	–178.20	1,018.10
2023	–12.38	9.67	0.201	–31.33	6.57	1,049.63
Insulin OOP costs						
2021	–233.26	6.32	<0.001	–245.64	–220.87	324.40
2022	–223.60	6.30	<0.001	–235.95	–211.24	304.36
2023	–37.55	8.95	<0.001	–55.10	–20.01	286.23
Noninsulin OOP costs						
2021	18.94	5.55	<0.001	8.05	29.83	674.59
2022	26.88	8.11	<0.001	10.98	42.79	718.81
2023	26.74	10.94	0.015	5.29	48.19	768.62
Total Part D costs						
2021	–209.50	9.67	<0.001	–228.45	–190.54	1,148.59
2022	–199.50	10.74	<0.001	–220.54	–178.46	1,191.17
2023	–25.51	11.80	0.031	–48.64	–2.39	1,224.43
Number of days—initial coverage						
2021	–0.20	0.01	<0.001	–0.23	–0.17	7.75
2022	–0.20	0.01	<0.001	–0.23	–0.18	7.89
2023	–0.15	0.02	<0.001	–0.19	–0.11	7.66
Number of days—coverage gap						
2021	0.31	0.02	<0.001	0.28	0.34	3.64
2022	0.30	0.02	<0.001	0.27	0.33	3.50
2023	0.28	0.02	<0.001	0.24	0.31	3.63
Number of days—catastrophic						
2021	–0.11	0.01	<0.001	–0.13	–0.09	0.79
2022	–0.09	0.01	<0.001	–0.11	–0.07	0.80
2023	–0.13	0.01	<0.001	–0.15	–0.10	0.89
Probability of ending year in initial coverage						
2021	–0.03	0.00	<0.001	–0.03	–0.02	0.31
2022	–0.04	0.00	<0.001	–0.04	–0.03	0.33

Outcome Measure	DD Coefficient	Standard Error	*P*-Value	95% CI Low	95% CI High	Treated Mean
2023	–0.03	0.00	<0.001	–0.03	–0.02	0.31
Probability of ending year in coverage gap						
2021	0.04	0.00	<0.001	0.04	0.05	0.49
2022	0.05	0.00	<0.001	0.04	0.06	0.47
2023	0.05	0.00	<0.001	0.04	0.06	0.47
Probability of ending year in catastrophic						
2021	–0.01	0.00	<0.001	–0.02	–0.01	0.20
2022	–0.01	0.00	<0.001	–0.01	–0.01	0.20
2023	–0.02	0.00	<0.001	–0.03	–0.02	0.22

SOURCES: Authors' analysis of PDE and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: This table shows coefficients from the plan- and beneficiary-level DD regression models estimated for PDSS-participating plans and our sample of insulin users. The comparison groups consisted of nonparticipating plans and insulin users enrolled in nonparticipating plans. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Table D.16 presents the detailed results for the PDP cost and benefit phase regressions.

Table D.16. Detailed PDP Cost and Benefit Phase Regression Results, by Year

Outcome Measure	DD Coefficient	Standard Error	*P*-Value	95% CI Low	95% CI High	Treated Mean
Total Part D premium						
2021	–3.59	2.31	0.12	–8.13	0.94	47.63
2022	5.30	2.19	0.02	0.99	9.60	60.64
2023	1.74	1.99	0.38	–2.15	5.64	58.81
Basic Part D premium						
2021	–6.88	1.84	<0.001	–10.48	–3.27	27.26
2022	–6.65	2.02	<0.001	–10.60	–2.70	29.47
2023	–8.79	1.83	<0.001	–12.38	–5.20	23.53
Supplemental Part D premium						
2021	7.50	1.62	<0.001	4.33	10.67	20.37
2022	16.47	1.81	<0.001	12.93	20.02	31.17
2023	17.04	1.94	<0.001	13.24	20.85	35.28
Total OOP costs						
2021	–363.61	9.26	<0.001	–381.76	–345.45	1,465.59
2022	–426.09	12.81	<0.001	–451.19	–400.99	1,528.71
2023	–69.30	16.65	<0.001	–101.93	–36.67	1,559.42
Insulin OOP costs						
2021	–367.85	11.79	<0.001	–390.96	–344.74	372.61
2022	–384.37	13.91	<0.001	–411.63	–357.11	361.98
2023	–3.09	15.40	0.841	–33.28	27.10	316.22
Noninsulin OOP costs						
2021	–2.28	4.70	0.628	–11.49	6.93	1,100.92
2022	–45.28	5.20	<0.001	–55.46	–35.09	1,175.51
2023	–74.29	7.47	<0.001	–88.92	–59.65	1,251.75
Total Part D costs						
2021	–309.49	13.07	<0.001	–335.12	–283.87	2,296.76
2022	–318.86	17.65	<0.001	–353.45	–284.26	2,425.42

Outcome Measure	DD Coefficient	Standard Error	*P*-Value	95% CI Low	95% CI High	Treated Mean
2023	84.72	27.94	0.002	29.96	139.47	2,510.73
Number of days—initial coverage phase						
2021	–0.10	0.02	<0.001	–0.13	–0.07	6.91
2022	–0.11	0.02	<0.001	–0.16	–0.07	6.97
2023	–0.05	0.03	0.137	–0.11	0.02	6.82
Number of days—coverage gap						
2021	0.31	0.01	<0.001	0.29	0.33	3.94
2022	0.36	0.02	<0.001	0.32	0.39	3.85
2023	0.37	0.03	<0.001	0.32	0.42	3.88
Number of days—catastrophic						
2021	–0.21	0.01	<0.001	–0.23	–0.20	1.36
2022	–0.25	0.01	<0.001	–0.27	–0.22	1.39
2023	–0.32	0.01	<0.001	–0.35	–0.29	1.51
Probability of ending year in initial phase						
2021	–0.01	0.00	<0.001	–0.01	–0.01	0.23
2022	–0.02	0.00	<0.001	–0.03	–0.02	0.25
2023	–0.01	0.00	0.018	–0.02	0.00	0.24
Probability of ending year in coverage gap						
2021	0.04	0.00	<0.001	0.04	0.04	0.45
2022	0.05	0.00	<0.001	0.05	0.06	0.44
2023	0.06	0.00	<0.001	0.05	0.06	0.42
Probability of ending year in catastrophic						
2021	–0.03	0.00	<0.001	–0.03	–0.03	0.32
2022	–0.03	0.00	<0.001	–0.03	–0.03	0.32
2023	–0.05	0.00	<0.001	–0.06	–0.04	0.34

SOURCES: Authors' analysis of PDE and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: This table shows coefficients from the plan- and beneficiary-level DD regression models estimated for PDSS-participating plans and our sample of insulin users. The comparison groups consisted of nonparticipating plans and insulin users enrolled in nonparticipating plans. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Part D Financial Regression Results

Table D.17 presents the balance statistics for the plan enrollment regression results.

Table D.17. Balance Statistics for Part D Financial Regression Results by Plan Type

Outcome Measure	Average *N*: PDSS Participants or Insulin Users	Average *N*: Comparison Plans or Beneficiaries	Average ESS	Mean ASMD	Maximum ASMD
MA-PDs					
Beneficiary level					
Total gross drug costs	188,122	68,015	42,717	0.044	0.101
Insulin gross drug costs	188,122	68,015	42,719	0.044	0.101
Plan level					
Part D basic bid	1,698	1,449	1,042	0.053	0.100
Part D bid plus supplemental	1,698	1,449	966	0.052	0.100
Part D administrative costs	1,698	1,449	1,150	0.049	0.100
Manufacturer rebates	1,698	1,446	1,144	0.042	0.100
Manufacturer gap discount payments	1,698	1,449	985	0.050	0.100
Part D costs to Medicare	1,669	1,433	1,139	0.041	0.100
Reinsurance costs	1,698	1,449	1,154	0.048	0.100
Medical spending	1,151	849	657	0.053	0.100
PDPs					
Beneficiary level					
Total gross drug costs	167,378	96,203	92,443	0.030	0.100
Insulin gross drug costs	167,378	96,203	92,443	0.029	0.100
Medical spending	167,378	96,203	91,903	0.039	0.112
Plan level					
Part D basic bid	317	415	68	0.073	0.239
Part D bid plus supplemental	317	415	76	0.056	0.100
Part D administrative costs	317	415	92	0.059	0.100
Manufacturer rebates	317	415	103	0.058	0.100
Manufacturer gap discount payments	317	415	113	0.057	0.100
Part D costs to Medicare	317	415	116	0.052	0.100
Reinsurance costs	317	415	116	0.056	0.100

SOURCES: Authors' analysis of Part D event and other data. See Appendix A for additional details on the data sources and methods used.
NOTE: ASMD = average standardized mean difference; ESS = effective sample size.

Table D.18 presents the detailed results for the MA-PD financial regressions.

Table D.18. Detailed MA-PD Part D Financial Regression Results, by Year

Outcome Measure	DD Coefficient	Standard Error	*P*-Value	95% CI Low	95% CI High	Treated Mean
Total gross drug costs						
2021	468.24	30.09	<0.001	409.26	527.21	8,809.04
2022	589.96	33.25	<0.001	524.79	655.13	9,149.95
2023	549.91	56.92	<0.001	438.34	661.48	10,117.99
Insulin gross drug costs						
2021	554.71	15.64	<0.001	524.05	585.38	4,526.76

Outcome Measure	DD Coefficient	Standard Error	*P*-Value	95% CI Low	95% CI High	Treated Mean
2022	609.45	15.37	<0.001	579.32	639.57	4,375.25
2023	438.32	26.70	<0.001	385.98	490.65	4,429.53
Part D basic bid						
2021	4.95	0.49	<0.001	3.99	5.92	43.91
2022	4.18	0.49	<0.001	3.21	5.15	41.73
2023	2.06	0.50	<0.001	1.08	3.05	38.89
Part D bid plus supplemental						
2021	6.93	0.63	<0.001	5.71	8.16	76.47
2022	8.29	0.64	<0.001	7.04	9.54	79.17
2023	8.46	0.63	<0.001	7.23	9.69	83.90
Part D administrative costs						
2021	–0.29	0.20	0.147	–0.69	0.10	13.86
2022	–0.32	0.19	0.098	–0.70	0.06	14.27
2023	0.46	0.20	0.024	0.06	0.86	15.20
Manufacturer rebates						
2021	2.27	0.561	<0.001	1.17	3.36	64.90
2022	3.21	0.565	<0.001	2.10	4.31	72.56
2023	2.52	0.662	<0.001	1.22	3.81	84.42
Manufacturer gap discount payments						
2021	1.84	0.24	<0.001	1.37	2.32	17.60
2022	2.76	0.23	<0.001	2.31	3.21	19.74
2023	2.46	0.25	<0.001	1.96	2.96	23.14
Part D costs to Medicare						
2021	–4.74	1.907	0.013	–8.48	–1.00	88.75
2022	–6.51	1.887	<0.001	–10.21	–2.81	86.83
2023	–10.84	2.067	<0.001	–14.89	–6.79	99.43
Reinsurance costs						
2021	–0.99	1.399	0.479	–3.73	1.75	57.54
2022	–1.26	1.374	0.361	–3.95	1.44	59.68
2023	–3.31	1.428	0.020	–6.11	–0.51	69.75
Medical spending						
2021	–0.01	–0.01	0.01	0.293	–0.03	6.72
2022	–0.01	–0.01	0.01	0.311	–0.03	6.79
2023	–0.01	–0.01	0.01	0.117	–0.03	6.82

SOURCES: Authors' analysis of Part D bid and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: This table shows coefficients on the PDSS model implementation indicator from the plan-level DD regression models. The comparison groups consisted of nonparticipating plans. 95% CIs are based on plan-clustered standard errors. Medical spending outcome results are presented as log-transformed effects. See Appendix A for additional technical details.

Table D.19 presents the detailed results for the PDP financial regressions.

Table D.19. Detailed PDP Part D Financial Regression Results, by Year

Outcome Measure	DD Coefficient	Standard Error	*P*-Value	95% CI Low	95% CI High	Treated Mean
Total gross drug costs						
2021	262.82	32.94	<0.001	198.27	327.38	11,186.37
2022	337.29	49.60	<0.001	240.07	434.51	11,822.23
2023	146.89	68.28	0.031	13.05	280.73	12,838.24
Insulin gross drug costs						
2021	391.47	19.24	<0.001	353.77	429.18	5,176.53
2022	458.90	32.57	<0.001	395.06	522.73	5,142.35
2023	231.47	46.21	<0.001	140.89	322.04	5,219.39
Part D basic bid						
2021	–6.87	1.80	<0.001	–10.39	–3.35	37.27
2022	–6.65	2.03	0.001	–10.62	–2.67	34.27
2023	–8.79	1.86	<0.001	–12.43	–5.15	25.50
Part D bid plus supplemental						
2021	–3.59	2.45	0.142	–8.39	1.21	57.64
2022	5.29	2.23	0.018	0.92	9.66	65.45
2023	1.73	1.90	0.362	–1.99	5.46	60.77
Part D administrative costs						
2021	–0.64	0.48	0.181	–1.57	0.30	13.88
2022	0.58	0.56	0.296	–0.51	1.68	15.30
2023	0.14	0.60	0.818	–1.04	1.31	15.01
Manufacturer rebates						
2021	7.49	1.033	<0.001	5.46	9.51	71.97
2022	16.21	1.367	<0.001	13.53	18.89	107.58
2023	22.32	1.925	<0.001	18.54	26.09	118.95
Manufacturer gap discount payments						
2021	4.06	0.61	<0.001	2.87	5.24	30.90
2022	7.96	0.72	<0.001	6.56	9.37	44.69
2023	10.35	0.90	<0.001	8.58	12.12	49.25
Part D costs to Medicare						
2021	–9.33	2.941	0.002	–15.09	–3.57	106.18
2022	–18.89	4.218	<0.001	–27.15	–10.62	111.44
2023	–17.09	3.747	<0.001	–24.44	–9.75	112.09
Reinsurance payments						
2021	–7.18	2.435	0.003	–11.95	–2.41	76.78
2022	–13.36	3.286	<0.001	–19.80	–6.92	87.74
2023	–13.02	2.600	<0.001	–18.12	–7.92	90.00
Medical spending						

Outcome Measure	DD Coefficient	Standard Error	*P*-Value	95% CI Low	95% CI High	Treated Mean
2021	0.14	0.01	<0.001	0.12	0.17	8.88
2022	0.02	0.01	0.020	0.00	0.03	8.77
2023	–0.02	0.01	0.017	–0.04	0.00	8.85

SOURCES: Authors' analysis of Part D bid and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: This table shows coefficients on the PDSS Model implementation indicator from the plan-level DD regression models. The comparison groups consisted of nonparticipating plans. 95% CIs are based on plan-clustered standard errors. Medical spending outcome results are presented as log-transformed effects. See Appendix A for additional technical details.

Spillover Effects Regression Results

Table D.20 presents the balance statistics for the plan enrollment regression results.

Table D.20. Balance Statistics for Spillover Effects Regression Results, by Plan Type

Outcome Measure	Average *N*: PDSS Participants or Insulin Users	Average *N*: Comparison Plans or Beneficiaries	Average ESS	Mean ASMD	Maximum ASMD
MA-PDs					
Plan level					
Noninsulin user enrollment	1,698	1,449	1,153	0.045	0.100
Dually eligible enrollment	1,698	1,449	1,155	0.039	0.100
LIS eligible enrollment	1,698	1,449	1,155	0.040	0.100
Beneficiary level					
Noninsulin user OOP costs	4,134,706	1,621,710	1,313,834	0.040	0.100
Noninsulin user Part D costs	4,134,706	1,621,710	1,313,640	0.040	0.100
Number of days—initial coverage	4,133,328	1,619,227	1,316,853	0.040	0.100
Number of days—coverage gap	4,134,706	1,621,710	1,318,604	0.040	0.100
Number of days—catastrophic	4,134,706	1,621,710	1,318,497	0.039	0.100
PDPs					
Plan level					
Noninsulin user enrollment	317	415	93	0.052	0.100
Dually eligible enrollment	317	415	103	0.056	0.099
LIS eligible enrollment	317	415	102	0.061	0.144
Beneficiary level					
Noninsulin user OOP costs	3,576,216	2,716,818	2,556,137	0.028	0.100
Noninsulin user Part D costs	3,576,216	2,716,818	2,535,605	0.029	0.100
Number of days—initial coverage	3,575,071	2,716,235	2,555,947	0.027	0.100
Number of days—coverage gap	3,576,216	2,716,818	2,556,529	0.028	0.100
Number of days—catastrophic	3,576,216	2,716,818	2,556,533	0.027	0.100

SOURCE: Authors' analysis of Part D event and other data. See Appendix A for additional details on the data sources and methods used.
NOTE: ASMD = average standardized mean difference; ESS = effective sample size.

Table D.21 presents the detailed results for the MA-PD spillover effects regressions.

Table D.21. Detailed MA-PD Spillover Effects Regression Results, by Year

Outcome Measure	DD Coefficient	Standard Error	*P*-Value	95% CI Low	95% CI High	Treated Mean
Noninsulin user enrollment						
2021	0.11	0.03	<0.001	0.05	0.17	6,721
2022	0.15	0.03	<0.001	0.09	0.21	6,386
2023	0.28	0.03	<0.001	0.22	0.34	5,979
Dually eligible enrollment						
2021	0.08	0.03	0.007	0.02	0.14	1,113
2022	0.10	0.03	0.002	0.04	0.16	1,006
2023	0.22	0.03	<0.001	0.16	0.28	842
LIS eligible enrollment						
2021	0.09	0.03	0.002	0.03	0.14	1,482
2022	0.10	0.03	<0.001	0.04	0.16	1,336
2023	0.22	0.03	<0.001	0.17	0.28	1,156
Noninsulin user OOP costs						
2021	16.08	3.24	<0.001	9.72	22.44	332.91
2022	27.20	5.09	<0.001	17.21	37.18	345.78
2023	27.05	6.83	<0.001	13.67	40.43	343.86
Noninsulin user Part D costs						
2021	17.21	5.85	0.003	5.75	28.67	476.84
2022	24.09	7.49	0.001	9.40	38.78	505.21
2023	3.41	11.02	0.757	–18.19	25.01	503.81
Number of days—initial coverage						
2021	–0.03	0.00	<0.001	–0.04	–0.02	11.53
2022	–0.06	0.01	<0.001	–0.07	–0.04	11.48
2023	–0.09	0.01	<0.001	–0.11	–0.07	11.38
Number of days—coverage gap						
2021	0.03	0.00	<0.001	0.02	0.04	0.54
2022	0.05	0.01	<0.001	0.04	0.06	0.59
2023	0.08	0.01	<0.001	0.06	0.10	0.68
Number of days—catastrophic						
2021	0.00	0.00	<0.001	0.00	0.00	0.11
2022	0.01	0.00	<0.001	0.01	0.01	0.11
2023	0.01	0.00	<0.001	0.01	0.01	0.13

SOURCES: Authors' analysis of PDE and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: This table shows coefficients from the plan- and beneficiary-level DD regression models. The comparison groups consisted of nonparticipating plans and noninsulin users enrolled in nonparticipating plans. 95% CIs are based on plan-clustered standard errors. Enrollment outcome results are presented as log-transformed effects. See Appendix A for covariates and additional technical details.

Table D.22 presents the detailed results for the PDP spillover effects regressions.

Table D.22. Detailed PDP Spillover Effects Regression Results, by Year

Outcome Measure	DD Coefficient	Standard Error	*P*-Value	95% CI Low	95% CI High	Treated Mean
Noninsulin user enrollment						
2021	0.17	0.04	<0.001	0.09	0.25	26,512
2022	0.11	0.05	0.033	0.01	0.20	21,936
2023	0.17	0.07	0.010	0.04	0.31	22,721
Dually eligible enrollment						
2021	0.03	0.03	0.283	–0.03	0.10	1,292
2022	–0.03	0.04	0.405	–0.11	0.05	950
2023	–0.04	0.06	0.544	–0.15	0.08	821
LIS eligible enrollment						
2021	0.03	0.03	0.260	–0.03	0.09	1,546
2022	–0.03	0.04	0.422	–0.11	0.05	1,118
2023	–0.02	0.05	0.682	–0.12	0.08	947
Noninsulin user OOP costs						
2021	–18.38	3.18	<0.001	–24.62	–12.14	602.34
2022	–40.22	3.50	<0.001	–47.09	–33.35	633.59
2023	–56.72	4.82	<0.001	–66.17	–47.27	619.42
Noninsulin user Part D costs						
2021	30.24	6.26	<0.001	17.96	42.52	1,281.12
2022	64.79	12.28	<0.001	40.73	88.85	1,385.56
2023	50.95	17.05	0.003	17.53	84.37	1,334.67
Number of days—initial coverage						
2021	–0.01	0.00	0.039	–0.01	0.00	11.27
2022	–0.03	0.01	<0.001	–0.04	–0.02	11.19
2023	–0.06	0.01	<0.001	–0.08	–0.05	11.18
Number of days—coverage gap						
2021	0.01	0.00	0.007	0.00	0.01	0.75
2022	0.04	0.01	<0.001	0.02	0.05	0.81
2023	0.06	0.01	<0.001	0.05	0.08	0.81
Number of days—catastrophic						
2021	0.00	0.00	<0.001	–0.01	0.00	0.19
2022	–0.01	0.00	<0.001	–0.01	0.00	0.20
2023	0.00	0.00	0.172	–0.01	0.00	0.21

SOURCES: Authors' analysis of PDE and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTE: This table shows coefficients from the plan- and beneficiary-level DD regression models. The comparison groups consisted of nonparticipating plans and noninsulin users enrolled in nonparticipating plans. 95% CIs are based on plan-clustered standard errors. Enrollment outcome results are presented as log-transformed effects. See Appendix A for covariates and additional technical details.

Appendix E. Qualitative Data Collection and Analysis Methods

This appendix describes the qualitative data collection and analysis methods that we used in this evaluation. The RAND Human Subjects Protection Committee reviewed and approved all research activities.

As in 2022, we fielded online surveys to all PDSS-participating POs and conducted semistructured interviews with a sample of POs whose representatives had completed the survey in 2023 and 2024. In 2024, we interviewed a sample of beneficiaries who used insulin and were enrolled in PDSS-participating plans to better understand their experiences with the model and solicit their perspectives on its outcomes. These interviews were similar to the ones that we conducted with insulin users in 2022. In 2024, we also conducted semistructured interviews with a convenience sample of SHIP counselors and independent insurance agents from five states with the highest number of Medicare beneficiaries (California, New York, Florida, Pennsylvania, and Texas). These interviews focused on PDSS awareness and the role lower insulin copayments played in beneficiary choice of MA plans, among other topics.

Below, we provide additional details about each data collection and analysis activity. Because our data collection and analytic approaches are similar to those we used in the first-year evaluation of the model, some text in this appendix closely mirrors the text from our previous report (Taylor et al., 2023).

Participating Parent Organizations

We conducted two waves of PO surveys, one in 2023 that focused on 2022 PDSS outcomes and one in 2024 that covered 2023 outcomes. The methods used for these two surveys were very similar, so we have grouped them together into one section and highlight any differences between the two survey rounds.

Survey Data Collection

We obtained a list of and contact information for all POs that participated in PDSS in 2022 and 2023. Because of mergers and acquisitions, we combined several entities together to reflect their updated PO status. Our final list of POs that participated in PDSS consisted of 100 POs in 2022 and 116 POs in 2023. We invited all PDSS-participating POs to complete the survey.

We used modified versions of the survey questions from the first evaluation report, which had been based on our previous experiences conducting PO surveys as part of a similar model test evaluation (Khodyakov et al., 2022) and the literature on diabetes management (McBrien et al., 2017; Sina, Graffy, and Simmons, 2018). The questionnaire included close-ended and open-ended questions about participation in the model (for example, types of plans entered, all plans

or a subset of plans), relationship with PBMs, barriers to beneficiaries' insulin use, impacts of PDSS on both plans and beneficiaries using insulin, and potential changes that plans would make to insulin coverage in the future. POs that entered only PDPs into the model received a shorter version of the survey that excluded certain outcomes of PDSS that PDPs are not directly responsible for, such as beneficiary health status.

We programmed the questionnaire into SelectSurvey and invited all POs to complete it in March 2023 and February 2024. The questionnaire had a consent form as its first screen, which POs were required to review and agree to before accessing the questionnaire. We monitored questionnaire completion and sent periodic reminders to the contacts for POs that had not responded. We closed the surveys in April 2023 and March 2024. For the 2023 survey, of the 100 POs contacted, 90 consented to be surveyed and completed at least half of the survey (90% response rate). For the 2024 survey, of the 116 POs contacted, 95 consented to be surveyed and completed at least half of the survey (82% response rate).

Survey Data Analysis

We cleaned and recoded survey data to prepare them for analysis. For example, we asked PO respondents what outcomes their organizations had observed that could be attributed to PDSS. For each outcome, participants used a 5-point scale to rate the direction and relative magnitude of any change they had seen (large decrease, small decrease, no impact, small increase, large increase). Relatively few respondents selected a large increase or decrease, so we condensed responses to a 3-point scale (decrease, no impact, increase). Because participants were not required to answer all questions, the number of respondents for each question varied.

We calculated descriptive statistics (counts, percentages, medians, modes, and ranges) for survey responses. There were several questions on the survey where respondents could write in free-text responses to explain their numeric responses or provide additional input. We reviewed all free-text survey responses to identify common themes or unique insights. For example, we provided PO respondents the opportunity to write about any additional outcomes they had already seen because of the model. Almost all respondents who wrote something stated that the data on outcomes were preliminary, the plan had not had a chance to evaluate this yet, or the IRA had made the model outcomes obsolete ("IRA overrode PDSS for 2023").

Interview Sampling

We used a purposive sampling strategy to select POs for in-depth interviews to further explore topics covered in the survey. For the 2023 PO interviews (Wave 2), we invited all nine POs that took part in the 2022 PO interviews (Wave 1). We also invited all nine POs that offered an R&I program as part of the model and the six largest POs participating in the risk corridor component (all POs with more than 45,000 beneficiaries in PDSS-participating plans).

Our goal was to interview representatives from up to 15 POs. Between April and June 2023, we interviewed 46 representatives of 13 PDSS-participating POs. Each PO was represented by

between one and nine individuals, including chief operating officers, directors of Medicare Advantage, directors of Government Pharmacy Product Strategy, and actuarial directors, as well as other staff involved in the design and administration of PDSS. We encouraged POs to invite representatives of their PBMs to attend the interviews; three POs invited PBMs to share their experiences with PDSS. Our final 2023 sample of 13 POs included:

- POs interviewed in 2022 ($N = 7$)
- POs offering R&I programs ($N = 3$)
- the largest POs participating in the risk corridor component ($N = 3$).

For 2024 PO interviews (Wave 3), we invited nine POs that we interviewed in 2023 (including four that we interviewed in 2022). We also invited four POs with large special needs plans entered into the model, six small POs (with at least 100 enrolled beneficiaries), and six POs with the largest participating enrollment not already sampled.

Our goal was to interview representatives from up to 15 POs. Between March and June 2024, we interviewed 51 representatives of 14 PDSS-participating POs. Each PO was represented by between one and 12 individuals, including chief operating officers, directors of Medicare Advantage, directors of Government Pharmacy Product Strategy, and actuarial directors, as well as other staff involved in the design and administration of PDSS. We encouraged POs to invite representatives of their PBMs to attend the interviews; three POs invited PBMs to share their experiences with PDSS. Our final 2024 sample of 14 POs included:

- POs interviewed in 2023 ($N = 8$), including four POs also interviewed in 2022
- POs with large special needs plans ($N = 1$)
- POs with the smallest participating enrollment ($N = 1$)
- POs with the largest participating enrollment not already sampled ($N = 4$).

Interview Process

We used the same interview approach for PO interviews in 2023 and 2024. We used a semistructured interview guide for PO interviews to better understand PO survey responses about the model and its outcomes and to ask additional questions about the process of formulary development and negotiations with insulin manufacturers. This guide was modified from the version that we used for the first model evaluation report. The interview guide covered such topics as background information about the PO (for those POs that we had previously interviewed, we reviewed the information from the previous interview), formulary development, PDSS impacts, and barriers to insulin adherence, among other topics. For the 2024 interviews, we also showed PO interview participants a slide with the major quantitative results from the first evaluation report and asked if these results aligned with their experiences. We reviewed each PO's survey responses before the interview and tailored the interview guide based on the survey information provided by each PO.

We conducted all interviews virtually. Two or three RAND researchers attended each interview, one of whom took detailed notes, while the other(s) took turns leading the discussion and asking follow-up questions. Participants provided their consent at the beginning of each interview. Interviews lasted approximately one hour. All interviews were audio-recorded and transcribed.

Data Analysis

We used the same analysis approach for PO interviews in 2023 and 2024. After each interview, two members of the qualitative research team used their notes to summarize PO interview responses in a standardized memo (Birks, Chapman, and Francis, 2008) with such headings as "Background," "PDSS Design Rationale," "Insulin Formulary Design," "Expected Model Outcomes," and "Impact of the IRA." Researchers used these memos and the interview guide to develop a set of initial codes for a code book. Two researchers independently coded the same transcript in Dedoose using the initial code book. Once that transcript was coded, they met to discuss any modifications of the code book to reflect any information not originally included in the memos, identify emerging subcategories of information not covered by the existing codes, and resolve minor coding discrepancies to ensure intercoder reliability. Each of these two researchers then coded half of the remaining transcripts. We successfully used a similar approach to qualitative data coding in previous RAND studies (Khodyakov et al., 2014; Concannon et al., 2015).

Once all transcripts were coded, we analyzed the text associated with each code to identify emerging themes and illustrative quotes using a qualitative content analysis approach (Graneheim and Lundman, 2004; Hsieh and Shannon, 2005). Where relevant, we used the PO interview results to expand the description of PO survey results, focusing on explaining the most common survey responses and identifying perspectives that differed substantially from the most typical responses. Finally, we incorporated key themes and quotations describing PO perspectives throughout the main body of this report.

SHIP Counselors and Insurance Agents

Recruitment Methods

We used different approaches to recruit SHIP counselors and independent insurance agents from five states with the highest number of Medicare beneficiaries (California, New York, Florida, Pennsylvania, and Texas). To recruit SHIP counselors, we worked with the Administration for Community Living's Office of Healthcare Information and Counseling that manages SHIP to identify and contact relevant state offices, local agencies, and community organizations that implement SHIP in each state we focused on. A contact person at each state provided contact information for SHIP counselors and coordinators who might be most qualified

to participate in the interview. This approach helped us streamline the recruitment process and engage with counselors who have been actively involved in advising Medicare beneficiaries. By using this approach, we successfully recruited two SHIP counselors from each focus state.

In parallel with our efforts to recruit SHIP counselors, we also sought to engage Medicare agents. To do so, we leveraged a national database of insurance agents who sell MA-PD, PDP, and Medigap policies managed by the American Association for Medicare Supplement Insurance (AAMSI), which includes names and contact information for licensed Medicare insurance agents across the United States. As with SHIP counselors, we focused on insurance agents licensed to sell policies in California, New York, Florida, Pennsylvania, and Texas. Within each of these five states, we concentrated our search efforts to within a 50-mile radius of major metropolitan areas. Because the AAMSI database generally did not include agents' email addresses, we conducted web searches to find such information for sampled agents.

In total, we reached out to 129 insurance agents and were able to successfully recruit and interview 10 of them. Two interviewees were based in Texas, four in Florida, two in California, one in Pennsylvania, and one in New York. All agents whom we interviewed were licensed to sell insurance in multiple states.

Data Collection

To conduct interviews with SHIP counselors and insurance agents, we relied on an approach similar to the one we used to interview PO representatives. Namely, we developed a semistructured interview guide with questions and probes about the interviewee's background and their business, resources and tools that they use while doing their jobs, factors that affect beneficiary plan choice, reasons why beneficiaries switch coverage, and awareness and knowledge of PDSS. These interviews were originally designed to better understand the model and its outcomes on beneficiaries. Their scope was later expanded, at no additional cost to the government, to address government interest in using the interview findings to inform the design of future MA-focused models.

Between January and May of 2024, we conducted all interviews virtually. A team of two researchers and a research assistant conducted each interview. A research assistant took detailed notes, while the researchers took turns leading the discussion and asking questions. Participants provided their consent at the beginning of each interview. Interviews lasted approximately one hour. All interviews were audio-recorded and transcribed.

Data Analysis

We relied on the same approach to code transcripts that we used to code PO interviews. First, two members of the qualitative research team used their notes to summarize SHIP counselor and insurance agent interview responses into a memo with sections for descriptions of the responsibilities of counselors and agents, agent compensation, tools and resources used, factors

affecting the choice of Original Medicare or Medicare Advantage, factors affecting the choice of Medicare Advantage or drug plans, and thoughts on the model.

Then, we used the memo and the interview guide to develop a set of codes for a code book. Two researchers used the initial code book to independently code the same transcript in Dedoose. Once that transcript was coded, we calculated a 77% agreement in the initial coding and met to discuss the coding and resolve minor coding discrepancies to ensure intercoder reliability. Each of these two researchers then coded half of the remaining transcripts.

After coding all the transcripts, we examined the text linked to each code to uncover emerging themes and representative quotes, employing a qualitative content analysis method (Graneheim and Lundman, 2004; Hsieh and Shannon, 2005). Ultimately, we integrated the central themes and quotations that reflect SHIP counselor and insurance agent viewpoints throughout the report.

Beneficiaries

Sampling and Data Collection

To explore beneficiary perspectives on the model, we interviewed insulin users enrolled in PDSS-participating plans (*targeted beneficiaries*). To do so, we followed an approach similar to the one we used in 2022 and described in our previous report (Taylor et al., 2023). To identify potential interviewees, we created a list of targeted beneficiaries who filled at least one plan-specified model insulin at any time during 2023 and were also continuously enrolled in a PDSS-participating plan for all of 2023.

We excluded LIS-eligible beneficiaries from this list because they were not eligible to receive PDSS benefits. To reduce the possibility of sampling individuals with cognitive impairments related to old age, we included only beneficiaries who were younger than 80 years of age. We also excluded beneficiaries from Puerto Rico plans because we conducted all our interviews only in English.

To achieve a target sample of 100 interviews, we identified 4,000 beneficiaries who met all the inclusion criteria described above. The identified beneficiaries consisted of the same number of MA-PDs and PDP enrollees, younger (between 65 and 74 years of age) and older (between 75 and 80 years of age) beneficiaries, and those who switched into a PDSS-participating plan on January 1, 2023 and those who were enrolled in it before. To ensure diversity of our sample, we used a stratified random sample to include beneficiaries from all PDSS-participating POs.

Recruitment Methods

On February 19, 2024, we mailed a one-page letter to all 4,000 sampled beneficiaries residing throughout the continental United States. The interview invitation letter provided information about the interview, stated that those who completed it would receive a $50 payment

by check, and asked beneficiaries who were interested in participating to call a toll-free number to schedule an appointment.

We received 175 telephone calls from beneficiaries interested in participating in our study. Prior to scheduling an interview appointment with a beneficiary, our telephone recruiters used a script to verify interview eligibility. To be eligible for the interview, beneficiaries had to speak English and hear well enough to participate in a telephone interview; they also had to be willing to have their interview audio-recorded. In addition, only beneficiaries who confirmed that they currently take insulin were eligible for the interview. As part of the screener, we also collected demographic information, including participants' education attainment level, work status, occupation, and insulin type. Of the 175 beneficiaries interested in participating, we screened 118 for eligibility, scheduled interviews with 109, and completed interviews with 100 beneficiaries. The most common reason for deeming a beneficiary ineligible for the interview was because they had reported no longer taking insulin.

Data Collection

Drawing from our prior experiences interviewing Medicare beneficiaries for the PDSS evaluation (Taylor et al., 2023), we developed a structured interview protocol that contained both open- and close-ended questions on the beneficiary's health status and medications taken, experience choosing a Part D plan, awareness of PDSS and its benefits, experiences paying for insulin, barriers to diabetes management, and the perceived impact of the model.

All interviewers were trained by the study's co-director prior to conducting any interviews to ensure that all interviewers understood the basics of the Part D benefit design, PDSS benefits, and insulin types, as well as the intent of all interview questions so that they could paraphrase them if needed.

Between March and April 2024, a team of six interviewers completed 100 telephone interviews with beneficiaries. Before the start of each interview, interviewers introduced themselves, reviewed the informed consent statement, and confirmed that the participant was willing to participate. Interviewers used digital recorders to record the interviews, and the audio recording did not begin until participants consented to be recorded. Interviewers used the same scripted interview guide to conduct the interviews. On average, the interviews lasted 30 minutes, although some interviews took 40–45 minutes. All audio recordings were professionally transcribed.

Data Analysis

Interviewers took detailed notes during the interview and entered their notes into a Microsoft Excel spreadsheet, which served as our data matrix, with beneficiaries as rows and interview questions as columns; interviewers entered their notes summarizing beneficiary responses to questions in the appropriate cells. In addition, for each section of the interview discussion guide, interviewers identified and entered exemplar quotes that could be used to illustrate key

sentiments expressed by beneficiaries. Organizing interview notes into a data matrix is the first step of the Framework Method that we used to conduct an applied thematic analysis of these interview data (Gale et al., 2013). Once the interview transcripts were delivered, two qualitative research team members reviewed the data matrix for completeness, filled in any missing information, and selected exemplar quotes identified by interviewers for each of the sections or themes discussed in the interviews.

Using the data matrix, we developed a series of binary indicators describing beneficiary awareness of PDSS and its benefits (for example, "Have you noticed that your insulin copayments have recently become $35 or less for a month supply?"), the types of insulin they were taking, and whether they confused a noninsulin diabetes medication with insulin, among others. To assess the impact of the model on various outcomes, we asked beneficiaries a series of binary questions about their behaviors before and after PDSS had begun (for example, "Before/After the model, have you spent less money on food, heat, or other basic needs so that you would have money for insulin?"). We categorized whether each beneficiary reported a certain behavior both before and after the model began, only before the model, only after the model, or neither before nor after and calculated the overall percentage of beneficiaries in each category. We also thematically analyzed responses to open-ended questions, such as what factors affect a beneficiary's decision to choose a Part D plan and then used basic descriptive statistics to identify the relative prevalence of each answer.

We used the results of beneficiary interviews to triangulate the results of our quantitative data modeling and the qualitative data that we collected from POs and insulin manufacturers. We specifically compared PO and beneficiary perspectives on the barriers to proper diabetes management to identify the extent to which they thought that the model addressed the most pressing barriers to insulin adherence.

Sample Description

Four-fifths (81%) of our interviewees had at least some college education, with 25% reporting having an advanced degree (Table E.1). The majority of the interviewed beneficiaries were retired (88%); 10% were still working for pay either full-time or part-time. Our sample included more beneficiaries enrolled in MA-PDs (64%) than in PDPs (36%) but roughly the same number of those who switched plans in 2023 (54%) and those who stayed in the same plan (46%).

Most interviewed beneficiaries rated their health as "good" (40%) or "fair" (27%); 22% of beneficiaries described their health as "very good" or "excellent." Nonetheless, participants reported taking, on average, eight different medications (mean 8.01, range 3–20). Most interviewees took one (54%) or two (45%) insulins. Pen was the primary insulin delivery device used by 78% of interviewed beneficiaries. It is worth noting that five beneficiaries reported using an insulin pump, and one reported using an inhaled insulin. Of all the interviewed beneficiaries, 15% reported using more than one insulin delivery device; most of them reported using both

pens and syringes to inject insulin. Besides taking insulin, 30% of our sample reported taking other noninsulin diabetes medications, with 20% of these beneficiaries taking GLP-1 agents.

Table E.1. Beneficiary Interview Sample Descriptive Statistics

Characteristic	Percentage
Level of education	
Some high school	4
High school or GED	15
Some college or two-year degree	37
Four years of college	19
Greater than four years of college	25
Work status	
Retired	88
Working for pay	10
Taking care of family members	1
Volunteering	1
Part D plan type	
MA-PD	64
PDP	36
Switched plans in 2023	
Yes	54
No	46
Self-rated health status	
Excellent	3
Very good	19
Good	40
Fair	27
Poor	11
Number of insulins used	
One	54
Two	45
Three	1
Insulin type(s) used (*N* = 96)[a]	
Long-acting	85
Rapid-acting	44
Short-acting	6
Intermediate-acting	4
Mixed	5

Characteristic	Percentage
Primary insulin delivery device[b]	
Pen	78
Vial	30
Pump	5
Inhaler	1
Mentioned taking noninsulin diabetes medication	
No	70
Yes	30
Number of medications taken	
Mean number of prescription medications	8.01

SOURCE: Authors' analysis of interviews with 100 insulin users from PDSS-participating plans conducted in 2023.
NOTE: GED = General Education Development certificate.
[a] Only 96 participants were able to name the insulins they were taking. Of these, 43 reported using more than one type of insulin.
[b] Fifteen participants reported using more than one insulin delivery device.

Almost all interviewed beneficiaries reported taking one or two insulins; only one beneficiary reported taking three different insulins. Ninety-six interviewees were able to provide the name of an insulin they were taking. Of these, more than two-fifths (45%) reported taking more than one insulin type. The majority (85%) reported using long-acting insulins; 44% reported using rapid-acting insulins. When asked about their primary mode of insulin delivery, most beneficiaries reported using pens (78%). Although beneficiaries were not asked specifically about noninsulin diabetes medication, 30% of participants brought up these medications during our interviews, with 20% of these specifically mentioning GLP-1 agents. The noninsulin diabetes medications mentioned by our interviewees included Jardiance, metformin, Ozempic, Trulicity, and Victoza.

Appendix F. Factors Affecting Beneficiary Plan Choices

This appendix presents the results of our interviews with beneficiaries, insurance agents, and SHIP counselors focused on the factors that affect beneficiary choice of a particular MA-PD or PDP and the reasons for switching their Part D coverage. They provide additional context for Chapter 3 results.

Once beneficiaries decide whether they want MA or Original Medicare, they must select a specific MA-PD or PDP. We asked beneficiaries, insurance agents, and SHIP counselors to name those factors that affect beneficiary choice of a particular plan. Table F.1 separately shows the main factors named by interviewed beneficiaries, for those enrolled in PDSS-participating MA-PDs and PDPs.

Table F.1. Factors Affecting Beneficiary Plan Choice, by Plan Type

Factor	MA-PDs (%)	PDPs (%)
Copayments	89	94
Coverage of current medications	81	97
Deductibles	81	74
Premiums	75	89
Coverage of MA supplemental benefits	73	NA
Coverage of potential future medications	22	30

SOURCE: Authors' analysis of data from a sample of 100 insulin users from PDSS-participating plans (64 from MA-PDs and 36 from PDPs).
NOTE: Percentages do not add up to 100 because beneficiaries could name more than one factor affecting their plan choice. NA = not applicable (because PDPs do not offer MA supplemental benefits).

Choice of an MA-PD

Our interviewees agreed that costs, medications, supplemental benefits, and provider networks were the top factors that influenced their choice of a particular MA-PD. Almost all interviewed beneficiaries named at least one cost-related factor as a reason for choosing an MA-PD, with 89% mentioning copayments, 81% calling out deductibles, and 75% citing premiums (Table F.1). In contrast to beneficiaries, interviewed insurance agents and SHIP counselors often discussed costs together with provider networks, saying that these two variables often determine whether a beneficiary chooses a preferred provider organization (PPO) or an HMO plan. Several SHIP counselors said that beneficiaries who want wide provider networks but worry about the high costs of Original Medicare, including many older beneficiaries, often choose PPOs, whereas younger beneficiaries seem to be more comfortable with HMO plans because this is what they had while working. Because PPOs seem to offer more provider flexibility than HMO plans and are more affordable than Original Medicare, they have become rather popular in certain markets.

Agent B stated that because two big national insurers recently added new PPOs with wide provider networks, some of his clients ended up switching from Original Medicare to MA. Finally, one of the SHIP counselors (Counselor G) said that he only recommends PPOs (not HMO plans) to his clients because of their concerns about narrow provider networks.

In deciding which MA-PD to choose, 81% of beneficiaries cited coverage of current medications taken and 22% cited coverage of medications they think they may be prescribed in the near future (Table F.1). Although striking, this difference in percentages is not surprising because most beneficiaries are not thinking about their future medication needs. Here is how one beneficiary explained it: "It [future drug needs] was not something I considered. I kind of have to live in the now; future is the future, past is past. So, can I say, I can't predict what else is gonna [sic] come."

While only 11% of interviewed beneficiaries cited MA supplemental benefits as a factor influencing their choice between Original Medicare and MA, 73% of our sample enrolled in an MA-PD cited supplemental benefits as a key factor in their plan choice (see Table 3.2 in Chapter 3). Agents and SHIP counselors agreed that supplemental benefits are very important in the MA-PD choice:

> More and more [supplemental benefits are] becoming a priority for individuals. Most individuals tend to know that their Medicare Advantage plans are going to cover their Part A and Part B. It's just a matter of cost sharing, what the copayments or co-insurance are going to be. Once we get past that and if all things are equal and they feel comfortable with all of that, then it becomes looking at the extras, the supplemental benefits, and the ones that are becoming more and more ubiquitous—like hearing, vision, dental, transportation, fitness—those were the key ones a few years ago. Now we'll hear individuals . . . want[ing] the Part B reimbursement and . . . SSBCI benefits [Special Supplemental Benefits for the Chronically Ill that include non-health related benefits, such as food and produce, and nonmedical transportation]. (Counselor B)

According to interviewed insurance agents and SHIP counselors, dental, vision, and Part B premium buydowns are typically more important than transportation, meals, or OTC allowances for more-affluent beneficiaries, whereas those with lower incomes, such as beneficiaries dually eligible for Medicare and Medicaid, prefer rich non-primarily health-related supplemental benefits, including card-delivered benefits, such as healthy food and utility allowances. According to Counselor E, they received a lot of "calls from people [who ask about plans that give you] $1,500 on a flex card every month" that has been widely advertised on television. Our interviewees noted, however, that SSBCI supplemental benefits are very confusing to beneficiaries because they do not realize that there are additional eligibility requirements (such as having certain diagnoses). Moreover, these benefits are not listed in the Plan Finder—a tool on the Medicare website that helps beneficiaries compare and select plans—and one needs to go to the description of each plan's benefits to find out all the details.

Choice of a PDP

When they start working with a client, SHIP counselors and insurance agents enter the full list of medications the client takes into the Medicare Plan Finder or a similar platform to find a plan that covers all of them and has the lowest annual total cost. Therefore, prescription drug costs and inclusion of medications on formularies are the most important factors that affect the PDP choice from the perspective of beneficiaries, insurance agents, and SHIP counselors. Indeed, as shown in Table F.1 above, 97% of beneficiaries who chose a PDP in our sample named coverage of current medications as one of the main factors influencing their plan choice, followed by three cost-related factors: copayments (94%), premiums (89%), and deductibles (74%).

Here is how Counselor B described the importance of covered medications and various types of plan costs: "We're looking at cost, we're looking at making sure that the individual's prescription drugs, their medications are on the plan's formulary at the lowest overall cost." For some, the deductible amount could also be important for those taking expensive medications:

> The deductible is also a big one because I've had clients in the past who've taken really expensive medications like Eliquis or Humira, and they'll say: "Well, I would rather not have to pay $545 during the month of January or combined over January and February to meet my drug plan deductible before the plan starts kicking in. Is there a way that I can pay a higher monthly premium and have no deductible?" (Counselor A)

According to insurance agents and SHIP counselors, there are other factors that might affect the choice of a particular PDP for some beneficiaries. For example, preferred pharmacies may be an important choice factor if a plan requires a beneficiary to change pharmacies (especially if the beneficiary prefers a small local pharmacy) to be able to get the lowest OOP costs. Here is how one interviewee described this:

> I do have some clients who say, absolutely, I will not go to any other pharmacy. This pharmacy has pharmacists that speak my native language, or I've been going there for 30 years, or they have these other benefits like they'll deliver stuff for free. So, whether or not the pharmacy is a preferred in-network pharmacy or regular in-network pharmacy is another sort of key piece of data. (Counselor A)

Star Ratings were not considered to be a big factor in the decisionmaking process because in many areas, there are no 5-star or even 4-star Part D plans. In such cases, insurance agents and SHIP counselors look for plans with 3 or more stars or those that are not under sanctions:

> One of the things we always look at is whether it is a plan with three [stars] or above. So, if it's a three or above, then it makes it a little bit easier. When it's below a three, we're going to make sure that it is not going to be sanctioned. We have one . . . plan that is sanctioned. So, anybody that comes to see us, if they happen to be in that plan, we're going to explain that the plan is sanctioned, at the end of 2024, that plan will cease to exist. (Counselor B)

Finally, utilization management techniques, including prior authorization and step therapy, may be important in some cases, but formularies and costs are more important. As Counselor A put it:

> If we're comparing these two plans and one of them requires prior authorization for this drug and the other one doesn't, and all other things being essentially the same, they'll probably pick the one that doesn't require prior authorization because nobody wants [prior authorization or] step therapy. So, if we can avoid that, we'll certainly try to explain that to them. But I would say usually cost is more important than some of those other pieces.

Reasons for Plan Switching

Our interview sample included beneficiaries who switched their MA-PDs or PDPs for plan year 2023 ($N = 48$). We asked these plan switchers to explain why they changed their insurance coverage; 43 provided an explanation, sometimes mentioning more than one reason. Table F.2 lists the main reasons provided.

Table F.2. Reasons for Switching Plans

Reason	*N*	Percentage
Drug coverage	13	30
Cost-related factors	11	26
Personal and situational factors	8	19
Provider network-related factors	6	14
Advice from friends or family	4	9
Advertising and/or contacted by agent	3	7
Coverage-related factors	3	7
Customer service–related factors	3	7

SOURCE: Authors' analysis of data from a sample of 43 insulin users from PDSS-participating plans who switched their insurance coverage for 2023 and explained the reason behind their decision.
NOTE: Percentages do not add up to 100 because beneficiaries could name more than one reason for switching coverage.

Not surprisingly, the main reason why interviewed beneficiaries decided to switch plans was drug coverage, which included both premiums and formularies. According to one beneficiary who changed PDPs, plan switching is an annual process because drug benefits change annually:

> I went in and looked at my meds, which [is an annoying annual] process. . . . You have to figure out what prescriptions you are on, what prescriptions you are likely to be on. And then, you have to go in and see if the formulary for your current provider is going to carry the prescriptions you anticipate having. And then, you need to make a decision, and sometimes it's based on cost. And so, you have to do that every year. . . . And this year, when I looked at that, it just seemed like the other program was a better fit.

Other reasons cited for switching insurance plans not listed in Table F.2 included more-generous coverage for dental and other MA supplemental benefits and in-network providers (for those in MA-PDs) and wider pharmacy networks and availability of mail-order pharmacies, and dissatisfaction with previous insurance benefits, among others.

Abbreviations

CI	confidence interval
CMR	Comprehensive Medication Review
CMS	Centers for Medicare & Medicaid Services
COVID-19	coronavirus disease 2019
DD	difference-in-differences
DIR	direct and indirect remuneration
ED	emergency department
ESRD	end-stage renal disease
FFS	fee-for-service
GDCA	gross drug costs above the catastrophic phase
GDCB	gross drug costs below the catastrophic phase
HEDIS	Healthcare Effectiveness Data and Information Set
HMO	health maintenance organization
HPMS	Health Plan Management System
IDR	Integrated Data Repository
IRA	Inflation Reduction Act
LIS	low-income subsidy
MA	Medicare Advantage plan
MA-PD	Medicare Advantage plan with Part D coverage
MPR	medication possession ratio
OACT	CMS Office of the Actuary
OOP	out-of-pocket
OTC	over-the-counter
Part D	Medicare Prescription Drug Benefit Program
PBM	pharmacy benefit manager
PDE	prescription drug event
PDP	prescription drug plan
PDSS	Part D Senior Savings
PMPM	per-member per-month
PO	parent organization
PPO	preferred provider organization
PQI	Prevention Quality Indicator
PRS	Payment Reconciliation System
R&I	rewards and incentives
SEP	Special Enrollment Period

SHIP	State Health Insurance Assistance Program

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