Project Report

Evaluation of the Part D Senior Savings Model

First Year of the Model Test (2021)

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About This Report

The Medicare Prescription Drug Benefit Program (Part D) offers outpatient prescription drug coverage to Medicare beneficiaries. Starting in 2021, the Center for Medicare & Medicaid Innovation began testing the effect of lower, predictable cost sharing for insulins via the Part D Senior Savings (PDSS) Model. PDSS-participating plans offer maximum $35 copayments per monthly supply of insulin to beneficiaries enrolled in these plans. In addition, PDSS-participating plans can elect two optional Model test components: (1) a narrower first risk corridor, 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 can offer beneficiaries with diabetes or prediabetes incentives for participation in various activities, including medication therapy management. This report presents findings of a mixed-methods evaluation of the first year of the Model test, across a range of outcomes, including access to insulins, plan enrollment and progression through the benefit phases, and costs to beneficiaries, manufacturers, and CMS.

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Summary

EVALUATION HIGHLIGHTS

In 2021, the Center for Medicare & Medicaid Innovation began testing the effects of lower, predictable cost sharing for insulin as part of the Part D Senior Savings (PDSS) Model. RAND researchers conducted a mixed-methods evaluation of the impact this Model test had on participating Part D plans—Medicare Advantage Prescription Drug plans (MA-PDs) and stand-alone Prescription Drug Plans (PDPs)—as well as beneficiaries, insulin manufacturers, and the Centers for Medicare & Medicaid Services (CMS) on various outcomes in the first year after the start of the Model test. Early evaluation results show strong evidence of positive impacts on **insulin users** in the form of increased utilization of insulins and decreased out-of-pocket (OOP) costs. However, total Part D costs increased for **noninsulin users** enrolled in participating PDPs. Although our analyses indicate that **plans** and **CMS** did not experience meaningful changes to their costs, **manufacturers** may have increased their total rebate payments to plans and increased their coverage gap discount payments as a result of the Model test. Together these findings suggest that, in its first year, the PDSS Model successfully reduced OOP costs for insulin users without shifting costs to plans or CMS.

The Medicare Prescription Drug Benefit Program (Part D) provides outpatient prescription drug coverage to Medicare beneficiaries. Brand-name prescription drug prices have increased substantially since the implementation of Part D in 2006, raising concerns about the ability of beneficiaries to afford their medications even with prescription drug coverage. In 2021, the Center for Medicare & Medicaid Innovation began testing the effects of lower, predictable cost sharing for drugs as part of the Part D Senior Savings Model test (referred to as "the PDSS Model" or "the Model test"). For its first three years (2021 through 2023), the Model test focused on insulin—a drug used to treat diabetes—as the Model test drug for which lower cost sharing would be applied. Both stand-alone Prescription Drug Plans (PDPs), which are offered by private insurers and operate alongside fee-for-service Medicare, and Medicare Advantage Prescription Drug plans (MA-PDs), which are also offered by private insurers but combine Traditional Medicare benefits, Part D coverage, and additional supplemental benefits, were eligible to participate in the PDSS Model.

MA-PDs and PDPs participating in the Model test agree to offer fixed copayments of no more than $35 per one-month supply of selected insulins through the first three benefit phases in Part D (that is, the deductible, initial coverage, and coverage gap phases). Insulin manufacturers applied to participate in the Model test and, if accepted, entered all covered Part D insulins into the Model test. From the list of PDSS-eligible insulins entered by manufacturers, PDSS-participating plans were required to select at least one vial and one pen dosage form for each of the four main types of insulin—short-acting, rapid-acting, intermediate-acting, and long-acting—for Model test coverage at the maximum $35 copay. Beneficiaries enrolled in PDSS-participating plans who take the plan-selected insulins simply pay the maximum $35 per-month copay when they have their prescriptions filled. For additional details on the Part D benefit

phases and how PDSS Model costs were shared across stakeholders, please see the first evaluation report (Taylor et al., 2022).

In addition to requiring participating plans to offer selected insulins at the maximum $35 monthly copay, the Model test also incorporated two optional components: a narrower first risk corridor and Part D Rewards and Incentives (R&I) programs. The narrower first risk corridor was designed to help protect participating plans from larger than expected losses associated with Model test participation, by sharing a larger proportion of profits and/or losses with the Centers for Medicare & Medicaid Services (CMS). Part D R&I programs enable participating plans to offer beneficiaries with diabetes or prediabetes to receive incentives, such as gift cards, in exchange for participation in disease management programs or medication therapy management.

This report presents findings from our evaluation of the first year of the PDSS Model. We assessed the effect of the Model test, including its optional components, on a variety of outcomes, such as access, plan enrollment and benefit phase progression, beneficiary out-of-pocket (OOP) costs, and costs to Part D plans and CMS. The impacts of this Model test can provide context to the Inflation Reduction Act (IRA), which, effective January 1, 2023, capped cost sharing for each insulin product covered by a Medicare Part D plan at $35 for a month's supply. This closely aligns with what was offered through the PDSS Model.

Approach

We conducted a mixed-methods evaluation combining quantitative data modeling with qualitative data collection and analysis. We used secondary data sources, including Part D Prescription Drug Event data; beneficiary demographic, plan enrollment, and risk score data; plan bid and direct and indirect remuneration data; and plan benefit design information to calculate outcome measures designed to assess the effect of the Model test on key stakeholders, including plans, beneficiaries, manufacturers, and CMS. We ran difference-in-differences (DD) regression models at the plan and beneficiary levels, separately for MA-PDs and PDPs, using eligible nonparticipating Part D plans as the comparison group. We focused our beneficiary-level analyses on beneficiaries who used insulin in the year immediately prior to PDSS Model implementation (2020) and who were enrolled in the same plan for all of 2020 and 2021, because those beneficiaries (or *insulin users*) were most likely to be affected by the Model test. We also analyzed the effect of the Model test on beneficiaries who were enrolled in participating plans but who did not use insulin (*noninsulin users*), because those beneficiaries may have experienced spillover effects of the Model test on their plan benefits, including the premium.

The DD models depend on the parallel trends assumption, which means that we assumed that the outcomes for PDSS-participating plans would have changed by the same amount as those for the nonparticipating plans *if the PDSS-participating plans had not participated.* Because this assumption cannot be tested empirically, we assessed the sensitivity of our analyses to potential violations of parallel trends. We classified our quantitative results into four categories based on

the strength of evidence, which combines statistical significance of the coefficient encoding the PDSS Model's effect in the DD regression and the robustness of our findings to the violations of the parallel trends assumption as follows:

- **Strong evidence**: p-value < 0.01, and the findings are robust to substantial violations of the DD parallel trends assumption.
- **Moderate evidence:** p-value < 0.05, and the findings are moderately robust to parallel trends assumption violations.
- **Limited evidence:** p-value < 0.05, and the findings are not robust to parallel trends assumption violations.
- **No or weak evidence:** p-value ≥ 0.05, regardless of robustness to parallel trends assumption violations.

To triangulate and contextualize the results of our quantitative analyses, we also invited all 2021 PDSS-participating Part D plan sponsors to complete a brief survey and conducted semistructured interviews with nine of them. In addition, we interviewed all five insulin manufacturers whose insulins are sold in the United States; three of them participated in the Model test in 2021, and two others joined the Model test in 2022. Finally, we also conducted semistructured interviews with a sample of 100 insulin users whose prescription drug coverage is provided by a PDSS-participating plan. We used descriptive statistics to summarize the survey responses about the outcomes of the Model test that insurers have already observed or expect to see. We also thematically analyzed the interview data to better understand key stakeholders' perspectives on the Model test, its limitations, and outcomes.

Key Findings

Our quantitative results, which have generally been corroborated by the qualitative findings, suggest that the PDSS Model increased access to insulins, decreased time for insulin users in the catastrophic phase of the Part D benefit, decreased insulin user OOP spending, and increased *gross drug costs* (that is, the amount paid at the pharmacy, which is split across the four Part D stakeholders—beneficiaries, plans, manufacturers, and CMS—depending on which benefit phase the beneficiary is in). For insulin users in PDSS-participating plans, we found:

- increases of nearly one additional 30-day insulin fill per year in both MA-PDs and PDPs (strong evidence)
- decreases in the amount of time insulin users spent in the catastrophic phase in both MA-PDs (–2.4 days; moderate evidence) and PDPs (–4.9 days; strong evidence), likely due to the decrease in insulin OOP copays in the deductible and coverage gap benefit phases
- decreases in insulin user OOP costs and total Part D costs (OOP plus Part D premium) for both MA-PDs and PDPs, driven largely by decreases in insulin OOP costs (–$198 and –$441, respectively; strong evidence).

Insulin users we interviewed—even those who did not experience major financial difficulties before the PDSS Model—appreciated the lower insulin copays and commented specifically

about the benefits of having predictable and consistent copay amounts throughout different benefit phases. Nonetheless, many beneficiaries also noted that they take more than one insulin, as well as noninsulin diabetes drugs, none of which are covered by the PDSS Model, and therefore, they pay more than $35 for their diabetes medications every month.

While we found no or weak evidence of an effect of the PDSS Model on noninsulin users' total OOP costs, we found limited evidence that the PDSS Model increased total Part D costs by $34 for noninsulin users enrolled in PDPs.

For PDSS-participating plans, we found that PDSS Model implementation was associated with:

- increased total plan enrollment for MA-PDs (10.0%; moderate evidence) and decreased total plan enrollment for PDPs (–42.2%; limited evidence)
- increased enrollment of insulin users in MA-PDs (27.2%; strong evidence) and decreased enrollment of insulin users in PDPs (–14.5%; limited evidence)
- increased enrollment of beneficiaries dually eligible for Medicare and Medicaid in MA-PDs (7.1%; limited evidence) and decreased enrollment of dually eligible beneficiaries in PDPs (–42.7%; strong evidence)
- increased total manufacturer rebates for both MA-PDs and PDPs ($1.38 per member per month [PMPM] and $21.41 PMPM, respectively; limited evidence), which lower the final costs of coverage for both Part D plans and CMS
- increased manufacturer coverage gap discount payments for both MA-PDs ($3.01; strong evidence) and PDPs ($18; limited evidence).

We found limited evidence that the PDSS Model increased Part D bids for MA-PDs ($5.68), and strong evidence of a decrease in Part D bids for PDPs (–$17). We found no or weak evidence that the PDSS Model changed total Part D premiums or costs to CMS of the Part D benefit. We note that the plan-level results should be interpreted with more caution than the beneficiary-level results, especially among PDPs: Participating and comparison groups for the plan-level analyses differed from each other on a variety of characteristics, and our sensitivity analyses, which used all nonparticipating PDPs as an alternative comparison group, suggested different conclusions about the PDSS Model's impacts on costs to CMS of the Part D benefit. Results of plan-level analyses for the MA-PDs were more robust to the use of alternative comparison groups.

Our qualitative findings generally supported the quantitative results and showed that both participating insurers and insulin manufacturers thought that the Model test would have the most significant impact on beneficiary OOP costs. Manufacturers, however, were concerned about their financial contribution to lowering beneficiary OOP costs as part of the Model test, and they suggested that all stakeholders, including plans and pharmacy benefit managers, should contribute more equally to making insulins affordable.

Conclusions

The findings of our mixed-methods evaluation of the first year of the PDSS Model suggest that it led to several expected outcomes. Lower and more predictable cost sharing for insulins through the first three Part D benefit phases led to increased utilization of insulin and lower total beneficiary costs for insulin users.

The shift in responsibility for insulin costs away from beneficiaries could have substantially increased total costs for plans, insulin manufacturers, or CMS. Although we found no evidence of cost shifts to plans or CMS, our findings suggest that drug manufacturers increased their contributions by paying more in total manufacturer rebate and gap discount dollars to PDSS-participating plans as a result of the Model test. In addition, the Model test may have increased total Part D costs by a small amount for noninsulin users who are enrolled in PDSS-participating PDPs, which can be considered an unintended outcome of the Model test.

In the remaining evaluation report, we will expand the outcomes assessed to include impacts on health status and health care utilization and spending.

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Chapter 1. Introduction

The Medicare Prescription Drug Benefit Program (Part D) provides Medicare beneficiaries with outpatient prescription drug coverage through private health insurance companies. Medicare beneficiaries who choose to enroll in a Part D plan may elect coverage through stand-alone Prescription Drug Plans (PDPs), which operate alongside fee-for-service (FFS) Medicare. Alternatively, they may obtain coverage through one of the Medicare Advantage Prescription Drug plans (MA-PDs), which combine FFS Medicare benefits, Part D coverage, and some additional plan-selected supplemental benefits into a single plan administered by the health insurer, which we refer to as the parent organization (PO) in this report.

While the insurance provided by Medicare Part D has reduced total out-of-pocket (OOP) costs for beneficiaries (Liu et al., 2011; Duggan and Morton, 2010; Millett et al., 2010), prices for brand-name prescription drugs have continued to rise since Part D was implemented in 2006 (Rome, Egilman, and Kesselheim, 2022; Congressional Budget Office, 2022). Beneficiaries enrolled in Part D now pay a portion of the total cost of each prescription drug fill after meeting any deductible; however, high and increasing drug prices over time have increased the amount beneficiaries pay (Dusetzina, Huskamp, and Keating, 2019; Erath and Dusetzina, 2020). The current Part D benefit design incorporates different phases of coverage (that is, deductible, initial coverage, coverage gap, and catastrophic), which have different cost-sharing rules. Beneficiaries progress through these phases throughout the year based on their drug spending. Beneficiaries, Part D plans, manufacturers, and the Centers for Medicare & Medicaid Services (CMS) contribute different shares of each drug fill's cost depending on the benefit phase (see Taylor et al., 2022 for further details on how the costs break down across stakeholders). As a result, beneficiaries end up paying different OOP amounts for the same drug throughout the year, depending on which Part D benefit phase they are in. The differences in OOP costs can be especially acute for brand-name drugs, because beneficiaries who pay a percentage of the drug's cost in the coverage gap phase may pay substantially more than they paid in fixed copayments in the initial coverage phase.

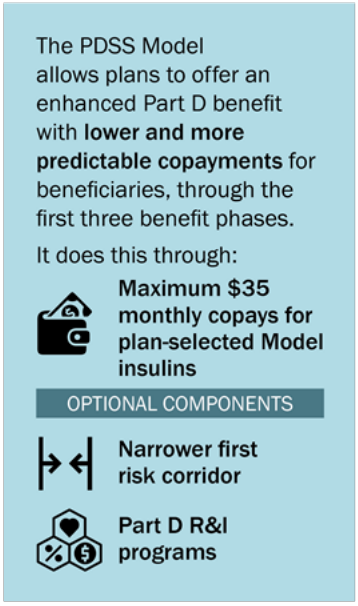
Part D Senior Savings Model

Beginning in 2021, the Center for Medicare & Medicaid Innovation has been testing the effects of offering lower, predictable cost sharing for beneficiaries through the first three Part D benefit phases via the Part D Senior Savings Model (hereafter referred to as "the PDSS Model" or "the Model test"). In its first three years of implementation (2021 through 2023), the Model test focused on insulin, which is used to treat diabetes (National Institute of Diabetes and Digestive and Kidney Diseases, 2022). Prior research suggests that higher OOP costs for insulin

result in lower adherence and the potential for adverse outcomes (Gokhale et al., 2020; Trish, Kaiser, and Joyce, 2021; McAdam-Marx et al., 2022; Curtis et al., 2017), making insulin an important target for interventions aimed at lowering OOP costs.

The PDSS Model (summarized in Figure 1.1) enables eligible enhanced plans to charge beneficiaries no more than a $35 copay per one-month supply of insulin through the first three phases of the Part D benefit. Cost sharing is generally greater in the first three phases than in the fourth, or catastrophic, phase. Only enhanced Part D plans may participate in the Model test because the cost-sharing reduction in the coverage gap phase is a supplemental benefit. Similarly, beneficiaries eligible for the Part D low-income subsidy (LIS) are excluded from the Model test because they already pay low, fixed copays for their medications. Enhanced Part D plans offer both basic Part D coverage, where the cost is partially subsidized by CMS, and supplemental benefits, where the cost is paid by beneficiaries in the form of higher premiums. MA-PDs are able to buy down the Part D premium using Medicare Advantage (MA) rebate dollars received from CMS. PDPs are not able to buy down any part of the Part D premium.

Figure 1.1.
PDSS Model Overview



Participating plans must offer, from a list of PDSS Model-eligible insulins covered by Medicare Part D and entered into the Model test by participating manufacturers, at least one vial and one pen dosage form of rapid-, short-, intermediate-, and long-acting insulins for the maximum $35 per month copay. Within each plan, drugs included as part of the Model test for the $35 maximum copay are called "plan-selected Model drugs." Participating plans may elect to participate in an optional narrower first risk corridor to protect themselves from unforeseen financial losses related to their participation in the Model test. Finally, participants may also offer an optional Part D Rewards and Incentives (R&I) program to financially encourage beneficiaries with diabetes and prediabetes to engage in such activities as medication therapy management or comprehensive medication review.

The PDSS Model is being tested in a larger policy context. In August 2022, President Joe Biden signed the Inflation Reduction Act (IRA) into law. Effective January 1, 2023, the IRA capped cost sharing for each insulin product covered by a Medicare Part D plan at $35 for a month's supply. The IRA provides this benefit to all beneficiaries, including LIS-eligible beneficiaries, through all phases of the Part D benefit (CMS, 2022).

Evaluation Approach

The Model test allows the CMS Innovation Center to gauge the effects of the PDSS Model benefits on a variety of outcomes, including plan enrollment, access, quality, and cost outcomes, thereby evaluating their impact on plans, manufacturers, beneficiaries, and CMS. Table 1.1 presents the research questions addressed in this report and specifies the level of analysis (plan, beneficiary, or both) conducted for each research question using the 2021 data.

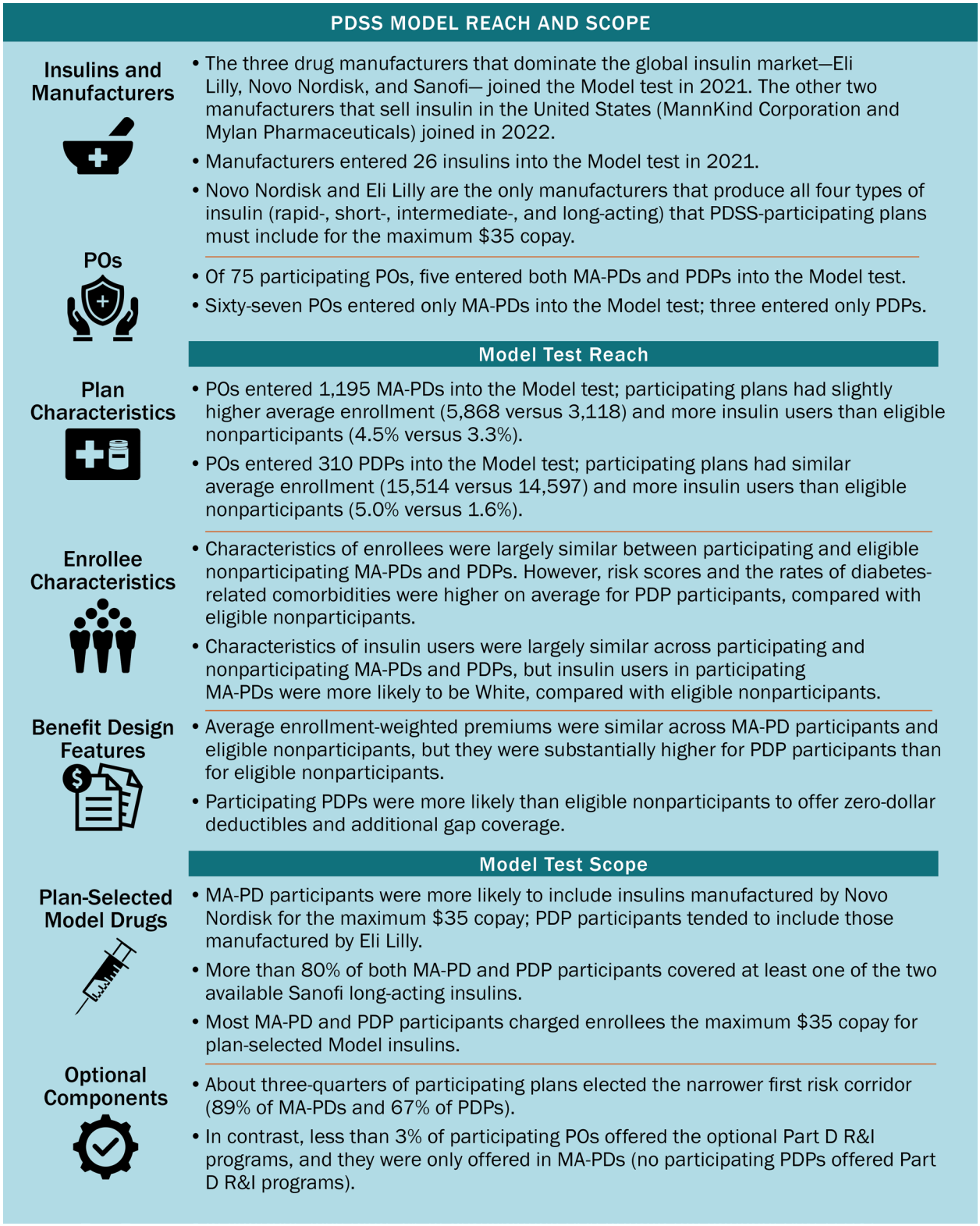
Table 1.1. Research Questions, by Outcome Domain

Research Question	Level(s) of Analysis
Enrollment and benefits	
What is the Model's impact on participating and nonparticipating plan enrollment over the course of the Model, overall, and by certain subpopulations (e.g., diabetics)?	Plan
Does the Model result in a change in insulin users and noninsulin users progressing through the Part D benefit phases?	Beneficiary
Access	
What is the Model's impact on access and adherence to insulin?	Beneficiary
Bids, premiums, and spending	
What is the Model's impact on Part D spending for both insulin users and noninsulin users in a participating plan? What is the Model's impact on Medicare and pharmaceutical manufacturers?	Beneficiary, Plan
What is the Model's impact on total cost of care, drug, and medical spending for both insulin users and noninsulin users in a participating plan? If there is a change, what were the main drivers?	Plan
What is the Model's impact on premiums and bids of participating and nonparticipating plans, including the bid's different components and beneficiaries not eligible for the Model? If there is a change, what were the main drivers?	Plan

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

To answer these research questions, we used a mixed-methods approach that combined quantitative assessments of the Model test's impact on key outcomes with qualitative analyses of data collected from key stakeholders to explain how and why the PDSS Model achieved these outcomes. While our quantitative results *estimate the impact* of the PDSS Model, the results of our qualitative data analyses *describe the opinions* of PO and manufacturer representatives, as well as insulin users from PDSS-participating plans, about the Model test, its limitations, and outcomes. This evaluation builds on our previous analyses of the Model test's reach and scope in its first two years (Taylor et al., 2022). Figure 1.2 provides a brief overview of the previously reported findings.

Figure 1.2. 2021 PDSS Model Reach and Scope

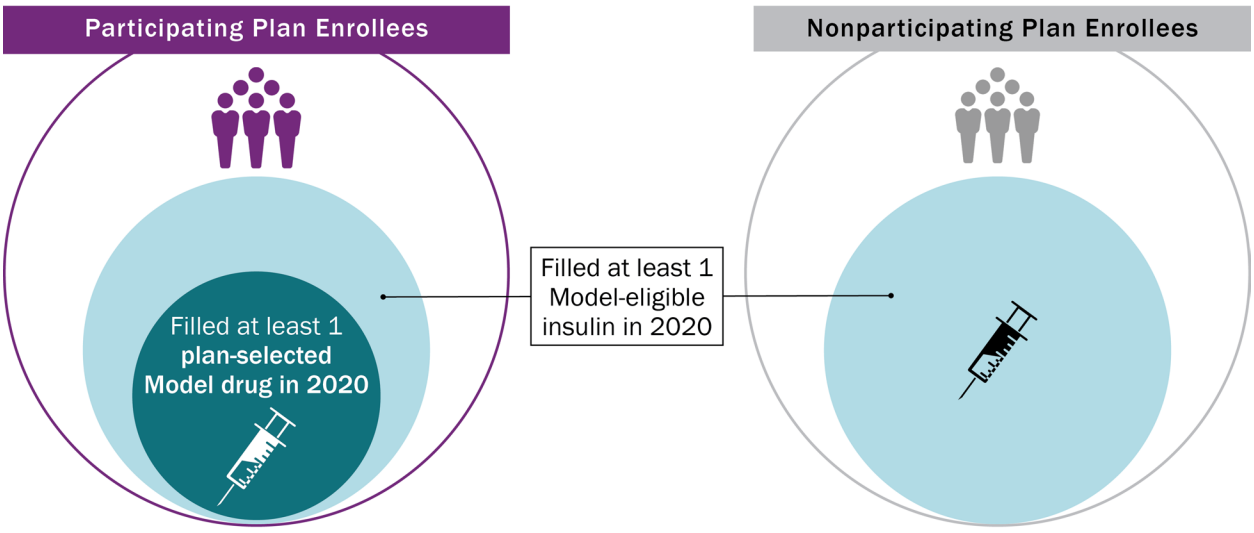


We used quantitative data sources, including Part D Prescription Drug Event (PDE) data, Part D bid data, direct and indirect remuneration (DIR) data, Payment Reconciliation System data, Health Plan Management System (HPMS) plan benefit design information, Part D formulary data, the list of PDSS Model-eligible insulins, and the Medicare beneficiary enrollment file to run difference-in-differences (DD) regression models designed to isolate the effect of the Model test on the outcomes of interest.

We ran the DD regression models at the beneficiary or plan level, depending on the outcome of interest, and we used data from participating and comparison plans (and their enrolled beneficiaries) (Figure 1.3). The primary comparison group for this evaluation consists of MA-PDs and PDPs that were eligible to participate in the Model test but did not (called "eligible nonparticipants"). As noted above, only MA-PDs and PDPs offering enhanced benefits were eligible to participate, and certain plan types were excluded from participation (Appendix A provides additional details). We also ran analyses using all eligible nonparticipating enhanced and eligible basic Part D plans as the comparison group to provide additional information on the effects of the PDSS Model compared with all Part D benefit types (summarized at the end of each quantitative chapter; Appendix D provides these results). We ran analyses separately for MA-PDs and PDPs, because the MA-PDs provide both medical coverage and prescription drug benefits, whereas PDPs provide only Part D coverage. Therefore, these two plan types have different incentives and may see different impacts of the Model test.

Figure 1.3. Selection of Analytic Comparison Groups and Beneficiary Samples

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



We ran beneficiary-level analyses for insulin users; that is, beneficiaries who used insulin in 2020—the year before the Model test began. (Insulin users are represented by the lighter blue circles in Figure 1.3.) We expected to see the majority of outcomes affecting this group because the Model test directly targeted one of the prescription drugs they use. PDSS-participating plans were required to cover a minimum set of PDSS Model-eligible insulins; the subset of PDSS Model-eligible insulins covered by participants were referred to as "plan-selected Model insulins." Because eligible nonparticipating comparison plans do not distinguish between PDSS Model-eligible and plan-selected Model insulins, our analyses compared the effects of the Model test across those beneficiaries who used any PDSS Model-eligible insulins.

We also evaluated the effect of the Model test on noninsulin users—beneficiaries who did not take insulin in 2020 (shown as the larger white-filled circles for both participating and nonparticipating plans in Figure 1.3). These beneficiaries may have experienced impacts of the PDSS Model to the extent that their plans altered benefit designs or increased premiums or other costs as part of their participation in the Model test. We excluded LIS-eligible beneficiaries from both groups because they are not eligible to participate in the PDSS Model due to the fact that they already generally pay low cost sharing for all of their medications.

We report estimates for the impact of the PDSS Model from DD regression models using 95% confidence intervals (CIs), which capture uncertainty in the estimates. For a DD regression model to produce unbiased estimates of the PDSS Model's effects, outcomes of interest in participating and comparison plans should, on average, move in parallel between 2020 and 2021 in the absence of the PDSS Model. If this parallel trends assumption is violated, the DD regression coefficient will not accurately capture the impact of the PDSS Model, because other factors might have contributed to the estimated effect. To address this possibility, we examined how outcomes in intervention and comparison plans evolved between 2019 and 2020—both years prior to the start of the Model test—to calculate CIs that account for the possibility that the parallel trends assumption may be violated.

To synthesize these results, we defined four categories that combine statistical significance with the parallel trends CIs to describe the strength of evidence (we provide additional details in Appendix A):

- **Strong evidence:** high statistical significance (p-value < 0.01) and robust to substantial violations of parallel trends that might be larger than those observed in the pre-period data (2019 to 2020)
- **Moderate evidence:** statistical significance (p-value < 0.05) and robust to violations of parallel trends assumption similar to those observed in the pre-period data
- **Limited evidence:** statistical significance (p-value < 0.05) but not robust to violations of parallel trends assumption
- **No or weak evidence:** not statistically significant at the $p < 0.05$ level, regardless of robustness to parallel trends assumption violations.

We use this terminology throughout the report to summarize the quantitative evidence for impacts of the PDSS Model. To put the results in context, we also report the magnitude of the estimated effect as a percentage of the average expected outcome for the group if the PDSS Model had not been implemented (this average expected outcome is often referred to as the "counterfactual"). We note that the plan-level results should be interpreted with more caution than the beneficiary-level results, especially among PDPs: Participating and comparison groups for the plan-level analyses differed from each other on a variety of characteristics, and our sensitivity analyses, which used all nonparticipating PDPs as an alternative comparison group, suggested different conclusions about the impacts of the PDSS Model on costs to CMS of the Part D benefit. Results of plan-level analyses for the MA-PDs were more robust to the use of alternative comparison groups than the results for PDPs.

For the qualitative component of our study, we collected data from POs (that is, legal entities that are contracted by CMS to offer Part D plans), manufacturers, and beneficiaries. Between January and April 2022, we fielded a survey to all 73 POs that participated in the PDSS Model in 2021 to assess their perspectives of the impact of the Model test on their plans and beneficiaries. Sixty-seven POs (92%) participated in the survey and answered at least half of the survey questions. We analyzed survey data descriptively to identify the most common responses and the range of perspectives. To further explore the impacts of the PDSS Model, we also completed semistructured interviews with representatives from nine of these POs after they provided their survey responses. In May 2022, we interviewed representatives from all five insulin manufacturers that participated in the Model test in 2022. Finally, between August and November 2022, we completed semistructured interviews with 100 insulin users enrolled in PDSS-participating plans. It is important to note that while we collected PO and manufacturer data before the IRA announcement on August 16, 2022, all beneficiary interviews occurred after that date.

We analyzed all interview data thematically to describe how the Model test affected POs, manufacturers, and beneficiaries and to identify differences and similarities in stakeholder perspectives on the Model test outcomes and mechanisms through which the PDSS Model might have affected key outcomes. Where possible, we tried to quantify qualitative data to identify the most and least common sentiments among stakeholders (see Appendix E for more details on our approach to qualitative data collection and analysis).

We triangulated our results by combining the insights from our quantitative models with the results of our qualitative interviews and surveys to be able to provide nuanced explanations of how and why the Model test affected plans, manufacturers, beneficiaries, and CMS. To protect the confidentiality of our interviewees, we did not identify POs or insulin manufacturers by name. Instead, we randomly assigned them letters, such as PO A or Manufacturer A.

Report Roadmap

The remainder of the report presents our findings from the evaluation of the first year of the Model test. Chapter 2 provides background and context on key stakeholder experiences and their perspectives on the Model test, derived from the primary data we collected from POs, manufacturers, and beneficiaries. The following three chapters describe the effects of the Model test on access to insulins (Chapter 3); plan enrollment and beneficiary progression through benefit phases (Chapter 4); and cost outcomes, including bids, premiums, and spending (Chapter 5). Chapter 6 outlines limitations of our evaluation, provides a brief summary of our results presented separately for plans, manufacturers, and beneficiaries, using both narrative and visual formats, and previews the analyses to be presented in future reports. The appendices provide additional information on the methods used for our quantitative analyses (Appendices A through D) and qualitative data collection and analyses (Appendix E).

Chapter 2. Stakeholder Perspectives on the PDSS Model

KEY TAKEAWAYS

Perspectives on the Model Test and Components

- Insulin users, as well as representatives of PDSS-participating POs and manufacturers, agreed that limiting copays to no more than $35 for a one-month supply of insulin addressed an important barrier to insulin adherence (cost). This barrier is particularly salient in the coverage gap phase, when OOP cost can substantially increase.
- Although the majority of PDSS-participating plans opted for the narrower first risk corridor to reduce potential financial risks related to the Model test, only a handful of plans implemented Part D R&I programs, and of these, all were MA-PDs. POs stated that they wanted to test the effectiveness of financial intervention first, noting that they already have robust diabetes management programs.

Perceived Shortcomings of the PDSS Model

- Stakeholders viewed the exclusion of LIS-eligible beneficiaries, insulins delivered via stationary pumps covered by Medicare Part B, and non-insulin diabetes medications as shortcomings of the Model test.
- Manufacturers wished that the Model test addressed the system of rebates and high drug list prices. Some of them also wanted the Model test to encourage participating plans to cover all available types and forms of insulin.

Suggestions on Drug Affordability

- Manufacturers advocated for rebates to be applied at the point of sale, which would ensure more equitable distribution of liability for drug costs among plans, pharmacy benefit managers (PBMs), and manufacturers.
- Manufacturers also called for creating an OOP maximum for beneficiaries and eliminating the coverage gap phase as strategies for addressing drug affordability.

This chapter describes stakeholder perspectives on, and experiences with, the Model test components, using the 2022 interview data we collected from PDSS-participating POs, insulin manufacturers, and insulin users enrolled in PDSS-participating plans. It also highlights the drawbacks of the Model test from the perspectives of these three stakeholder groups and explains which of the PDSS Model limitations will be addressed by the IRA implementation. Finally, this chapter describes additional strategies proposed by insulin manufacturers as a potential way to help address high drug costs. Results presented in this chapter help contextualize and explain the impact of the PDSS Model on the outcomes presented in subsequent chapters.

Perspectives on the PDSS Model Components

The PDSS Model has three components: fixed and predictable insulin copays, a narrower first risk corridor, and Part D R&I programs.

Lower and More Predictable Insulin Copays

Beneficiaries—even those who did not experience financial difficulties before the PDSS Model—appreciated having lower copays and commented specifically about the benefits of having predictable and consistent copay amounts throughout different benefit phases. One beneficiary described how their copays were more variable before the Model test began:

> I'm paying $35 for … a copay … [and] my insurance company is paying in the order of a couple thousand dollars. So that's why I say that's a bargain. But there have been times, for example, when I was in the donut hole and at that time … paying a thousand dollars, and I can afford to pay that and I have paid that, but it hurts.

PO representatives we interviewed felt that, by capping insulin copays at no more than $35 per one-month supply, the PDSS Model addressed an important barrier to beneficiary insulin adherence, particularly in the coverage gap benefit phase. As a PO C representative explained: "[The PDSS Model is] just better for the members. They have some protection when they do reach the gap." A PO G representative added that the PDSS Model is particularly useful in PDPs, because POs have few options to reduce premiums and add enhanced coverage: "You just don't have as many levers as you do in MA-PDs on this side of things. So, when there's something that you can do, it's very exciting. … [PDSS] makes things easier for members."

Other PO representatives noted the importance of ensuring that beneficiaries pay the same amount for insulin throughout all phases of the Part D benefit design. Even if plans charge copays in the initial coverage phase, they often revert to coinsurance in the coverage gap phase for insulins outside the Model test. Thus, according to a PO H representative, "[the Model test] lowered [copays] slightly in the initial coverage phase, but tremendously in the [coverage] gap."

Manufacturers agreed that the PDSS Model addressed an important cost barrier and said that they appreciated the Model test's focus on market-based solutions to the problem of insulin affordability. For example, Manufacturer B representatives framed the PDSS Model as "one of several steps that we've taken over the past several years to address the issue of affordability challenges faced by people who are taking [our] insulins."

Manufacturer C representatives emphasized the importance of two market-based elements of the Model test: its voluntary nature and the fact that the U.S. government did not regulate manufacturers' negotiations with *pharmacy benefit managers* (PBMs; that is, companies that manage prescription drug benefits for insurance companies and other payers) and POs:

> The [CMS] administrator and the administration were aware of the limitations of the non-interference clause and did not try to influence or overstep the interactions and negotiations that occur between two private-sector entities. They were clear about what the expectations were of each, but participation was voluntary for both, and, ultimately, how it played out in real life was a reflection of market-based negotiations.

Narrower First Risk Corridor

The uptake of this optional Model test component was substantial in 2021: 73% of participating POs elected the narrower first risk corridor in at least one of their participating plans, and a total of 71% of all participating plans chose this option. This finding suggests that PDSS Model participants might have expected an increase in insulin user enrollment in their plans, which, in turn, could increase their anticipated costs.

Our PO interview sample, however, included primarily those insurers that did not elect the narrower first risk corridor. Of the nine POs we interviewed, representatives of six POs were not sure why their organization did not choose this option. The representatives of the other three POs we interviewed, however, cited uncertainty about the impact of the Model test as the factor that affected their decisionmaking about whether to adopt the narrower first risk corridor, but for different reasons. PO G and V representatives stated that, because they were uncertain whether the Model test would increase the number of insulin-using beneficiaries in their plans, they decided not to opt for the narrower first risk corridor. As a representative of PO G explained:

> It felt like it didn't end up providing that much additional protection. And then on the flip side of that, I think it's a two-way risk-sharing program, so if we were to overperform, we wouldn't want to share that unnecessarily.

In contrast, PO A representatives—the only PO in our interview sample that implemented this optional component—said that uncertainty about the Model test's impact made the narrower first risk corridor very attractive to them:

> We were expecting that we would potentially enroll quite a large number of insulin users, and we just wanted to protect against the downside risk that the experience of that population would be significant. We didn't have really a great feel for just what could happen. That's why we opted into the narrower risk corridor.

Part D R&I Programs

The uptake of the optional Part D R&I program component among PDSS Model participants was low: only five POs offered them in 32 participating plans in 2021. Moreover, POs that chose to offer Part D R&I programs did so only in MA-PDs. MA-PDs' financial incentives for disease and care management differ from those of PDPs because MA-PDs are responsible for both drug and medical costs. According to representatives of PO G, which entered PDPs into the PDSS Model:

> With the stand-alone PDP, you're really only able to influence drug costs and expenses…. So incentive-type programs, we don't have much of an appetite to increase the spend on the plan, and there isn't anything that really calls out to us as a very effective, very impactful program that would reduce drug costs meaningfully. So, it's just we weren't really aware of a great cost-benefit relationship for any sort of incentive that we could implement.

Interviewed POs that chose not to implement Part D R&I programs stated that they wanted to test the PDSS Model without adding extra complexity. They cited three main reasons for not offering such programs. First, PO H representatives stated that OOP cost in the coverage gap phase was the main barrier to insulin adherence and that the Model test already offered a strong incentive to increase insulin adherence:

> We've known for several years that we had members rationing insulin, particularly when they hit the gap. This has been something we've been trying to do for a really long time, so when CMS proposed this demonstration program, we were extremely excited to participate. Even without that rewards incentive, the discount and the coverage through the gap [were] incentive enough for the members at this point.

Second, PO D and E representatives stated that they already offered robust diabetes education and care management programs and that did not feel the need to add financial rewards through the PDSS Model.

Finally, PO A and C representatives stated that they did not expect Part D R&I programs to yield a positive return on investment because running such programs would be administratively burdensome and costly.

Representatives of PO F, the only PO we interviewed that implemented a Part D R&I program said, however, that this optional Model test component offered an opportunity to test a reward program for engaging with a targeted set of beneficiaries with diabetes:

> [In] general, rewards programs, you activate everybody who might be eligible. Sometimes, obviously, those diabetic numbers are the most expensive. They're the ones that may be the hardest to intervene with, because they're already getting a large amount of care. So, we really felt like this was an extra avenue to be able to advise them to partner with the plan.

Shortcomings of the Model Test

Although all stakeholders we interviewed stated that the PDSS Model was a step in the right direction toward addressing the problem of insulin affordability and adherence, they identified several factors that may limit its effectiveness.

From the PO perspective, the PDSS Model fell short on two main fronts. First, LIS-eligible beneficiaries were not eligible for the maximum $35 copays offered by PDSS-participating plans as part of the Model test. This meant that a small number of POs that offered $0 insulin copays in their PDSS-participating plans as part of the Model test were not able to eliminate copays for LIS-eligible beneficiaries, who still had to pay some copays when they filled their prescriptions. "That's the hardest conversation to have, like somebody who in all likelihood probably needs the most help," explained a representative of PO F, "and if you didn't qualify for LIS, you can get [insulin] at zero [dollars in our PDSS-participating plans]." The exclusion of LIS-eligible beneficiaries created a potential for inequity within a small number of PDSS-participating plans that eliminated insulin copays for their enrollees. This limitation, however, was addressed as of

January 1, 2023, when the IRA provisions, which apply to all people with Medicare drug coverage, were implemented (CMS, 2022).

Second, not all insulins are covered by Medicare Part D. Insulins delivered via stationary pumps, which are considered DME, are covered by Medicare Part B. Therefore, beneficiaries using stationary insulin pumps cannot benefit from the lower insulin copays offered as part of the PDSS Model. PO C and H representatives noted that the exclusion of Part B-covered insulins was difficult to explain to beneficiaries. A PO C representative added that it is not always possible for beneficiaries to switch to a Part D-covered insulin: "By the time you need the pump, you're generally a more brittle diabetic, and you require higher doses that really can't be administered subcutaneously." To address this issue, PO H changed its coinsurance for Part B-covered insulins to approximate the $35 copay for Part D insulins under the Model test. This PDSS Model limitation, however, will also be addressed by the IRA, which will cap beneficiary OOP costs for each Part B-covered insulin to no more than $35 starting on July 1, 2023 (CMS, 2022).

Although manufacturers liked the market-driven solutions offered by the PDSS Model, they stated that more could be done to address insulin affordability. Representatives of all five insulin manufacturers stated that the Model test did not address the system of manufacturer rebates that are calculated based on high list prices that were driving the affordability problem for beneficiaries (see text box for additional explanation). Thus, the Manufacturer E representative felt that the PDSS Model only offered a "band-aid" solution to insulin affordability and adherence. According to manufacturers, reducing beneficiary copays for insulin shifted costs from beneficiaries to plans, manufacturers, and CMS, but this cost shift did not address the underlying issue of high prescription drug prices overall.

Manufacturer Rebates

Manufacturers negotiate with PBMs, health insurers, or both regarding the price of their products and other factors that affect their sales volume. Factors affecting the number of drugs sold include whether a drug is covered, which formulary tier it is placed on, and whether there are restrictions on which beneficiaries can access a drug. For some drug classes, manufacturers pay PBMs and insurers a so-called rebate to increase the volume of their products that are sold. This rebate is often a discount off of the list price if the PBM or insurer agrees to put the drug on a lower tier, for example. Rebates are paid by manufacturers to the PBMs and insurers after a drug is dispensed. Drug classes with many therapeutic alternatives, such as insulin, tend to have high rebates for brand-name products. Previous studies have estimated insulin rebates to be as high as 70–80% of the list price (Hernandez et al., 2020; Mulcahy et al., 2021).

Furthermore, while manufacturers recognized that participating plans choose what insulins they want to cover as part of the Model test, some wanted the PDSS Model to require participating plans to offer all available insulin products at no more than $35, including insulin types that are less commonly found on formularies. For example, one of the manufacturers we interviewed noted that the Model test required participating plans to cover at least one vial and one pen dosage form (the two forms with the largest market presence) of each of four insulin types but did not require plans to cover other forms of insulins.

Similarly, manufacturers of biosimilar and generic insulins raised a concern that the Model test did not encourage the use of these insulin products because it did not give plans any incentives either to cover them or to further lower patient cost sharing (relative to originator insulins). They reported being unsuccessful in convincing PBMs and plans to cover biosimilars and generic insulins because plans' financial responsibility for these insulins in the coverage gap phase is substantially higher than that for brand-name products. Moreover, some manufacturers also noted that biosimilar and generic insulins are covered by Medicaid and are popular with cash-paying patients. Therefore, manufacturers of biosimilar and generic insulins generally thought that requiring plans to put these insulins on lower cost-sharing tiers than the reference products or capping the copays on all biosimilars and generics, would be a better solution for drug affordability than capping copays for all insulins at the same level.

Although beneficiaries appreciated lower and more predictable insulin copays, many felt that the Model test did not go far enough. For example, the Model test did not include non-insulin diabetes medications, such as Ozempic, Victoza, and Trulicity, which many beneficiaries using insulin also take. As one beneficiary stated:

> I just wish they would allow us to have Ozempic [for $35]. I started on that, and when you have to go away from it [because you cannot afford it], it's like giving candy to a baby and then taking the candy away from him and saying you can't have that. Because I did so well on it, and it was once a week instead of twice a day. And then being afraid to go to the doctor because you're not sure what he's going to tell you that your bloodwork says. When you were on Ozempic, everything was perfect.

This beneficiary concern, however, has not been addressed with the implementation of the IRA, because the IRA's insulin provisions do not apply to non-insulin diabetes medications.

Moreover, before the IRA caps beneficiary OOP costs to $2,000 starting in 2025, insulin users may continue experiencing financial hardship because many of them take several types of insulins. Indeed, nearly half (48%) of the insulin users we interviewed reported taking multiple insulins, most often one rapid-acting and one long-acting insulin. As a result, their combined monthly insulin copays exceeded $35. One beneficiary described this situation during an interview that took place after the IRA was announced:

> There have been a lot of discussions [in] the past few weeks that the government was going to put a limit on how much they would pay [for] your insulin. But nobody qualified [whether] that is insulin in the plural or in the singular. Because, for example, in the evening, I take something that's the slow release when I go to bed. And in the morning, it's a combination of medium and slow. Those are two different items.

Additional Strategies for Addressing Drug Affordability Problems

Insulin manufacturers identified three additional strategies to address drug affordability issues beyond the Model test. The first strategy called for applying manufacturer rebates at the

point of sale as a way to reform the current Part D benefit structure. This approach would lower beneficiary OOP costs by applying drug-specific manufacturer rebates at the pharmacy as opposed to paying manufacturer rebates to POs or their PBMs. A Manufacturer E representative stated that such a broader reform would be preferable to pursuing policies that focus just on one drug class:

> [The PDSS Model may not work] very well for other disease states. I hear a lot of questions about that. I think it's kind of a unique model because it is expensive. I think the better thing is to look at rebate pass-through and to look at reforming the Part D benefit design.

Another suggestion favored by Manufacturers B and C focused on ensuring that liability for drug costs would be shared more equally among plans and manufacturers across different benefit phases to ensure that all key stakeholders, including PBMs, financially contribute to lowering prices for beneficiaries. According to a Manufacturer B representative, doing so would give plans:

> accountability where they [plans] don't currently have so much of it, such as in the coverage gap or in the catastrophic phase. [This] can potentially be plugged into a model like this to make it work better for all participants but also to give beneficiaries even more relief in terms of their out-of-pocket costs.

Finally, a Manufacturer C representative stated that regardless of what policy is selected, it should uphold the "market-based innovative ecosystem" that rewards innovation and ensures that the benefits of lower prices are passed down to beneficiaries. Manufacturers thought that creating an OOP maximum for beneficiaries and eliminating the coverage gap phase would be useful reforms for the Part D benefit design. It is worth noting that the IRA added an OOP maximum of $2,000 starting in 2025, along with the elimination of the coverage gap phase (CMS, 2022).

Summary

Beneficiaries valued having lower and more predictable copays, even if their personal finances allowed them to afford higher copays in certain Part D benefit phases without threatening their medication adherence. POs and manufacturers generally viewed the PDSS Model as helping to lessen the unpredictability of beneficiary OOP costs as they progress through Part D benefit phases, which can pose a barrier to insulin adherence. Manufacturers particularly liked the voluntary, market-based approach to the Model test.

POs and manufacturers noted two main shortcomings of the Model test, namely the exclusion of LIS-eligible beneficiaries, which could lead to some inequities because LIS Level 4 beneficiaries may pay more than $35 for their insulin, and the absence of a requirement for participating plans to cover all forms and types of insulin, which may work well for some beneficiaries. Moreover, beneficiaries noted that the Model test does not include any non-insulin diabetes medications and that the lower and flat copay may not be as helpful to beneficiaries who take multiple types of insulin along with other medications.

Finally, manufacturer representatives also argued that the elimination of the coverage gap and the creation of an OOP maximum, as well as strategies for distributing costs more equally among plans, PBMs, and manufacturers across benefit phases, would be needed to address drug affordability. Implementation of the IRA, which was announced after we interviewed manufacturers, addressed some of their suggestions.

Chapter 3. Access Outcomes: Insulin Utilization and Adherence

KEY TAKEAWAYS

Insulin Coverage

- PDSS-participating plans did not substantially change the average number of covered insulins after the Model test began, believing such changes would disrupt beneficiary care.
- Manufacturers reported not experiencing large increases in the volume of insulins sold under the Model test.

Utilization

- Insulin fills increased by an average of nearly one 30-day fill for insulin users in both PDSS-participating MA-PDs and PDPs (strong evidence).
- PO survey and interview data also showed that the PDSS Model had a positive impact on insulin utilization.

Adherence

- The likelihood of insulin users being adherent to basal insulin increased by 2.4% in PDSS-participating MA-PDs (strong evidence) and by 1.2% in PDPs (limited evidence).
- Insulin users in PDSS-participating MA-PDs and PDPs had short- and rapid-acting insulins on hand 45% and 47% of the time, respectively. This reflects a 3.3% increase in the Medication Possession Ratio (MPR) for MA-PDs (moderate evidence) and a 5.5% increase for PDPs (strong evidence), as a result of the Model test.
- Insulin users in PDSS-participating MA-PDs and PDPs had mixed insulins on hand 55% and 56% of the time, respectively. This reflects an average increase of 2.9% in PDSS-participating MA-PDs (limited evidence) and an average increase of 6.9% in PDPs (strong evidence).
- As with utilization, the PO survey and interview data showed that the PDSS Model had a positive impact on insulin adherence.
- Insulin users and their insurers agreed that costs are a key barrier to diabetes management and insulin adherence. However, lifestyle barriers (such as following diet and exercise regimens) were the highest-rated barriers among beneficiaries, and medication management challenges (such as polypharmacy and taking drugs with complex dosing regimens) were the highest-rated barriers among PO representatives.

This chapter presents the results of quantitative and qualitative analyses assessing the effect of the PDSS Model test on access to insulins, which was measured as both utilization and adherence. Part D enrollee access to insulin is affected by the inclusion of insulins on Part D plan formularies. In addition, beneficiaries face lower barriers to insulin access when they experience lower and more consistent insulin cost sharing, which in turn may improve their ability to adhere to their insulin therapy. We assessed trends in coverage of insulin both before and after the Model test began and also created a set of key insulin utilization and adherence metrics to evaluate the effect of the Model test on insulin access (shown in Table 3.1).

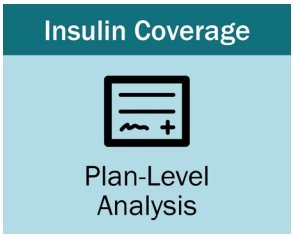
Table 3.1. Insulin Utilization and Adherence Outcome Measures

Measure	Analysis Level	Description
Number of covered insulins	Plan	Average number of PDSS Model-eligible insulins covered by PDSS-participating plans in 2020 and 2021
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 using the days supplied variable
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 an established period after the previous fill
Medication possession ratio (MPR)	Beneficiary	Constructed as three separate adherence measures assessing the proportion of days in a year during which each insulin user had a specific type of insulin in their possession

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

To evaluate the impact of the Model test on insulin utilization and adherence, we restricted our analyses to beneficiaries who used insulin in 2020 (the year before the Model test began) and were enrolled in the same plan for all of 2020 and 2021. The regression models used data from 2019–2021 and included a set of beneficiary- and plan-level control variables (shown in Appendix A). We provide further detail on the outcome measures in Appendix B, and the regression results can be found in Appendix C. The main quantitative results included in this chapter used the eligible nonparticipating plans as the comparison group. Appendix D contains sensitivity analyses using all nonparticipating plans in the comparison group.

Insulin Formulary Changes as Part of the Model Test



As previously described, the PDSS Model requires participating plans to cover at least one vial and one pen dosage form of rapid-, short-, intermediate-, and long-acting insulins. In 2021, MA-PDs were more likely to include rapid-, short-, and intermediate-acting insulins from Novo Nordisk on their formularies, whereas PDPs were more likely to include these insulin types from Eli Lilly. About 75% to 80% of formularies for both MA-PDs and PDPs included at least one Sanofi long-acting insulin. About 60% of MA-PDs also included a highly concentrated formulation of insulin (Humulin R 500), whereas only 27% of PDPs did so (Taylor et al., 2022).

Interviews with PO representatives echo these findings. All PO representatives stated that they tended to cover insulins from one of the two largest insulin manufacturers (Eli Lilly or Novo Nordisk), supplementing them with other popular insulin products by other manufacturers, such as the Sanofi-manufactured Lantus, the most prescribed insulin in Part D (CMS, undated). Because the two largest insulin manufacturers offer all insulin types, POs can negotiate with one

of these two manufacturers for their entire product line. According to a PBM representative working with PO C, "to help drive premium reductions and cost savings with our plans and our members, we negotiate with the different companies to help accomplish that goal and then choose a preferred strategy based on that."

PDSS-participating plans made small changes to the number of covered insulins between 2020 and 2021 (Table 3.2). The average number of rapid-acting insulins covered by MA-PDs and PDPs increased slightly (from 1.9 to 2.3 for MA-PDs and from 1.9 to 2.2 for PDPs). The average number of mixed insulins included on formularies increased from 2.1 to 2.5 for MA-PDs. The average number of covered long-acting, combination, and mixed insulins slightly decreased for PDPs.

Table 3.2. Average Number of Covered Insulins, by Type of PDSS-Participating Plan

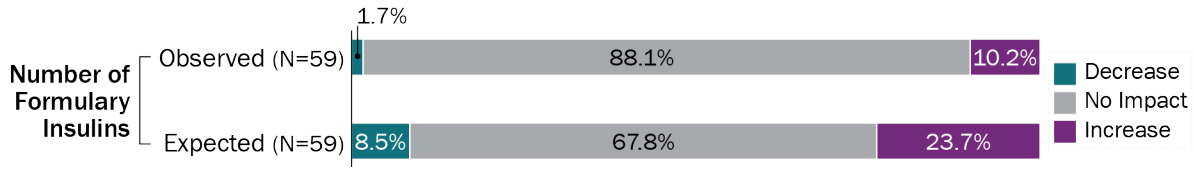
Insulin Type	MA-PDs 2020	MA-PDs 2021	PDPs 2020	PDPs 2021
Rapid-acting	1.9	2.3	1.9	2.2
	(1, 6)	(1, 8)	(1, 5)	(1, 3)
Short-acting	1.1	1.0	1.0	1.0
	(1, 2)	(1, 2)	(1, 2)	(1, 1)
Intermediate-acting	1.1	1.0	1.0	1.0
	(1,2)	(1, 2)	(1, 2)	(1, 1)
Long-acting	3.8	3.7	3.4	3.1
	(1, 5)	(2, 5)	(3, 5)	(2, 5)
Combination	1.2	1.3	1.6	1.4
	(0, 2)	(0, 2)	(0, 2)	(0, 2)
Concentrate	1.0	1.0	1.0	1.0
	(0, 1)	(0, 1)	(1, 1)	(0, 1)
Mixed	2.1	2.5	2.3	2.2
	(2, 4)	(2, 6)	(2, 4)	(2, 3)

SOURCE: Authors' analysis of quarterly CMS Part D formulary data accessed from CMS, 2023; and the sponsor-provided 2021 PDSS Model-eligible insulin list.
NOTES: This table shows the mean number of insulins, with minimum and maximum values in parentheses.

Our interviews generally corroborated these findings: Representatives of POs we interviewed said that they did not make major changes to insulin formularies for the Model test because they did not want to disrupt care for beneficiaries. A representative of PO A explained: "We have historically had primarily Lilly insulin coverage on our plans and being mindful of the experience for our beneficiaries year over year to switch from Lilly to, let's say, the Novo products, that's a pretty significant change for our beneficiaries."

Indeed, representatives of only 10% of POs completing our survey stated that they increased the number of insulins on their formulary because of their participation in the Model test (Figure 3.1). However, roughly one-quarter of survey participants (24%) stated that they expect that the Model test will lead to the inclusion of additional insulins on their formulary in the future (next three to five years).

Figure 3.1. PO Survey Results on PDSS Model Impact on Already Observed and Expected Changes to Insulin Formularies



SOURCE: Authors' analysis of response data from 2021 PDSS-participating POs surveyed in 2022.

Representatives of PO H, one of the few POs that made changes to its formulary for the Model test, stated that they added the concentrated insulin to their formulary, but only for the second year of participation:

> That's about the only insulin that we've ever changed partially due to the Part D Senior Savings Program. Novo Nordisk does not offer a high-concentration insulin, so we just thought that—you know, we had the opportunity to add that product and still keep our current rebates that we had with Novo. So, we added that product, specifically the high-concentration insulin, just to offer that to our members, as well as to obtain this discount for them, because it just didn't seem fair that we weren't offering them an alternative.

In discussing other formulary changes that were driven by PDSS, PO G representatives stated that they decided to vary copays between network and non-network pharmacies as part of the Model test rather than change their formulary.

Representatives of PO A, which did not reduce copays for all of their covered insulins, said that they did not see much evidence of beneficiaries switching to insulins with the lower copays under the PDSS Model:

> Once [beneficiaries are] on [insulin], and once they're stabilized on it, they're not huge fans of switching, especially if they're a particularly complex patient. Not to say that they never switch, but it's one that once you figure out what works and it's keeping your A1C low, you don't want to mess around if it's working for you. If the drug is still covered by your formulary and you can reasonably afford it, there's not been a huge stimulus for a patient to want to change or a prescriber to want to change that [patient's insulin].

None of the POs we interviewed were planning on including biosimilar or inhaled insulins in the near future.[1] Respondents cited the rebate process as the main reason for not including the biosimilar. "I think the addition of the interchangeable version might change the game a little bit, but … frankly, it's been more beneficial due to rebate strategies and financials … to not have [the biosimilars] in a preferred position," said a PO C representative. PO F representatives added

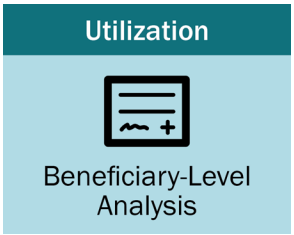
[1] The U.S. Food and Drug Administration has approved two biosimilar insulins: the first in 2020 and the second, an interchangeable biosimilar insulin, in summer 2021. Both are manufactured by Viatris, which joined the Model test in 2022. MannKind manufactures the inhaled insulin, which was also entered into the Model test in 2022.

that "the manufacturers are paying rebates in an amount for the other products that kind of make it prohibitive to make those moves at this point." Finally, PO D representatives noted that utilization of or demand for the biosimilars across markets (as seen through requests for coverage) have not been high enough to warrant changes in coverage, although the biosimilar products have not been on the market long. Other PO representatives said that their organizations were still evaluating whether to include the inhaled insulin and want to see more information on its effectiveness and value.

The unwillingness of POs to cover biosimilar and inhaled insulins, however, was of concern to those manufacturers who produce them. From their perspective, the PDSS Model reduced the incentives for PBMs and POs to cover biosimilar insulins, as well as older, authorized generic insulins. The main selling point of an interchangeable biosimilar or authorized generic is the lower OOP cost for beneficiaries; therefore, any benefit design that lowers beneficiary cost sharing for reference or brand-name products reduces the competitive advantage of the biosimilars. As a Manufacturer D representative explained, "The advantages [of bringing an interchangeable biosimilar] to the market were to some degree taken away by the broad implementation of this particular program."

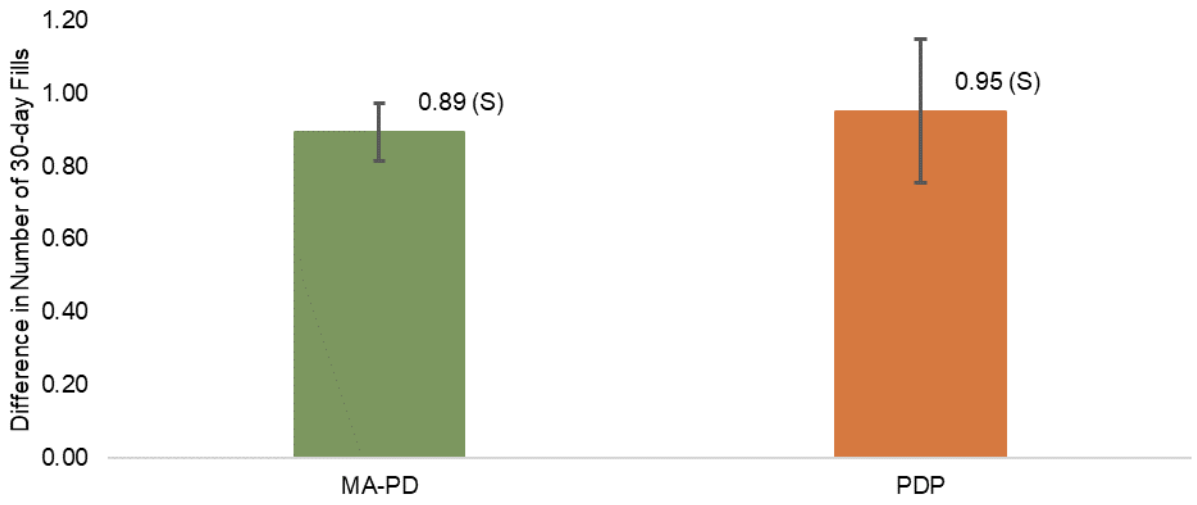
In general, manufacturers were much more pessimistic than PO representatives about the impact of the PDSS Model on access to a broad range of insulin products. Manufacturer A representatives hoped that their participation in the Model test would lead to more widespread coverage of their products by Part D plans. This change, however, has not occurred, possibly because many participating plans provided insulin coverage that met the Model test's requirements even before the Model test was launched and thus did not need to make major changes to their covered insulins. This is consistent with the PO observation that beneficiaries do not like to switch insulins and may avoid doing so even if it means higher OOP costs.

Number of 30-Day Insulin Fills



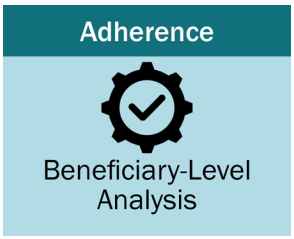
We found strong evidence that the PDSS Model led to an increased number of 30-day insulin fills—a key utilization measure—for insulin users in both MA-PDs and PDPs (Figure 3.2). Specifically, the Model test led to a statistically significant increase of 0.89 monthly fills (95% confidence interval [CI] of 0.81 to 0.97) for insulin users in MA-PDs and 0.95 monthly fills (95% CI of 0.75 to 1.15) for insulin users in PDPs, which is equivalent to an increase of 8.5% for insulin users in MA-PDs relative to the expected mean of 10.5 30-day fills in the absence of the Model test and an increase of 8.4% for insulin users in PDPs relative to the expected mean of 11.3 30-day fills.

Figure 3.2. Estimated Effect of the PDSS Model on the Number of 30-Day Fills for Insulin Users, by Plan Type



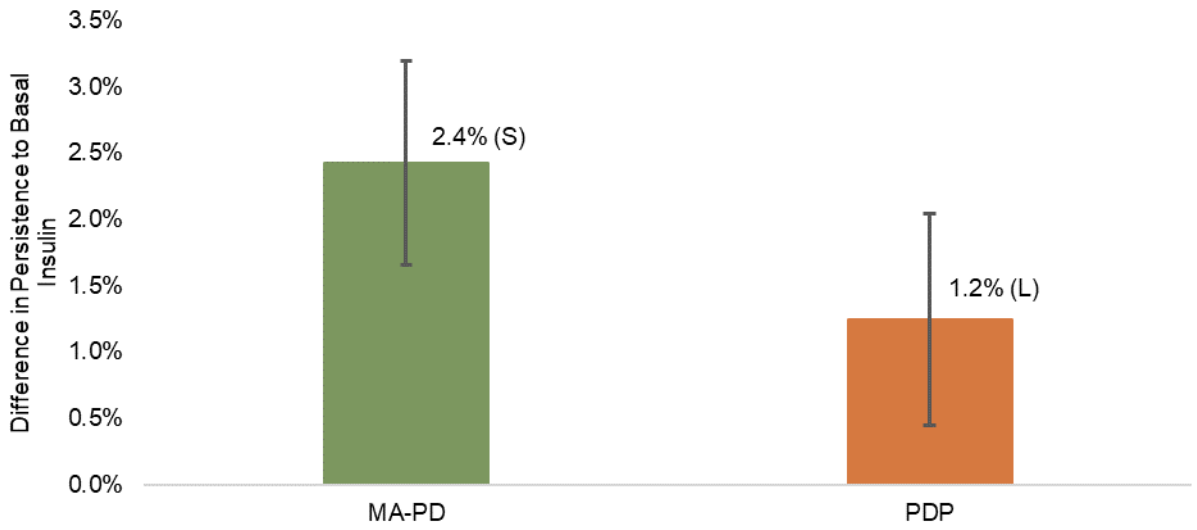
SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for a complete list of data sources and variables.
NOTES: (S) = strong evidence; (M) = moderate evidence; (L) = limited evidence; (N/W) = no or weak evidence. This figure shows coefficients on the PDSS Model implementation indicator from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in eligible nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021 to be included in the analysis. Beneficiaries eligible for the LIS were excluded from the analysis. *N* = 848,830 for MA-PDs and *N* = 509,662 for PDPs. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Persistence to Basal Insulin



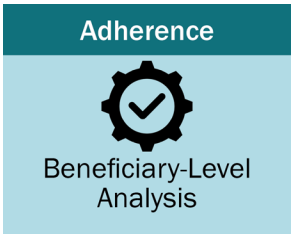
When examining whether beneficiaries were likely to have refilled their basal insulin prescriptions within the expected time frame, we found strong evidence of an increase in persistence to basal insulin for insulin users in MA-PDs and limited evidence of such an increase for insulin users in PDPs (Figure 3.3). Specifically, we found that insulin users were 2.4% (95% CI of 1.7% to 3.2%) more likely to be persistent to basal insulin in PDSS-participating MA-PDs and 1.2% more likely in PDSS-participating PDPs (95% CI 0.4% to 2.0%). This corresponds to a 3.8% increase in persistence for insulin users in MA-PDs, relative to an expected average persistence rate of 63.4% in the absence of the Model test. For PDPs, this effect represents a 1.9% increase in persistence to basal insulin among insulin users relative to an expected average rate of 66.6% in the absence of the Model test.

Figure 3.3. Estimated Effect of the PDSS Model on Insulin Users' Persistence to Basal Insulin, by Plan Type



SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for a complete list of data sources and variables.
NOTES: (S) = strong evidence; (M) = moderate evidence; (L) = limited evidence; (N/W) = no or weak evidence. This figure shows coefficients on the PDSS Model implementation indicator from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in eligible nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021 to be included in the analysis. Beneficiaries eligible for the LIS were excluded from the analysis. *N* = 602,809 for MA-PDs and *N* = 374,763 for PDPs. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

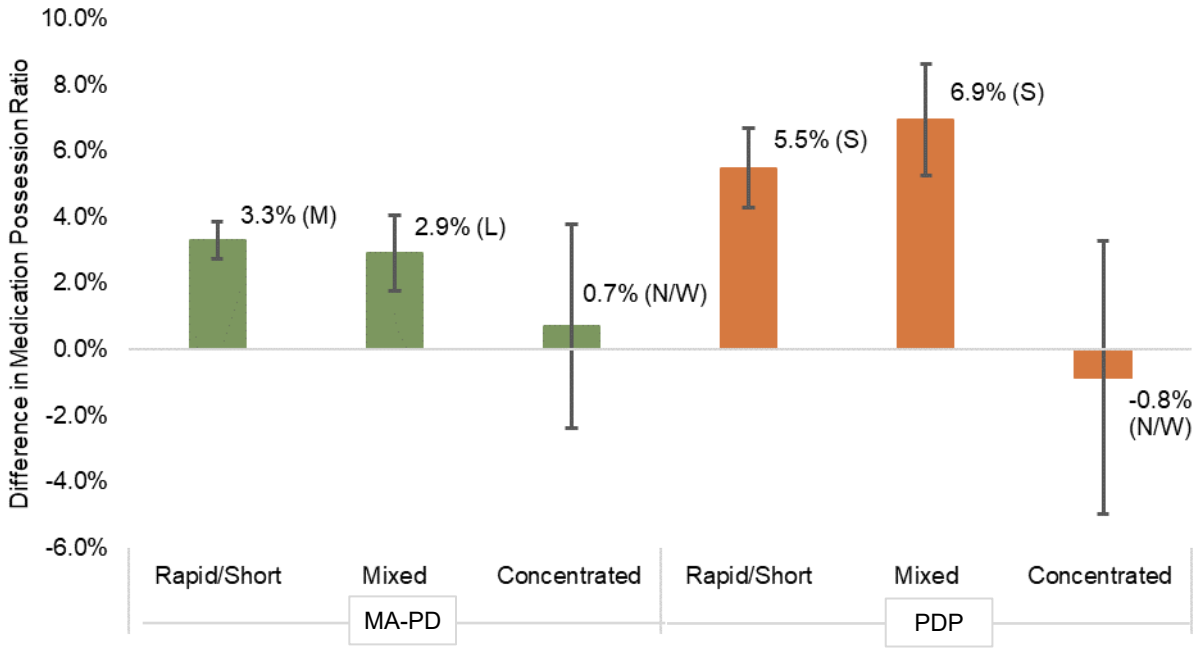
Medication Possession Ratios for Specific Insulin Types



We found evidence of an increase in the proportion of time insulin users had their insulin in hand for two of the three insulin types considered: rapid- and short-acting (rapid/short), and mixed (Figure 3.4). We found moderate evidence of a 3.3% (95% CI of 2.7% to 3.9%) increase in the rapid/short insulin MPR in MA-PDs and strong evidence of a 5.5% (95% CI of 4.3% to 6.7%) increase in the MPR in PDPs. Similarly, we found limited evidence of a 2.9% increase (95% CI of 1.8% to 4.0%) in the MPR for mixed insulins for MA-PDs and strong evidence of a 6.9% (95% CI of 5.2% to 8.6%) increase in the MPR for PDPs. This finding is somewhat surprising as PDSS-participating plans were not required to include mixed insulins at the maximum $35 copay. We found no or weak evidence of an effect of the PDSS Model on the MPR for concentrated insulins for both MA-PDs and PDPs. Very few beneficiaries (between 3,300 and 4,500) in our sample used the concentrated insulin (see the Figure 3.4 note). The Model test, however, did not require participating plans to include concentrated insulins for the maximum $35 copay, which may also explain the lack of evidence of an effect.

To put the results in perspective, the 3.3% increase for rapid/short insulins for MA-PDs corresponds to a 7.9% increase in the expected average of 41.5% (that is, beneficiaries having the insulin in possession 41.5% of the time) in the absence of the Model test. For PDPs, the 5.5% increase corresponds to a 13.1% increase in the expected average of 41.8% in the absence of the Model test. For mixed insulins, insulin users in MA-PDs experienced a 5.5% increase in MPR relative to the expected average of 52.6% in the absence of the Model test; insulin users in PDPs experienced a 14.0% increase in MPR relative to the expected average of 49.3% in the absence of the Model test.

Figure 3.4. Estimated Effect of the PDSS Model on Insulin Adherence, by Insulin and Plan Type



SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for a complete list of data sources and variables.
NOTES: (S) = strong evidence; (M) = moderate evidence; (L) = limited evidence; (N/W) = no or weak evidence. This figure shows coefficients on the PDSS Model implementation indicator from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in eligible nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021 to be included in the analysis. Beneficiaries eligible for the LIS were excluded from the analysis. For MA-PDs, *N* = 285,782 rapid/short insulin users; *N* = 96,614 mixed insulin users; and N = 4,410 concentrated insulin users. For PDPs, *N* = 206,759 rapid/short insulin users; *N* = 43,608 mixed insulin users; and *N* = 3,361 concentrated insulin users. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Sensitivity of Quantitative Results to Alternative Comparison Group

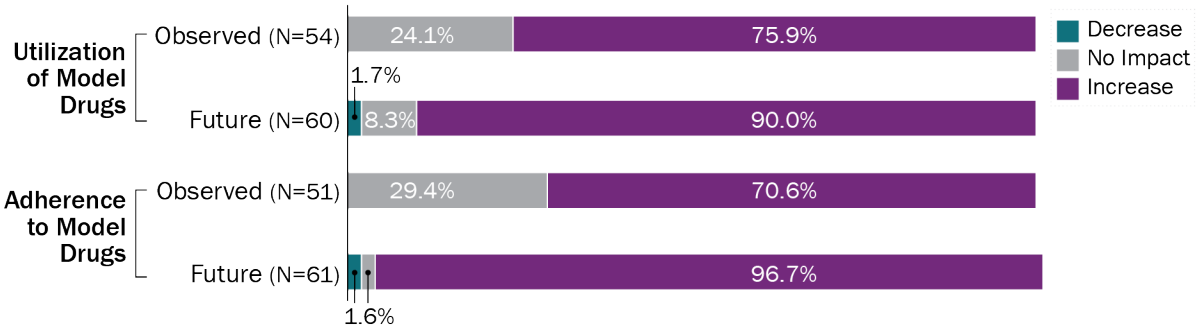
The above results compared beneficiaries in participating plans with beneficiaries in eligible nonparticipating plans. To provide additional context and to determine whether the main findings were sensitive to a different comparison group, we also compared beneficiaries in participating

plans with beneficiaries in all nonparticipating plans, which includes the basic Part D plans in addition to the enhanced plans. For the number of 30-day insulin fills, the effects of the PDSS Model in this alternative comparison are similar in magnitude and significance to the main quantitative results shown in this chapter, although the estimated average increase in insulin fills is higher for eligible nonparticipating PDPs than for all nonparticipating PDPs (an estimated 0.95 versus 0.86, respectively). The estimated effect of the Model test on the MPRs for rapid/short, mixed, and concentrated insulin types in the alternative comparison are also similar in magnitude and significance to the above results. Full details of these additional analyses can be found in Appendix D.

Stakeholder Perspectives on Insulin Utilization and Adherence

Our PO survey data generally support the quantitative findings described above, showing that PO representatives think that the PDSS Model has already increased insulin utilization and adherence (75.9% and 70.6%, respectively) and that utilization and adherence are likely to continue increasing in the future (90% utilization and 96.7% adherence) (see Figure 3.5).

Figure 3.5. PO Survey Results on PDSS Model Impact on Already Observed and Expected Changes to Insulin Utilization and Adherence



SOURCE: Authors' analysis of response data from 2021 PDSS-participating POs surveyed in 2022.

During interviews, representatives of four POs (A, E, G, and H) specifically stated that they have already observed increased insulin utilization and adherence in their PDSS-participating plans, which they often discussed together. For example, a PO H representative explained that insulin adherence among beneficiaries was flat between 2019 and 2020:

> But then it jumped up about eight or nine points in 2021. I think everybody felt pretty comfortable attributing that directly to the program [because] at that same time period, the average copay per script fell from about $60 to $30. So, pretty much, as the copays went down, the adherence had improved at that time.

Another PO H representative said that the lower copays in the coverage gap phase drove the change in insulin adherence: "Historically speaking, when we had members in the gap, the

adherence had fallen by about 15 to 20 points. And with the program now, it's a pretty flat adherence metric, independent of what phase they're in."

In discussing the impact of the Model test, PO E representatives also stated that increases in insulin adherence led to "an improvement in A1C control, so blood sugar control, which is a kind of HEDIS [Healthcare Effectiveness Data and Information Set] Star measure, as well. And then we're also seeing improvements directionally in some of our medical utilization metrics, as well as medical costs." Finally, PO F representatives stated that adherence in other drug classes (statins, in particular) had improved because of their launch of the optional R&I program component of the PDSS Model.

Nonetheless, several PO representatives noted that the coronavirus disease 2019 (COVID-19) pandemic affected their ability to understand whether changes in utilization and adherence outcomes were really due to the PDSS Model. As a PO H representative explained:

> It seems logical that as people are adherent to their [insulin] medications, that they're utilizing less ER [emergency room] services and maybe less services, in general. So, we would anticipate that the total cost of care would go down. But … it's really hard right now in the middle of a pandemic to necessarily prove that.

Moreover, PO G representatives noted that they saw medication adherence increase during the COVID-19 pandemic across multiple drug classes, which they attributed to the use of mail order pharmacies: "I think what drove that is we did see more members shift to mail order utilization…. I think people were less comfortable going to retail pharmacies, switched to mail order. Our mail order pharmacy goes in 90-day supplies, so then that's going to increase adherence." From a quantitative perspective, we would expect to capture these changes as long as pandemic-related changes in utilization were the same across PDSS-participating and comparison plans.

In comparison with PO representatives, manufacturers were more pessimistic about the impact the PDSS Model had on insulin utilization and adherence. For example, Manufacturer B representatives reported not seeing any improvements in insulin adherence or increases in insulin sales: "We see no evidence of higher volumes … and no evidence of higher patient adherence." Manufacturer C representatives also questioned whether improved insulin access actually led to lower health care utilization for beneficiaries enrolled in PDSS-participating plans.

Beneficiaries we interviewed were similarly more reserved in describing the impact of the PDSS Model on their insulin use; many beneficiaries said that they were fortunate enough to be able "to afford to pay whatever [they] had to pay for insulin" even before the start of the Model test. To further elicit beneficiaries' perceptions of the impact of the PDSS Model, we asked whether they had taken specific actions to save money or make their insulin supply last longer, including spending less money on food and other necessities to afford insulin, delaying filling their insulin prescription, reducing or skipping insulin doses, or using someone else's insulin, before and after they started paying $35 or less for a 30-day supply of insulin. More than 80% of

beneficiaries interviewed reported not taking any of these actions either before or after the PDSS Model began (see Table 3.3), and only roughly one-third (36%) of beneficiaries reported taking at least one of these steps (data not shown). This finding suggests that the perceived impact of the Model test on the interviewed beneficiaries might have been modest. This could potentially be explained by the fact that the PDSS Model excluded the most price-sensitive beneficiaries, such as those who are eligible for LIS, or because our interview sample excluded those individuals who were prescribed insulin but did not fill their prescription.

Table 3.3. Percentage of Beneficiaries Who Reported Using 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
Spent less money on food, heat, or other basic needs so that you would have money for insulin	10.1% (9)	0.0% (0)	9.0% (8)	80.9% (72)
Delayed filling an insulin prescription	10.1% (9)	1.1% (1)	5.6% (5)	83.1% (74)
Took less insulin per dose	9.0% (8)	1.1% (1)	5.6% (5)	84.3% (75)
Skipped insulin doses	7.9% (7)	2.2% (2)	7.9% (7)	82.0% (73)
Used someone else's insulin	1.1% (1)	0.0% (0)	4.5% (4)	94.4% (84)

SOURCE: Authors' analysis of data from a sample of 100 insulin users in PDSS-participating plans interviewed in 2022.
NOTES: Counts (*n*) are shown in parentheses. Responses refer to strategies employed before and after the PDSS Model began. Eleven beneficiaries did not answer these questions because they either did not notice that they had started paying $35 or less per 30-day supply of insulin or started taking insulin only after the start of the Model test, or they did not answer these questions for other reasons. *N* = 89.

Nonetheless, it is worth highlighting that about one-tenth of the interviewed beneficiaries, none of whom are officially considered low income, reported that, after the PDSS Model began, they no longer needed to restrict their spending on food, heat, or other basic needs to pay for their insulin. Moreover, roughly 10% of the interviewed beneficiaries reported no longer needing to delay filling an insulin prescription, take less insulin per dose, or skip a dose after the start of the Model test. One beneficiary described the impact of the PDSS Model by saying: "I'm being really honest here; there was a time when I actually took [insulin] that somebody else was not going to finish out because they changed to a new medication, which was the only thing that saved me."

Additional Barriers to Diabetes Management and Insulin Adherence

Despite the estimated improvements in insulin utilization and adherence under the Model test, PO representatives and beneficiaries reported that cost-related barriers are not the only ones that negatively impact proper diabetes management. Therefore, addressing only cost barriers

may not be enough to substantially improve insulin adherence or to maintain these improvements in the long run.

On the survey, we asked PO representatives to use a 4-point Likert scale to rate the extent to which they agree that their enrollees experience different barriers limiting the appropriate medical management of diabetes (Table 3.4). Two barriers related to medication management—polypharmacy and taking drugs with complex dosing requirements—emerged as the top barriers based on the percentage of POs either agreeing or strongly agreeing that these barriers affected their beneficiaries (93% and 90%, respectively). At the same time, 89% of POs also strongly agreed or agreed that cost-related barriers, including costs in the coverage gap, costs associated with specialty drugs or taking multiple drugs, and out-of-pocket costs, were key barriers to appropriate diabetes management.

Table 3.4. Barriers to Appropriate Diabetes Management Among Beneficiaries as Rated by POs

Barrier	Strongly Disagree	Disagree	Agree	Strongly Agree	Percentage of POs That Strongly Agree or Agree
Medication management					
Taking multiple drugs (polypharmacy) (*n* = 61)	0	4	45	12	93%
Taking drugs with complex dosing regimens (when and how often drugs are taken) (*n* = 63)	0	6	49	8	90%
Underuse of medication therapy management/ reconciliation services (*n* = 63)	0	19	38	6	70%
Mode of insulin administration (for instance, hesitancy to use needles; pen versus vial) (*n* = 63)	0	22	35	6	65%
Cost					
Beneficiary costs in the coverage gap (*n* = 65)	0	7	24	34	89%
Beneficiary costs associated with taking “specialty drugs” (high-cost medications) (*n* = 64)	0	7	27	30	89%
Beneficiary costs associated with taking multiple drugs (*n* = 65)	0	7	29	29	89%
Beneficiary costs (deductibles, copays, coinsurance) (*n* = 64)	2	9	28	25	83%
Health literacy and self-efficacy					
Low health literacy levels (not having the knowledge to manage condition) (*n* = 61)	1	12	39	9	79%
Lack of self-efficacy (feeling like they cannot manage condition) (*n* = 62)	1	11	43	7	81%

Barrier	Strongly Disagree	Disagree	Agree	Strongly Agree	Percentage of POs That Strongly Agree or Agree
Access					
Limited access to nutritious food (*n* = 62)	3	16	38	5	69%
Limited access to transportation (*n* = 62)	3	24	32	3	56%
Limited access to physical activity opportunities (*n* = 61)	2	28	30	1	51%
Limited access to health care providers (*n* = 63)	6	40	15	2	27%

SOURCE: Authors' analysis of response data from 2021 PDSS-participating POs surveyed in 2022.
NOTES: 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?" Not all survey participants answered each question.

During our interviews, PO F representatives described a constellation of barriers to appropriate diabetes management beyond high cost sharing:

> But there are many other factors: access to pharmacies, access to providers, there's not a whole lot of endocrinologists in the state. Sometimes getting appointments to be able to get drugs is challenging. Acceptance of diabetes, willingness to treat yourself, thinking that you know better than a doctor to follow regimens, and just general, like, people being on appropriate drugs ... are likely many of the contributing factors.

In addition to asking POs survey and interview questions about barriers their beneficiaries experience, we asked beneficiaries to identify key challenges with proper diabetes management and insulin adherence. Granted our beneficiary sample was not random, large, or representative of all insulin users in PDSS-participating plans, but we still observed notable differences in beneficiary and PO perspectives. Table 3.5 shows that the two most frequently reported barriers by beneficiaries were lifestyle barriers: difficulty following a diet (51.0%) and difficulty being physically active (45.0%). As one beneficiary put it, "When you're 72 years old and used to eating certain things and, all the sudden, it takes the sugar way up. Yeah, it's hard to get used to some of that."

Table 3.5. Barriers to Diabetes Management and Insulin Adherence as Reported by Beneficiaries

Barrier	Number Reporting	Percentage Reporting
Cost		
Paying for insulin (copays, deductibles) (*n* = 98)	25	25.5%
Paying for all the drugs that you may be taking (*n* = 99)	23	23.2%
Paying for diabetes testing supplies or continuous glucose monitors (*n* = 100)	9	9.0%
Medication management		
Managing side effects of insulin (e.g., weight gain, low blood sugar) (*n* = 100)	25	25.0%
Knowing how to manage high blood sugar (*n* = 100)	14	14.0%
Knowing when and how often to take insulin (*n* = 99)	10	10.1%
Overcoming hesitancy using needles to deliver insulin (*n* = 100)	7	7.0%
Taking multiple drugs (*n* = 96)	5	5.2%

Barrier	Number Reporting	Percentage Reporting
Keeping insulin cold (*n* = 100)	4	4.0%
Access		
Accessing nutritious food (*n* = 100)	13	13.0%
Getting appointments with a doctor who helps you manage high blood sugar (*n* = 100)	7	7.0%
Finding a reliable way to get to medical appointments (transportation issues) (*n* = 100)	7	7.0%
Lifestyle		
Following a diet (*n* = 100)	51	51.0%
Begin physically active (*n* = 100)	45	45.0%

SOURCE: Authors' analysis of data from a sample of 100 insulin users in PDSS-participating plans interviewed in 2022.
NOTES: Beneficiaries stated whether or not they experienced each of the listed barriers by answering the question: "Have you had difficulty … ?" Not all beneficiaries answered each question.

Insulin copays and deductibles, however, were the third most frequently encountered barrier, mentioned by roughly one-quarter of beneficiaries we interviewed (25.5%). This result was similar for beneficiaries in MA-PDs and PDPs (data not shown). Management of insulin side effects was also considered a barrier by one-quarter of the insulin users we interviewed. Paying for all drugs taken was also a commonly mentioned barrier to insulin adherence—23.2% of our beneficiary sample mentioned it.

We note, however, that beneficiaries and POs had somewhat different perspectives on the barriers related to medication management. Although difficulty managing multiple drugs and complex dosing regimens were among the most frequently reported barriers by POs, only 10% or less of beneficiaries reported experiencing such barriers. Similarly, a much higher proportion of POs than beneficiaries rated knowing how to manage high blood sugar, managing side effects of insulin, and needle hesitancy as barriers.

Several beneficiaries also mentioned other barriers not listed in Table 3.5, including difficulty with mobility or physical disability; side effects from or allergies to prescribed medications, such as metformin; and difficulty accessing educational resources on diabetes management, including classes and materials about how to plan meals with diabetes.

Summary

PDSS-participating plans did not substantially change the number of covered insulins under the Model test, arguing that any major changes to covered insulins may disrupt care for beneficiaries and negatively affect beneficiary care experiences. PO representatives also reported not planning to add coverage for biosimilar or inhaled insulins. POs' reluctance to cover these insulins, however, concerned the manufacturers of such products; these manufacturers advocated for the Model test to incentivize the coverage of biosimilar and generic products.

The PDSS Model was associated with an increase in the number of 30-day insulin fills for insulin users in both MA-PDs and PDPs. Our quantitative results and PO interview findings

showed that the PDSS Model had a positive impact on insulin adherence as measured by two of the three MPR metrics, as well as an increase in persistence to basal insulin. Our interviews with manufacturers, however, revealed that they did not see any increases in insulin adherence based on the volume of insulin sold. Beneficiaries were similarly reserved during the interviews in describing the impact of the Model test on their insulin use.

Increased access to insulins as a result of the Model test may be attributable to the lower cost sharing for insulin, which led to reduced rationing of insulins and shorter delays in beneficiaries obtaining their medications. Improvements in insulin utilization and adherence are associated with clinical improvements, including better blood sugar (A1c) control, more frequent visits with providers, lower use of urgent or emergency care, and improved quality measures related to disease control (Cani et al., 2015; Chinthammit et al., 2021; Perez-Nieves et al., 2018). The final PDSS Model evaluation report will explore the effect of the Model test on these outcomes. Regarding the specific finding of one additional 30-day fill, a previous study found that an increase of one fill was associated with a decrease in blood sugar (Randløv and Poulsen, 2008), suggesting that the effects described in this chapter may be clinically meaningful for insulin users enrolled in PDSS-participating plans.

Finally, PO representatives and beneficiaries noted that there are additional—but different—barriers to improving insulin adherence and diabetes management beyond cost that the Model test does not address: POs flagged self-management of diabetes, and beneficiaries cited lifestyle changes as important barriers to insulin adherence.

Chapter 4. Enrollment and Benefit Phase Outcomes

KEY TAKEAWAYS

Enrollment

- Total plan enrollment increased by an average of 10.0% in MA-PDs (moderate evidence) and decreased by an average of 42.2% in PDPs (limited evidence).
- Enrollment among insulin users increased by an average of 27.2% in MA-PDs (strong evidence) and decreased by an average of 14.5% in PDPs (limited evidence).
- Some PO representatives reported seeing insulin users from their other MA-PD plans switching into PDSS-participating plans.
- Enrollment among dually eligible beneficiaries increased by an average of 5.3% in MA-PDs (limited evidence) and decreased by 43.1% in PDPs (strong evidence). Similarly, enrollment among LIS-eligible beneficiaries increased by an average of 7.1% in MA-PDs (limited evidence) and decreased by an average of 42.7% in PDPs (strong evidence).

Part D Benefit Phases

- Time spent in the catastrophic phase among insulin users decreased by an average of 2.4 days in MA-PDs (moderate evidence) and by an average 4.9 days in PDPs (strong evidence).
- Insulin users enrolled in MA-PDs and PDPs were 0.8% and 2.5% less likely, respectively, to end the year in the catastrophic (fourth) phase (strong evidence for MA-PDs; moderate evidence for PDPs), and they were 2.7% and 4.0% more likely, respectively, to end the year in the coverage gap (limited evidence for MA-PDs; strong evidence for PDPs).
- PO representatives stated that the extent to which the Model test affected beneficiaries' progression to the catastrophic phase may depend on the number of other drugs beneficiaries take.
- Time spent in the coverage gap increased by an average of 1.5 days in MA-PDs (moderate evidence).
- PO and manufacturer representatives reported that insulin users stayed in the coverage gap phase longer than before the PDSS Model, which delayed their progression to the catastrophic phase. As a result, insulin manufacturers said they paid more to the plans in the form of the 70% manufacturer discount and the negotiated insulin rebate in the coverage gap phase.

In this chapter, we report the results of our mixed-methods analyses that assessed the effect of the PDSS Model on plan enrollment and beneficiary progression through the benefit phases. PDSS-participating plans might attract insulin users as a result of offering lower, more predictable insulin cost sharing. However, if premiums and other benefit design characteristics change as a result of Model test participation, enrollees not taking insulin or not eligible for the Model test (that is, beneficiaries eligible for the LIS) may leave the plan.

Reducing beneficiary OOP costs for insulins through the first three benefit phases may increase utilization of insulins and other prescription drugs. We determined beneficiary movement through the Part D benefit phases as follows: Beneficiaries exit the initial coverage phase based on *gross drug costs*, which are generally the total cost for the prescription drug fill

as paid to the pharmacy, where the gross drug cost is split across different payers (Code of Federal Regulations, Title 42, Part 423, Section 423.308) . Increased gross drug costs due to increased insulin utilization may therefore move insulin users into the coverage gap phase sooner. Beneficiaries exit the coverage gap and move into the catastrophic phase based on a different metric, namely the sum of beneficiary OOP costs and manufacturer gap discounts. Reduced spending by insulin users for their insulin prescriptions while in the coverage gap may increase the amount of time they spend in this phase and, by extension, reduce the amount of time they spend in the catastrophic phase. CMS contributes approximately 80% of the cost of prescription fills in the catastrophic phase, so reduced time in the catastrophic phase may reduce CMS payments. Table 4.1 shows the measures we constructed to assess the effect of the PDSS Model on these outcomes.

Table 4.1. Enrollment and Benefit Phase 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
Enrollment by groups: • Insulin users • Noninsulin users • Dually eligible • LIS eligibles	Plan	Number of beneficiaries in each subgroup (separately for each group) enrolled in the plan as of July 1st of the year
Time spent in benefit phases: • Initial coverage • Coverage gap • Catastrophic	Beneficiary	The number of 30-day periods 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: More details on measure selection and construction can be found in Appendix B.

We ran DD regression models separately for MA-PDs and PDPs using eligible nonparticipating plans as the primary comparison group. We converted enrollment numbers at the plan level to log(y+1) scale to assess the effect of the Model test on the percent change in enrollment. We supplement the results of the quantitative analyses with insights from our qualitative data collection from POs, manufacturers, and beneficiaries.

Enrollment

We found evidence that the Model test was associated with enrollment changes for MA-PDs and PDPs participating in the Model test (Figure 4.1). We found moderate evidence that total enrollment for MA-PDs increased by 10.0% (95% CI of 5.0% to 15.3%), while there was limited evidence that total enrollment for PDPs decreased by 42.2% (95% CI of –48.3% to –35.5%). We estimated that in the absence of the PDSS Model, MA-PDs would have had, on average, 6,483 enrollees; the DD effect of 10.0% represents an increase of 723 enrollees from that estimate. For PDPs, we estimated an average total enrollment of 24,781 in the absence of the PDSS Model; the DD effect of –42.2% represents 7,359 fewer enrollees.

Figure 4.1. Estimated Effect of the PDSS Model Test on Total Plan Enrollment and the Number of New Enrollees

SOURCE: Authors' analysis of Part D enrollment and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTES: (S) = strong evidence; (M) = moderate evidence; (L) = limited evidence; (N/W) = no or weak evidence. This figure shows coefficients on the PDSS Model implementation indicator from the plan-level DD regression model. The comparison groups consisted of eligible nonparticipating plans. The *N*s represent the number of plans included in the analyses across all three years of data. *N* = 7,085 plan-years for MA-PDs and *N* = 1,285 plan-years for PDPs. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

We found evidence that both MA-PDs and PDPs experienced increases in new enrollees as a result of the Model test. We found moderate evidence of a 25.8% (95% CI of 15.5% to 36.9%) increase and limited evidence of a 25.5% (95% CI of 5.5% to 49.2%) increase in MA-PDs and PDPs, respectively. We estimated that MA-PDs would have had, on average, 734 new enrollees in the absence of the Model test; the DD effect of 25.8% represents an increase of 255 enrollees from that estimate. For PDPs, we estimated they would have received, on average, 1,013 new

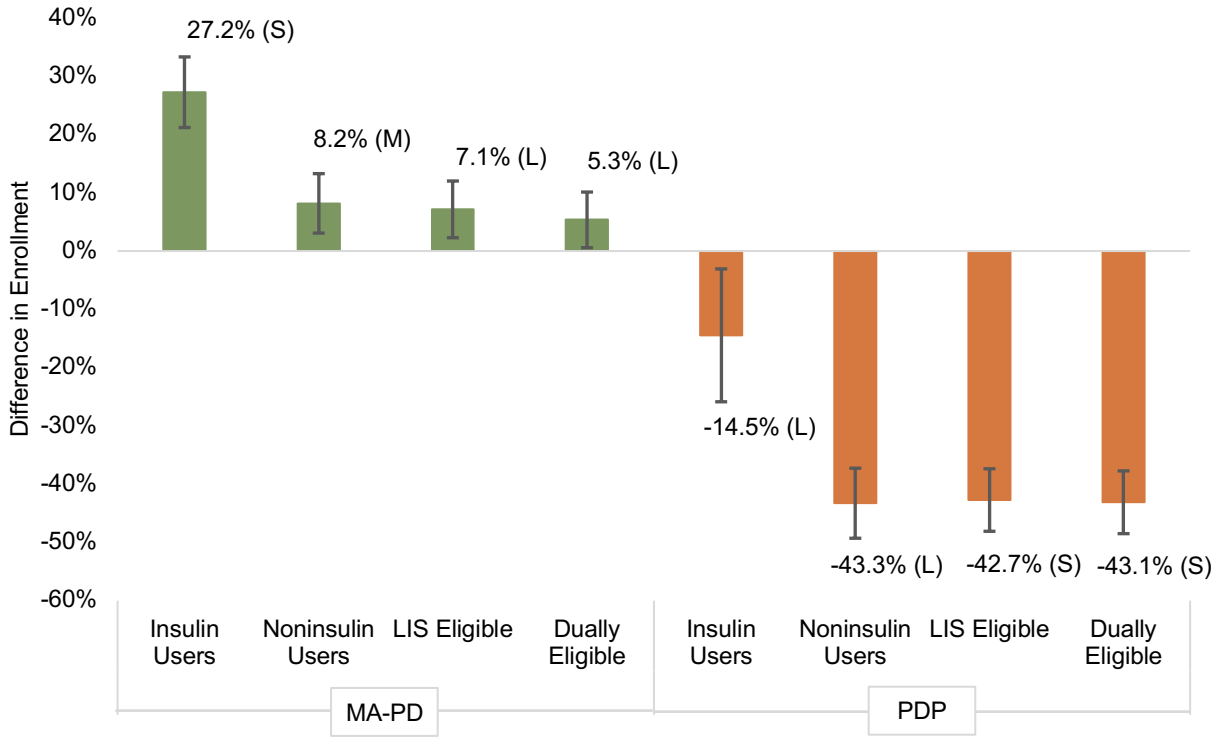
enrollees in the absence of the PDSS Model; the DD effect of 25.5% represents 347 additional new enrollees.

Taking the total enrollment and new enrollee findings together, we found that the PDSS Model was associated with an increase in total enrollment and new enrollees for MA-PDs but a decrease in total enrollment and an increase in new enrollees for PDPs. We note that the findings for PDPs reflect limited evidence because the trends in total enrollment, in particular, were very different across the PDSS-participating and eligible nonparticipating PDPs; therefore, these results should be interpreted with caution.

We split enrollment into subcategories of beneficiaries to further assess the effect of the PDSS Model on enrollment by insulin users, noninsulin users, and beneficiaries who were either receiving the LIS or who were dually eligible for Medicare and Medicaid. We hypothesized that enrollment of insulin users might increase because they would specifically benefit from the Model test and that enrollment of noninsulin users, LIS-eligible beneficiaries, and dual-eligible beneficiaries may or may not change, depending on how other benefits changed (for example, premiums).

We found strong evidence of increased enrollment of insulin users in MA-PDs and limited evidence of decreased enrollment of insulin users in PDPs (Figure 4.2). On average, MA-PDs experienced a 27.2% increase (95% CI of 21.2% to 33.6%) in insulin users. This percentage increase in enrollment corresponded to an additional 90 insulin users based on an estimated average of 240 insulin users enrolling in MA-PDs in the absence of the Model test. However, we found limited evidence that PDPs experienced a 14.5% decrease (95% CI of –25.9% to –1.3%). In addition, we found moderate evidence of an increase in enrollment of noninsulin users in MA-PDs (8.2%; 95% CI of 3.1% to 13.5%) and limited evidence of a decrease in enrollment of noninsulin users in PDPs (43.3%; 95% CI of –49.3% to –36.5%).

Figure 4.2. Estimated Effect of the PDSS Model on Plan Enrollment Across Beneficiary Characteristics, by Plan Type

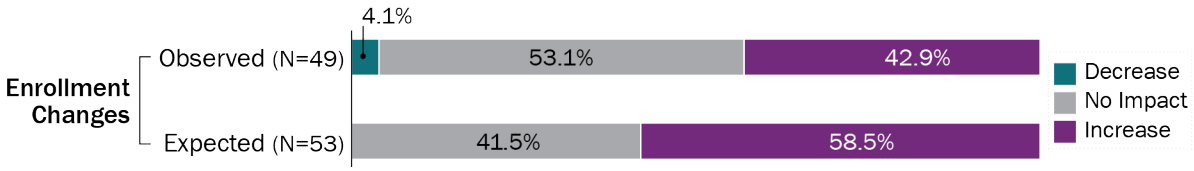


SOURCE: Authors' analysis of Part D enrollment and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTES: (S) = strong evidence; (M) = moderate evidence; (L) = limited evidence; (N/W) = no or weak evidence. This figure shows coefficients on the PDSS Model implementation indicator from the plan-level DD regression model. The comparison groups consisted of eligible nonparticipating plans. The Ns represent the number of plans included in the analyses across all three years of data. The Ns represent the number of plans included in the analyses across all three years of data. N = 7,085 plan-years for MA-PDs and N = 1,285 plan-years for PDPs. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

Finally, the Model test was associated with increases in enrollment of LIS- and dual-eligible beneficiaries for MA-PDs and decreases of such enrollees for PDPs, with similar effects for both subgroups within each plan type (see Figure 4.2). The limited evidence of an increase in enrollment of dual-eligible beneficiaries in MA-PDs (5.3%; 95% CI of 0.6% to 10.3%) suggests that the plan benefits offered by PDSS-participating MA-PDs were appealing to beneficiaries not eligible for the PDSS Model. In the absence of the PDSS Model, we estimated that MA-PDs would have, on average, 783 dual-eligible enrollees; the DD effect of 5.3% represents an increase of 44 dual-eligible enrollees. The reductions in enrollment across these subgroups, as well as similar effect size findings of a reduction in enrollment across age categories and by race/ethnicity (results shown in Appendix D), suggest that enrollment is shifting out of PDPs. We found strong evidence of a 43.1% (95% CI of –48.5% to –37.2%) decrease in enrollment for dual-eligible beneficiaries in PDPs. We estimated that PDPs would have had, on average, 1,127 dual-eligible enrollees in the absence of the Model test; the DD effect of –43.1% represents 340 fewer dual-eligible enrollees relative to our estimate.

PO survey results show that Model test participants have different perspectives on the impact of the PDSS Model on enrollment (Figure 4.3). Although most PO survey participants indicated that they saw no impact on enrollment (53.1%) or expect to see an increase in the future (58.5%), the proportion of PO respondents who reported already seeing an increase (42.9%) or not expecting an impact in the future (41.5%) was also substantial. Because the unit of analysis in this survey was the PO and only 12% of the POs completing the survey entered PDPs into the Model test, we cannot present these results broken down by plan type.

Figure 4.3. PO Survey Results on PDSS Model Impact on Already Observed and Expected Changes to Enrollment



SOURCE: Authors' analysis of response data from 2021 PDSS-participating POs surveyed in 2022.

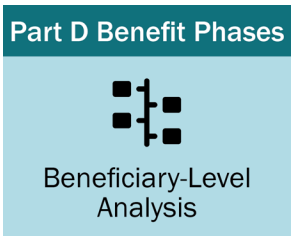
In describing the impact of the PDSS Model on enrollment during our interviews, PO E and F representatives stated that some of their enrollees had already switched from one of their non-PDSS plans into a PDSS-participating plan. PO E representatives also reported that their participation in the Model test helped attract new enrollees and retain existing members: "We think that it is helping with retention—member retention of our insulin users. And we do see that insulin users prefer our plans that offer the Insulin Savings Program [PDSS] over plans that do not offer the Insulin Savings Program, suggesting that it is kind of influential in terms of plan choice." Indeed, while PDSS-participating POs generally did not change the insulins included on their formularies, a small proportion of them lowered insulin copays to well below the required maximum $35 to drive or retain plan enrollment.

When it comes to the beneficiary perspective and the extent to which the Model test may have influenced their plan enrollment decisions, only 18% of insulin users we interviewed were aware of the Model test and the fact that it limited insulin copays to $35 for a one-month supply. Six percent of insulin users were somewhat aware of the Model test, stating that they were familiar to some extent but were unaware of the Model test's details or its relevance to them. Several beneficiaries expressed a misunderstanding of the Model test, often confusing the PDSS Model with the provisions of the recently passed IRA.

While discussing the reasons for choosing their current plan, almost all insulin users we interviewed mentioned costs in general, including premiums, copays, and deductibles. However, less than one-third (31%) of them reported specifically considering insulin costs or copays when choosing their health coverage. This lack of specific focus on insulin costs in choosing a plan could be explained by the fact that older adults who use insulin are at greater risk for such

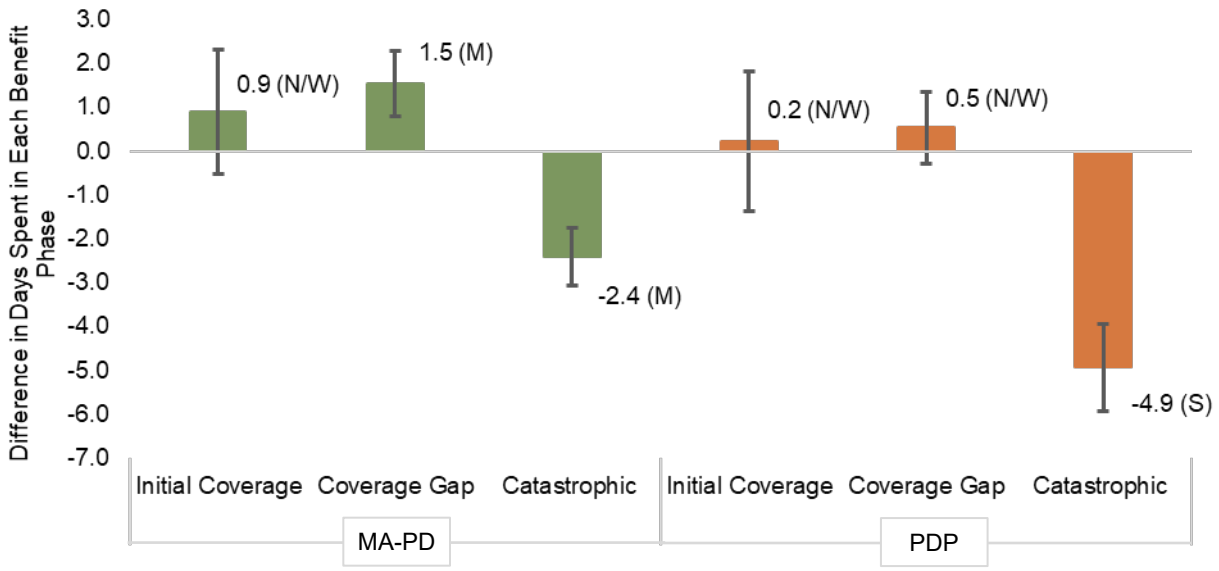
comorbid conditions as hypertension, stroke, and coronary heart disease, among others, and therefore take multiple medications (ElSayed et al., 2023). Indeed, beneficiaries in our sample took an average of eight medications, and some beneficiaries took up to 20. Therefore, it is not surprising that insulin was only one of many drugs for which they needed to consider costs when choosing a plan.

Benefit Phases



The DD regression results indicated that insulin users in PDSS-participating MA-PDs and PDPs spent less time in the catastrophic phase and that insulin users enrolled in PDSS-participating MA-PDs, in particular, spent slightly more time in the coverage gap phase (see Figure 4.4). Specifically, for MA-PDs, there was moderate evidence that insulin users enrolled in MA-PDs spent 2.4 fewer days in the catastrophic phase (95% CI of –3.1 to –1.8) and 1.5 additional days in the coverage gap phase (95% CI of 0.8 to 2.3). Our estimates correspond to a 9.5% reduction in time spent in the catastrophic phase based on an expected average of 25.5 days for insulin users enrolled in MA-PDs in the absence of the Model test. Meanwhile, we found an increase of 1.5 days would correspond to a 5.3% increase in time spent in the coverage gap based on an expected average of 29.9 days among insulin users enrolled in MA-PDs in the absence of the Model test.

Figure 4.4. Estimated Effect of the PDSS Model on the Amount of Time Insulin Users Spent in Benefit Phases, by Plan Type



SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources.
NOTES: (S) = strong evidence; (M) = moderate evidence; (L) = limited evidence; (N/W) = no or weak evidence. This figure shows coefficients on the PDSS Model implementation indicator from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in eligible nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021 to be included in the analysis. Beneficiaries eligible for the LIS were excluded from the analysis. *N* = 848,830 for MA-PDs and *N* = 509,662 for PDPs. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

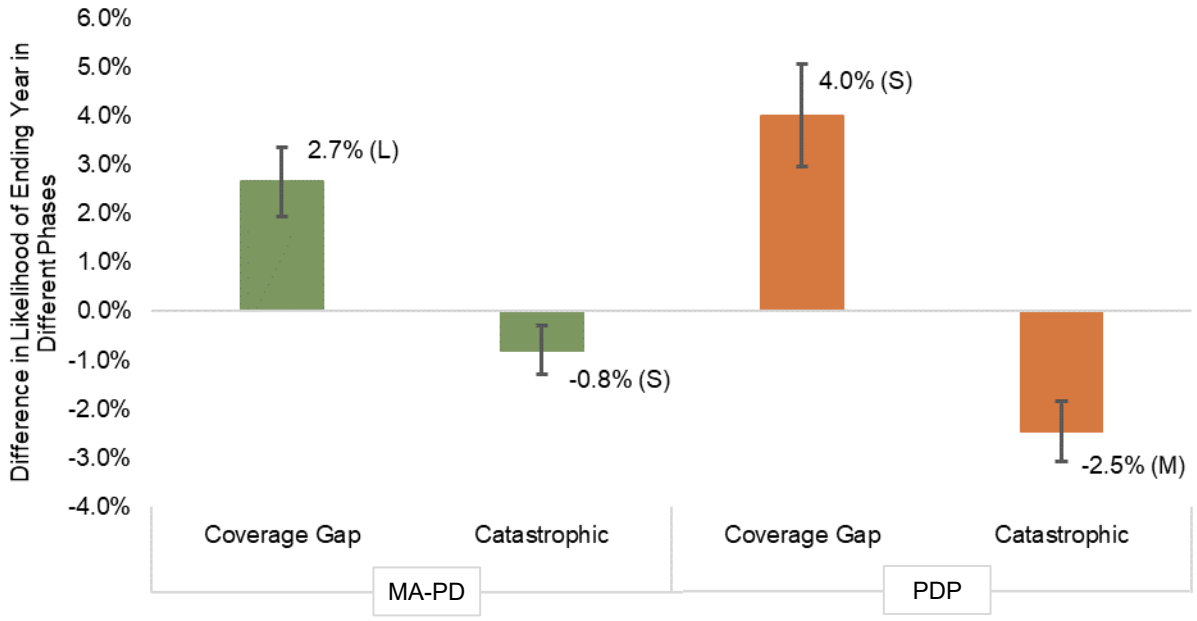
We found strong evidence that insulin users in PDPs spent on average 4.9 fewer days in the catastrophic phase (95% CI of –5.9 to –3.9), although there was no or weak evidence of a change in the amount of time they spent in the coverage gap. Based on an estimated average of 46.2 days in the catastrophic phase for insulin users in PDPs in the absence of the Model test, an average decrease of 4.9 days corresponds to a 10.7% decrease in time spent in the catastrophic phase.

We further analyzed the effect of the Model test on the likelihood that insulin users enrolled in PDSS-participating plans ended the year in either the coverage gap or catastrophic phase (Figure 4.5). We found limited evidence that the Model test increased the likelihood that insulin users enrolled in MA-PDs ended the year in the coverage gap phase (2.7%; 95% CI of 1.9% to 3.4%) and strong evidence that the Model test increased the likelihood that insulin users in PDPs ended the year in the coverage gap phase (4.0%; 95% CI 3.0% to 5.1%). This effect corresponds to a 5.7% and 9.9% increase in likelihood, for insulin users enrolled in MA-PDs and PDPs, respectively, in ending the year in the coverage gap phase, compared with an expected average percentage of 46.5% and 40.6%, respectively, of insulin users ending the year in the coverage gap in the absence of the Model test. We also found strong evidence of a decreased likelihood of ending the year in the catastrophic phase for insulin users in MA-PDs (–0.8%; 95% CI of –1.3% to –0.28%) and moderate evidence of a decreased likelihood of ending the year in the

catastrophic phase (–2.5%; 95% CI of –3.1% to –1.8%). This effect corresponds to a 3.9% and 7.1% decrease in insulin users in MA-PDs and PDPs ending the year in the catastrophic phase, relative to an estimated average of 20.1% and 34.5%, respectively, in the absence of the Model test.

We did not expect noninsulin users to change their progression through the benefit phases as a result of the PDSS Model, and we found limited evidence of very small changes (Tables C.9 and C.10 in Appendix C show these results).

Figure 4.5. Estimated Effect of the PDSS Model on the Likelihood of Insulin Users Ending the Year in the Coverage Gap or Catastrophic Phase, by Plan Type



SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources.
NOTES: (S) = strong evidence; (M) = moderate evidence; (L) = limited evidence; (N/W) = no or weak evidence. This figure shows coefficients on the PDSS Model implementation indicator from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in eligible nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021 to be included in the analysis. Beneficiaries eligible for the LIS were excluded from the analysis. *N* = 848,830 for MA-PDs and *N* = 509,662 for PDPs. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

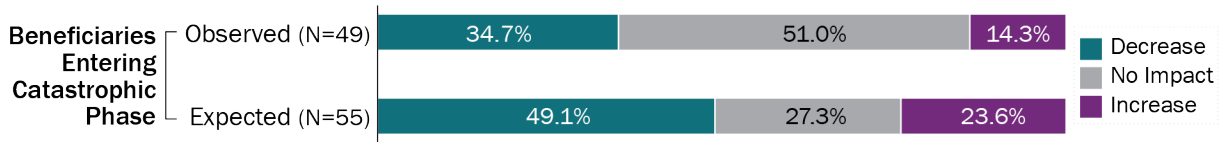
Although we could not use beneficiary interview data to assess the impact of the PDSS Model on beneficiary progression through benefit phases because of the complexity of Part D design and the limited understanding of its nuances among beneficiaries, we did use the results of our analysis of PO and manufacturer interviews; these results generally supported our quantitative findings. According to PO A representatives, the PDSS Model has already led to some of their beneficiaries staying in the coverage gap phase longer, which by definition delayed their progression to the catastrophic phase: "We saw a reduction in the number of insulin users

that are hitting the catastrophic phase because they're kind of stuck in the gap phase. Previously they were paying a coinsurance of the allowed cost, whereas now they're paying whatever the copay is."

Representatives of three insulin manufacturers also stated that beneficiaries are staying in the coverage gap phase longer (an additional two to three weeks, according to one of them). Because manufacturers pay the 70-percent manufacturer's discount plus the same negotiated rebate in the coverage gap phase (a situation Manufacturer B described as a "double-dip problem"), they "lose money" on every fill of insulin while a beneficiary is in the coverage gap phase. We assess the financial implications of beneficiaries remaining in the coverage gap phase longer in Chapter 5.

On the survey, PO representatives reported on the impact of the PDSS Model on the number of beneficiaries entering the catastrophic phase. Results show that, although 51.0% of POs who completed the survey stated not seeing an impact on this metric, 49.1% of POs reported that they expected to see a decrease in the number of beneficiaries entering the catastrophic phase in the future (Figure 4.6).

Figure 4.6. PO Survey Results on PDSS Model Impact on Already Observed and Expected Number of Beneficiaries Entering Catastrophic Phase



SOURCE: Authors' analysis of response data from 2021 PDSS-participating POs surveyed in 2022.

A PO F representative stated that the relationship between lower insulin copays and progression through benefit phases may be uncertain as beneficiaries with diabetes often take multiple drugs: "I think it's not uncommon to see [people with diabetes taking] eight, ten, 12, 15 [medications]. While insulin is certainly a factor that drives [a beneficiary's entry into] the catastrophic phase, it's not always the only one." Therefore, the Model test's impact on beneficiaries, including insulin utilization and OOP costs, may vary depending on the number of drugs beneficiaries take.

Manufacturer C and E representatives agreed with the PO F representative, confirming that many beneficiaries indeed take multiple drugs. According to these manufacturers, beneficiaries may actually experience increased total cost sharing even if their insulin cost sharing goes down, because they may increase their utilization of other drugs due to the lower insulin copays offered by the PDSS Model.

Sensitivity of Quantitative Results to the Alternative Comparison Group

The effect of the PDSS Model on plan enrollment was largely similar for MA-PDs when we compared the results of the eligible nonparticipating group with those of all nonparticipating plans. As noted elsewhere, this finding is likely due to the fact that the vast majority of MA-PDs are enhanced Part D plans; thus, adding a few basic plans offered by MA-PDs to the comparison group makes little difference to the results. However, we did find differences when comparing the results for enrollment across the two PDP comparison groups. For total enrollment and the number of new enrollees, the estimated effects were in the same direction, but our estimate for the percentage decrease in total enrollment was smaller and the estimated percentage increase in enrollment for new enrollees was much larger when we used the alternative all nonparticipating plans comparison group (as opposed to eligible nonparticipating plans). For insulin users, the estimated effect of the PDSS Model switched from a decrease to an increase, suggesting that PDSS-participating PDPs saw enrollment growth among insulin users when compared with all nonparticipating plans, though not when compared with eligible nonparticipating PDPs. Sensitivity of the results to the comparison group reduces the strength of evidence for the primary finding, which may be driven by insulin users switching out of basic PDPs and into PDSS-participating PDPs. For noninsulin users, the finding of a decrease in enrollment was attenuated when compared with the all nonparticipating plans group versus the eligible nonparticipating plans. Finally, the results for enrollment of LIS- and dual-eligible beneficiaries were smaller when compared with all nonparticipating plans than they were in relation to eligible nonparticipating plans.

For the amount of time spent in each benefit phase and the likelihood of ending the year in either the coverage gap or catastrophic phase, the findings were similar for the alternative comparison group with those presented in this chapter, across both MA-PDs and PDPs. However, there was one exception in that the findings related to the time spent in the initial coverage phase for insulin users in PDSS-participating PDPs became larger and statistically significant.

Summary

Results of our quantitative analyses suggest that the PDSS Model increased total enrollment in MA-PDs but decreased total enrollment for PDPs. We also found an effect on new enrollment in both MA-PDs and PDPs: MA-PDs experienced a 25.8% increase, and PDPs saw a 25.5% increase. We note, however, that the PDP findings reflect limited evidence, and the average total enrollment for PDSS-participating PDPs shows very different patterns compared with the eligible nonparticipating PDPs. Therefore, these findings should be interpreted with caution.

The PDSS Model was associated with a 27.2% increase in enrollment by insulin users in MA-PDs. PDPs, however, experienced a reduction in insulin user enrollment of an average of 14.5%. The estimated reduction in enrollment percentage for insulin users, however, was lower

than the estimated reductions in enrollment by subgroups in PDPs, which ranged from about 39% to 44%. We further found increased enrollment by dual- and LIS-eligible beneficiaries in MA-PDs and decreased enrollment by these same beneficiary groups in PDPs.

Our interviews with insulin users showed that only about one-third of them specifically considered insulin costs when choosing their Part D coverage. Insulin users often take multiple prescription drugs and consider other costs as well, including copays for other drugs and monthly premiums, when deciding what plan to choose. Moreover, the level of awareness of the PDSS Model and the benefits it offers was low among the beneficiaries we interviewed.

In addition, we found that beneficiaries spent less time in the catastrophic benefit phase as a result of the Model test and that beneficiaries in PDSS-participating MA-PDs increased the amount of time they spent in the coverage gap phase. Beneficiaries were also more likely to end the year in the coverage gap. This finding may be due to the Model test reducing beneficiary cost contributions in the coverage gap, which in turn extended the amount of time beneficiaries spent in the gap relative to the time they would have spent in the absence of the Model test. PO and manufacturer interviews supported these findings. Manufacturers were concerned that beneficiaries' increased time in the coverage gap increased manufacturers' financial liability because they have to pay manufacturer discounts to PBMs and POs (applicable only in the coverage gap phase) longer than they did before the Model test.

Chapter 5. Cost Outcomes: Bids, Premiums, and Spending

KEY TAKEAWAYS

OOP Costs and Premiums

- We found no or weak evidence of effects of the PDSS Model on MA-PD or PDP Part D premiums.
- Total OOP costs among insulin users decreased by an average of $198 in MA-PDs and by an average of $441 in PDPs (strong evidence). This decrease was likely driven by a reduction in OOP costs for insulin.
- Total Part D costs (OOP plus premiums) for noninsulin users increased by an average of $34 in PDPs (limited evidence).
- POs considered the reduction in OOP costs to be the most significant outcome of the Model test for their beneficiaries.
- Most interviewed insulin users noticed paying $35 or less for insulins after the start of the Model test and generally considered these savings to be substantial.

Gross Drug Costs

- Among insulin users, the cost of drugs paid at the pharmacy (gross drug costs) increased by an average of $501 in MA-PDs (strong evidence) and by an average of $546 in PDPs (moderate evidence).
- PO representatives had differing views on the impact of the Model test on drug spending. Some POs expected more insulin users to join their plans and for beneficiaries to use more insulins. Others assumed that insulin users in the Model test would experience fewer exacerbations of symptoms, which require less medication use.

Part D Bids

- Part D bids increased by an average of $5.68 per month for MA-PDs (limited evidence). Part D bids decreased by an average of $16.91 per month for PDPs (strong evidence).
- Administrative costs decreased by an average of $0.50 PMPM in MA-PDs and by an average of $1.63 PMPM in PDPs (limited evidence).
- On the survey, however, most POs reported no impact on administrative costs.

Manufacturer Payments

- Total manufacturer rebates paid to plans increased by an average of $1.38 and $21 PMPM in MA-PDs and PDPs, respectively (limited evidence).
- Manufacturer coverage gap discount payments increased by an average of $3.01 and $18 in MA-PDs and PDPs, respectively (strong evidence for MA-PDs, limited evidence for PDPs).
- These findings confirm some insulin manufacturers' expectations that the Model test would increase their financial contributions.

Part D Costs to CMS

- We found no or weak evidence of an effect of the PDSS Model on Part D costs to CMS. There was no evidence of changes to reinsurance payments made by CMS.
- PO survey data confirmed that the Model test did not affect reinsurance payments.

In this chapter, we report on the effects of the PDSS Model on Part D cost outcomes assessed using quantitative and qualitative methods. The PDSS Model was designed to reduce beneficiary cost sharing for insulin through the first three phases of the Part D benefit; thus, we anticipated

that the PDSS Model would reduce insulin users' OOP costs. In addition, the PDSS Model may have affected noninsulin users' OOP costs and total OOP costs via changes in beneficiaries' health care needs and the amount of time beneficiaries spent in each phase of the Part D benefit.

We also examined the effects of the Model test on plan-level prescription drug coverage costs, including plan bids and premiums. We assessed the effect of the Model test on manufacturer rebates and payments made for prescriptions dispensed in the coverage gap phase. In addition, we assessed the PDSS Model's effect on Part D costs to CMS. Impacts on plan bids and measures of costs are unclear, but they represent an important dimension of the Model test's impact on Part D. Table 5.1 shows the cost outcome measures assessed in this chapter.

Table 5.1. Cost Outcome Measures

Measure	Analysis Level	Description
Part D premium, split into: • Basic • Supplemental	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.
Beneficiary costs, including: • Total OOP drug costs • Insulin OOP costs • Noninsulin OOP costs • Total Part D costs	Beneficiary	The total amount beneficiaries were responsible for paying OOP for all of their drug fills in a year, also split out by insulin and noninsulin OOP costs. Total Part D costs are calculated as the sum of total OOP drug costs plus 12 months of the Part D premium for the plan.
Gross drug costs, including: • Insulin • Noninsulin	Beneficiary	The price paid at the pharmacy for all drugs filled by a beneficiary in the year, as a total and also by insulin and noninsulin 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 per-member per-month (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.
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 direct and indirect remuneration (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 Medicare	Plan	The final costs to CMS for Part D coverage provided by a given plan, calculated as a PMPM amount

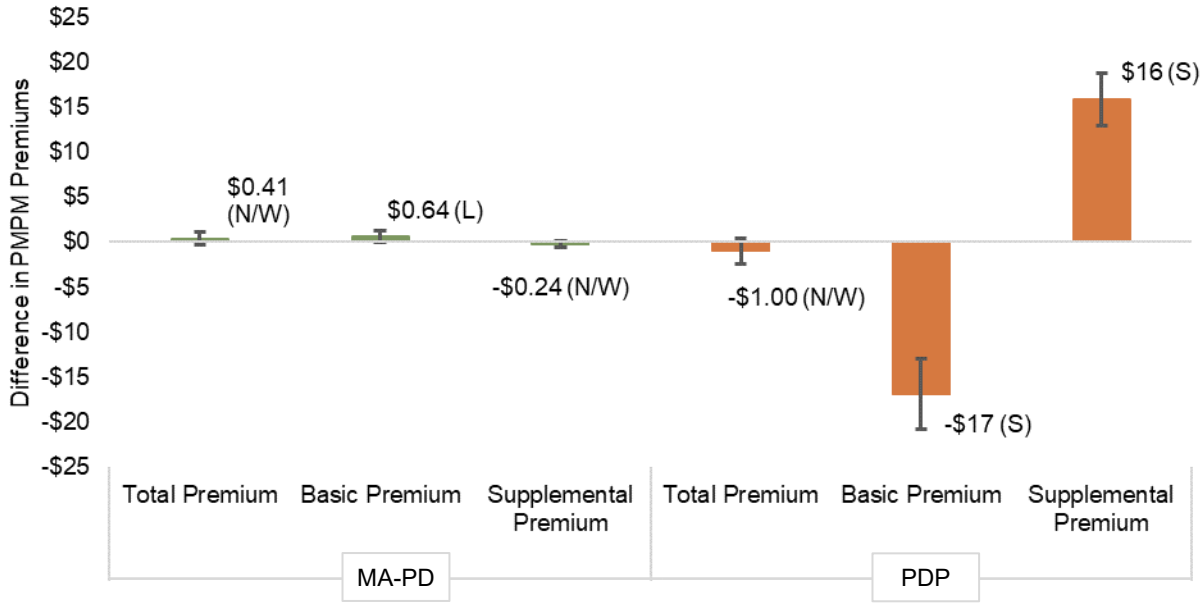
NOTE: See Appendix B for more details on measure selection and construction.

We ran DD regression analyses at the plan and beneficiary levels, and depending on the outcome measure of interest, we used eligible nonparticipating plans as the comparison groups for PDSS-participating MA-PDs and PDPs. We supplement the results of our quantitative analyses with insights from our qualitative data collection from POs, manufacturers, and beneficiaries.

Part D Premiums

We found no or weak evidence of an effect of the PDSS Model on total premiums for MA-PDs and PDPs. When we split the total premium into its basic and supplemental components, we found limited evidence of a $0.64 increase in the basic premium for MA-PDs (95% CI of $0.00 to $1.28) and strong evidence that the two components changed substantially in opposite directions for PDPs (Figure 5.1). More specifically, the basic premium for PDPs decreased by $17 (95% CI of –$21 to –$13), and the supplemental premium increased by $16 (95% CI of $13 to $19). We estimated that the average MA-PD basic premium would have been $12 in the absence of the Model test; the DD effect of $0.64 represents a 5.4% increase in the premium. We estimated that the average PDP basic premium would have been $36 in the absence of the Model test; the DD effect of –$17 represents a 46.7% decrease in the premium relative to this estimate. For the PDP supplemental premium, we estimated that the average premium would have been $14 in the absence of the Model test; the DD effect of $16 represents a 111.6% increase in the supplemental premium relative to this estimate.

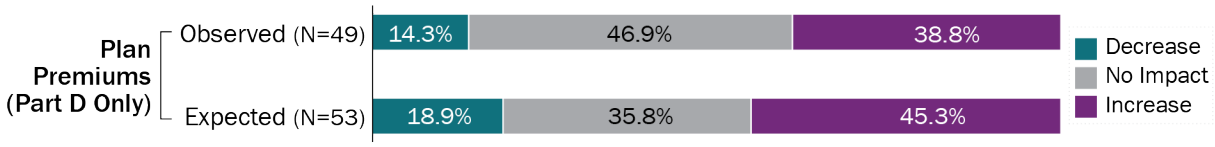
Figure 5.1. Estimated Effect of the PDSS Model on Part D Premiums, by Plan Type



SOURCE: Authors' analysis of Part D plan premiums and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTES: (S) = strong evidence; (M) = moderate evidence; (L) = limited evidence; (N/W) = no or weak evidence. This figure shows coefficients on the PDSS Model implementation indicator from the plan-level DD regression model. The comparison groups consisted of eligible nonparticipating plans. The *N*s represent the number of plans included in the analyses across all three years of data. *N* = 7,085 plan-years for MA-PDs and *N* = 1,285 plan-years for PDPs. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

The estimated impacts of the PDSS Model on premiums were generally supported by our qualitative findings: Most (46.9%) PO survey respondents stated that the Model test had no impact on Part D premiums (Figure 5.2). About two-fifths (38.8%) of POs, however, reported increasing their premiums; the remaining 14.3% of POs reported decreasing their premiums. When asked to think about the future impact of the PDSS Model, close to half of PO survey respondents (45.3%) reported expecting increases in their Part D premiums. In discussing plan premiums during our interview, PO F representatives noted that while premiums increased for Part D coverage under the Model test, their net premium amount for MA-PDs remained flat because they were able to absorb the increase for beneficiaries with the MA rebate dollars, which PDPs are not able to do.

Figure 5.2. PO Survey Results on PDSS Model Impact on Already Observed and Expected Changes to Premiums



SOURCE: Authors' analysis of response data from 2021 PDSS-participating POs surveyed in 2022.

Beneficiary Spending

OOP Costs and Premiums

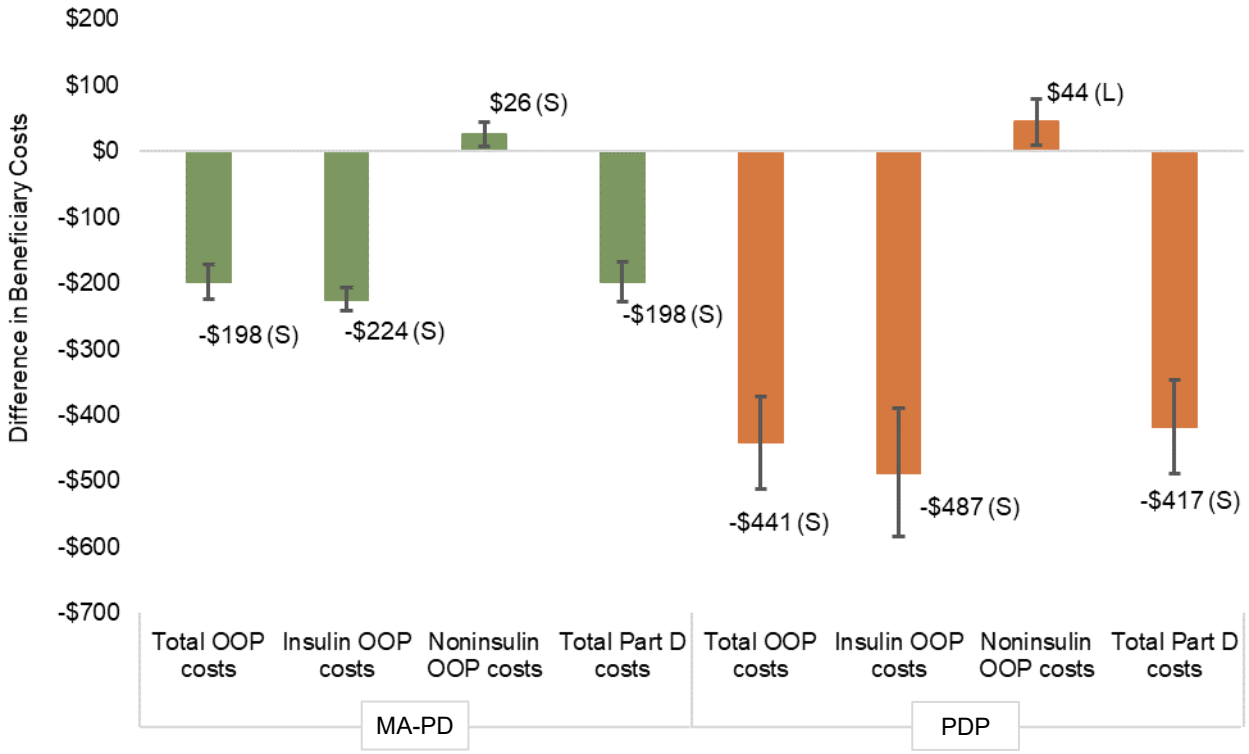
Beneficiary-Level Analysis

This section describes quantitative and qualitative findings about the impact of the PDSS Model on beneficiary costs. Outcomes in this section measure OOP spending and other beneficiary costs on an annual (not monthly) basis.

Insulin Users

We found strong evidence that the PDSS Model decreased total OOP costs for insulin users in both MA-PDs and PDPs (Figure 5.3). For MA-PDs, total OOP costs decreased by an average of $198 (95% CI of –$225 to –$171), a 17.1% reduction relative to an estimated average total OOP cost of $1,158 for MA-PDs in the absence of the Model test. For PDPs, total OOP costs decreased by $441 (95% CI –$511 to –$372), a 23.1% reduction relative to an estimated average total OOP cost of $1,910 for PDPs in the absence of the Model test.

Figure 5.3. Estimated Effect of the PDSS Model on Beneficiary Costs for Insulin Users, by Plan Type



SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources.
NOTES: (S) = strong evidence; (M) = moderate evidence; (L) = limited evidence; (N/W) = no or weak evidence. This figure shows coefficients on the PDSS Model implementation indicator from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in eligible nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021 to be included in the analysis. Beneficiaries eligible for the LIS were excluded from the analysis. *N* = 848,830 for MA-PDs and *N* = 509,662 for PDPs. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

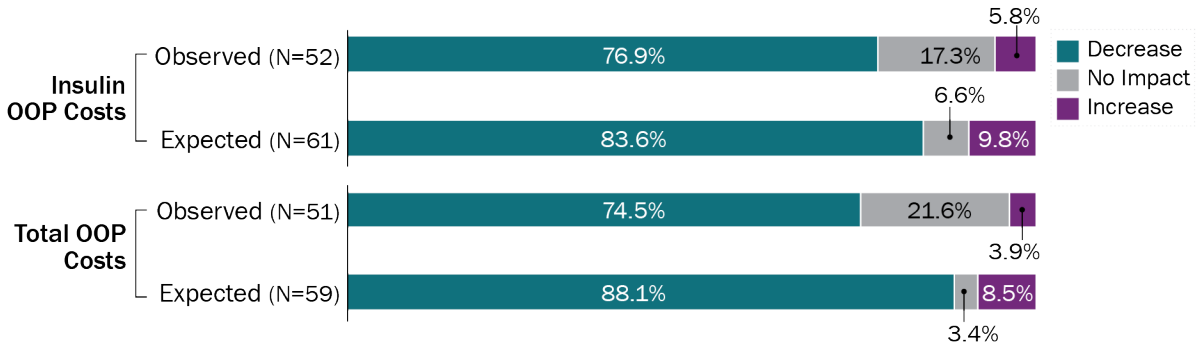
For both MA-PDs and PDPs, the estimated OOP cost reductions were driven by decreases in insulin OOP costs (strong evidence). The estimated impact of the PDSS Model on insulin OOP costs in MA-PDs was a $224 reduction (95% CI of –$242 to –$206), a 41.5% reduction relative to an estimated average of $539 for MA-PDs in the absence of the PDSS Model. The estimated impact of the PDSS Model on insulin OOP costs in PDPs was a $487 reduction (95% CI of –$583 to –$390), a 56.5% reduction relative to an estimated average of $862 for PDPs in the absence of the Model test.

We found strong evidence that noninsulin OOP costs for insulin users increased for MA-PDs, and limited evidence of an increase for PDPs. The estimated impact of the PDSS Model on noninsulin OOP costs in MA-PDs was a $26 increase (95% CI of $7.05 to $45), and for PDPs, the estimated impact was a $44 increase (95% CI of $9 to $80). This effect represents a 4.2% increase relative to the estimated average of $619 and $1,051 for MA-PDs and PDPs, respectively, in the absence of the Model test.

When we included Part D premiums in our measure of total Part D costs, we found strong evidence that the PDSS Model reduced total beneficiary costs for insulin users enrolled in both MA-PDs and PDPs. On average, insulin users enrolled in MA-PDs experienced a reduction of $198 (95% CI of –$228 to –$168) in total costs, a 15.1% decrease relative to the estimated average of $1,307 for insulin users in MA-PDs in the absence of the Model test. Insulin users enrolled in PDPs had a larger average reduction of $417 (95% CI of –$489 to –$346), but this group also had higher average costs than insulin users in MA-PDs; thus, the estimated PDSS Model impact represented a 15.2% decrease relative to the estimated average of $2,754 for insulin users in PDPs in the absence of the Model test.

The PO survey results support these quantitative findings (Figure 5.4), and they showed that the majority of POs saw decreased insulin and total OOP costs for their beneficiaries (76.9% and 74.5%, respectively). The percentage of POs expecting decreases in these costs in three to five years was higher (83.6% and 88.1%, respectively). Notably, survey participants reported that reductions in insulin costs are the most significant beneficiary-level outcomes that the Model test has achieved and will continue to achieve in the future (data not shown). In discussing how the PDSS Model has affected OOP costs, a PO A representative stated that "the more adherent [beneficiaries] are to their insulins, there may be fewer office visits and other types of out-of-pocket spending," which would reduce beneficiary OOP costs for both medical and drug spending.

Figure 5.4. PO Survey Results on PDSS Model Impact on Already Observed and Expected Changes to OOP Costs



SOURCE: Authors' analysis of response data from 2021 PDSS-participating POs surveyed in 2022.

Our beneficiary interviews showed that the vast majority (82%) of the 100 insulin users in our sample reported paying less than $35 per one-month supply of insulin. Nonetheless, 18% of insulin users stated that they still pay more than $35 per month for their insulins. Upon reviewing the medications they reported taking, we discovered that some beneficiaries confused their noninsulin diabetes medications with insulin and that others take more than one insulin.

To better explain the impact of the Model test on beneficiary spending, we asked beneficiaries if they noticed any major changes in the amount they paid for insulin within the

past year or two and what they thought about these changes. Roughly two-thirds (65%) of interviewed insulin users reported noticing changes. Of those, 38 beneficiaries (58.5%) stated that they now pay less for insulin, 22 beneficiaries (33.8%) said that they pay more, and five beneficiaries (7.7%) reported noticing only small fluctuations in either direction. Among interviewed beneficiaries who saw noticeable increases in their insulin OOP costs, many reported paying nominal amounts before 2021. The increases in their OOP costs could potentially be explained by recall bias, a change in their insurance plan, the loss of the LIS, or deterioration in their health. Of the 38 beneficiaries who reported paying less for insulin, 21 interview respondents (55.3%) stated that these savings were substantial enough to help them pay for utilities, groceries, gas, or gifts for their grandchildren. In describing the impact of the PDSS Model, one beneficiary stated: "It lets me not worry about whether or not ... I can do other things if I wanted to. I wouldn't have to skimp on some other things just to make sure I had the medicine."

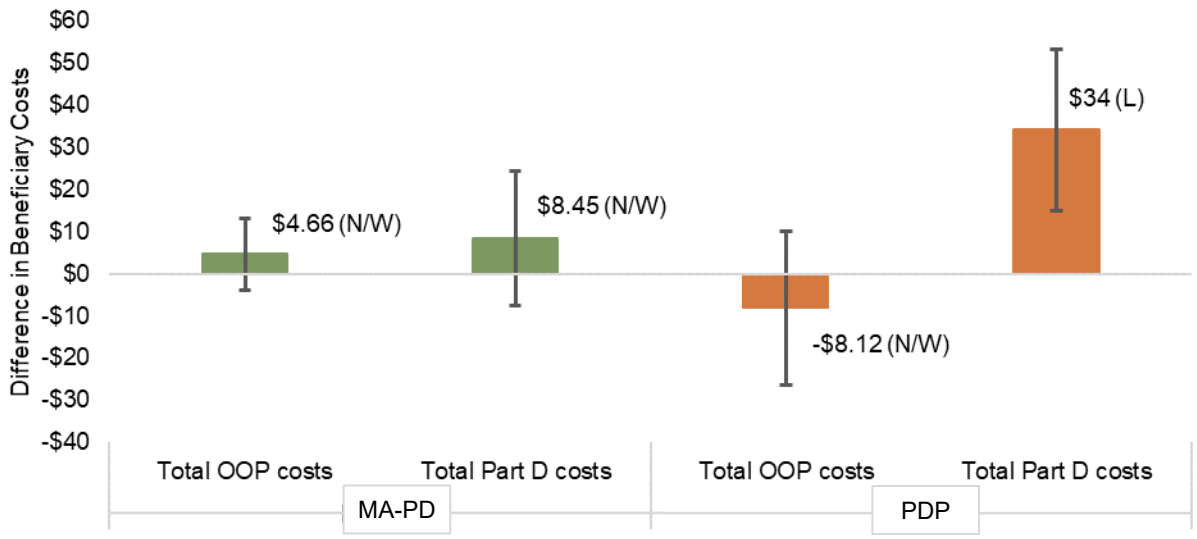
Finally, we asked beneficiaries about their insulin copay consistency throughout the year. About two-thirds of beneficiaries (64%) noted that their insulin OOP costs were the same. However, 30% of respondents noticed inconsistencies in their insulin copays; that is, some noted that copays varied based on whether they had reached their deductible or whether they were in the "donut hole" (the coverage gap phase). Six percent of interviewed beneficiaries did not remember whether their copays were consistent throughout the year.

Noninsulin Users

The PDSS Model may have had spillover effects on noninsulin users enrolled in participating plans via increased cost sharing for noninsulin medications and increased premiums for the enhanced insulin coverage. We analyzed the effects of the PDSS Model on total OOP costs and total Part D costs for noninsulin users enrolled in participating plans, although our qualitative data collection did not focus on the impact of the Model test on noninsulin users.

Our findings showed no or weak evidence of a change in total OOP costs for noninsulin users in both MA-PDs and PDPs (Figure 5.5). However, we found some evidence that the Model test increased total Part D costs for noninsulin users enrolled in PDPs by $34 (95% CI of $15 to $53). Given that the PDSS Model did not affect total OOP costs for noninsulin users, it appears that premium increases by PDPs may have been a contributing factor in the increased total beneficiary costs. However, as shown in Figure 5.1, we found no or weak evidence that the PDSS Model increased Part D premiums, on average, in PDPs. The estimated PDSS Model impact represents a 2.6% increase relative to the estimated average total Part D cost of $1,309 for noninsulin users in PDPs in the absence of the Model test.

Figure 5.5. Estimated Effect of the PDSS Model on Beneficiary Costs for Noninsulin Users, by Plan Type



SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources.
NOTES: (S) = strong evidence; (M) = moderate evidence; (L) = limited evidence; (N/W) = no or weak evidence. This figure shows coefficients on the PDSS Model implementation indicator from the beneficiary-level DD regression model estimated for our sample of noninsulin users. The comparison groups consisted of noninsulin users enrolled in eligible nonparticipating plans. Noninsulin users must have been continuously enrolled in the same plan for all of 2020 and 2021 to be included in the analysis. Beneficiaries eligible for the LIS were excluded from the analysis. *N* = 17,219,502 for MA-PDs and *N* = 11,470,769 for PDPs. Error bars indicate 95% Cis based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

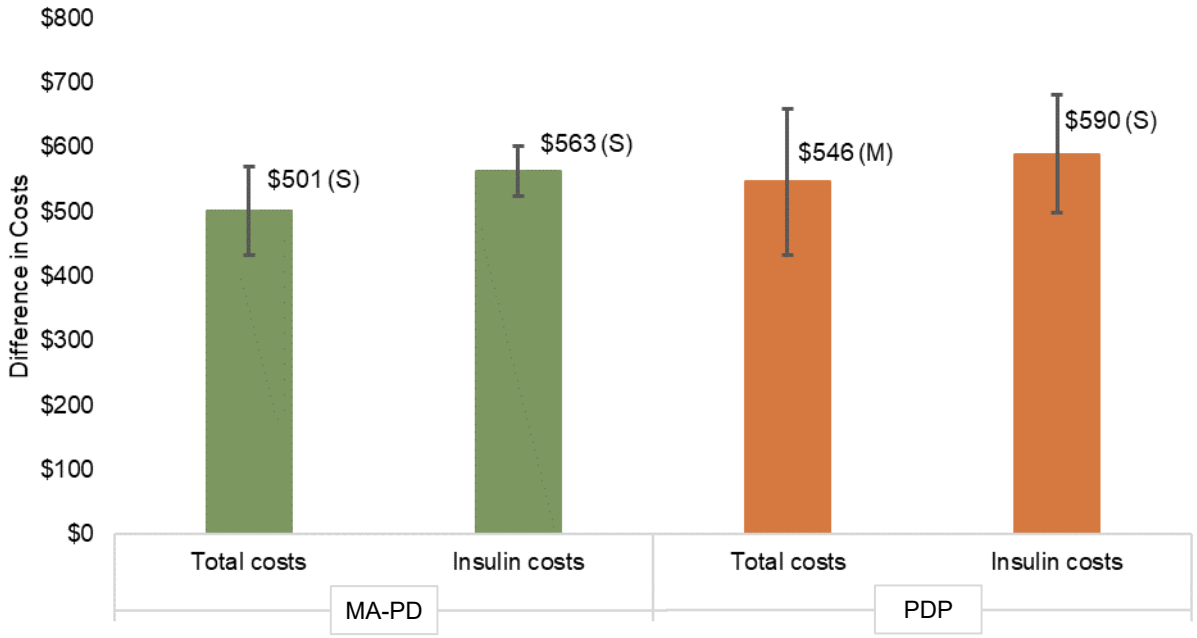
Gross Drug Costs

The PDSS Model may have had an impact on total drug spending across all stakeholders; therefore, we assessed the effect of the Model test on gross drug costs. These costs are calculated as the amount paid to the pharmacy, split across all stakeholders, for the prescription drug fill before any rebates or other DIR are applied, and summed to an annual total.

Insulin Users

We found strong evidence that the PDSS Model increased total gross drug costs for insulin users enrolled in MA-PDs and PDPs (Figure 5.6). Insulin users enrolled in MA-PDs experienced average increases in gross drug costs of $501 (95% CI of $432 to $570), a 6.1% increase relative to estimated average gross drug costs of $8,146 in the absence of the Model test. Insulin users enrolled in PDPs experienced average increases in gross drug costs of $546 (95% CI of $433 to $660), a 5.1% increase relative to the estimated average gross drug costs of $10,625 in the absence of the Model test.

Figure 5.6. Estimated Effect of the PDSS Model on Gross Drug Costs for Insulin Users, by Plan Type



SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources.
NOTES: (S) = strong evidence; (M) = moderate evidence; (L) = limited evidence; (N/W) = no or weak evidence. This figure shows coefficients on the PDSS Model implementation indicator from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in eligible nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021 to be included in the analysis. Beneficiaries eligible for the LIS were excluded from the analysis. *N* = 848,830 for MA-PDs and *N* = 509,662 for PDPs. Error bars indicate 95% Cis based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

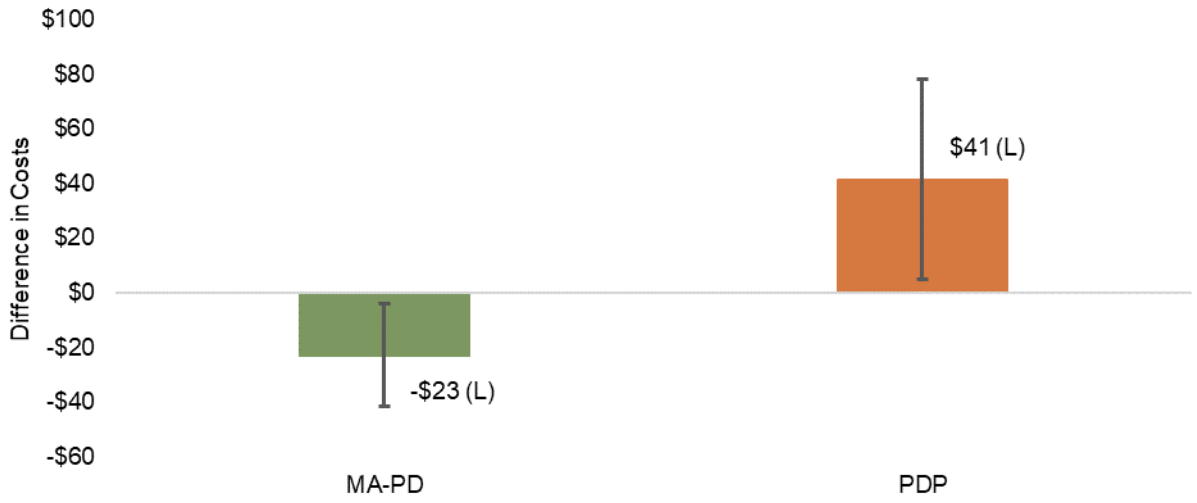
Focusing on insulin gross drug costs, we further found strong evidence of average increases for both plan types. Insulin gross drug costs for insulin users enrolled in MA-PDs increased on average by $562 (95% CI of $524 to $601), a 14.4% increase relative to estimated average gross insulin drug costs of $3,901 in the absence of the PDSS Model. Insulin gross drug costs for insulin users enrolled in PDPs increased on average by $590 (95% CI of $498 to $682), a 12.9% increase relative to the estimated average gross insulin drug costs of $4,562 in the absence of the Model test.

Noninsulin Users

We found limited evidence that the PDSS Model resulted in decreased gross drug costs for noninsulin users enrolled in MA-PDs, but we found increased gross drug costs for noninsulin users enrolled in PDPs (Figure 5.7). Noninsulin users enrolled in MA-PDs experienced an average decrease of $23 (95% CI of –$42 to –$4.13) in gross drug costs, while noninsulin users in PDPs saw an average increase of $41 (95% CI of $4.84 to $78). However, these effects are small compared with average gross drug costs for these groups of beneficiaries. The estimated

effect of the PDSS Model for MA-PDs represents a 1.2% decrease relative to the estimated average gross drug cost of $1,919 in the absence of the Model test, while the estimated PDSS Model impact for PDPs represents a 1.6% increase relative to the estimated average gross drug cost of $2,639 in the absence of the Model test.

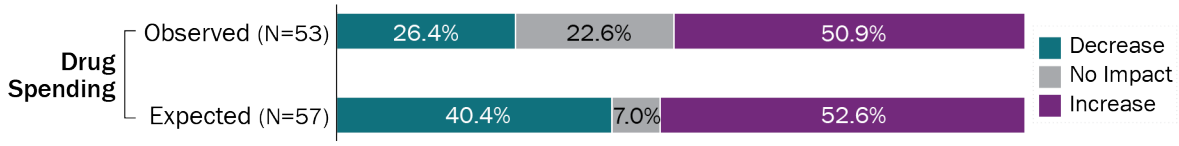
Figure 5.7. Estimated Effect of the PDSS Model on Gross Drug Costs for Noninsulin Users, by Plan Type



SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources.
NOTES: (S) = strong evidence; (M) = moderate evidence; (L) = limited evidence; (N/W) = no or weak evidence. This Figure shows coefficients on the PDSS Model implementation indicator from the beneficiary-level DD regression model estimated for our sample of noninsulin users. The comparison groups consisted of noninsulin users enrolled in eligible nonparticipating plans. Noninsulin users must have been continuously enrolled in the same plan for all of 2020 and 2021 to be included in the analysis. Beneficiaries eligible for the LIS were excluded from the analysis. *N* = 17,219,502 for MA-PDs and *N* = 11,470,769 for PDPs. Error bars indicate 95% Cis based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

From the perspective of PO survey respondents, the PDSS Model had the most significant impact on their plans' drug spending—19% of respondents chose this outcome as the one that has been affected most by the Model (data not shown). Figure 5.8 shows that slightly more than half of POs reported already seeing increased drug spending; roughly the same proportion of POs also reported expecting to see increased drug spending in the future as a result of the PDSS Model. It is worth pointing out that the proportion of POs expecting to see decreased drug spending in the future increased to 40.4% (from 26.4% of PO survey respondents who reported seeing decreases already).

Figure 5.8. PO Survey Results on PDSS Model Impact on Already Observed and Expected Changes to Drug Spending



SOURCE: Authors' analysis of response data from 2021 PDSS-participating POs surveyed in 2022.

PO representatives had differing views on whether drug spending due to increased insulin adherence would increase or decrease under the Model test. Some interviewees thought that drug spending should increase because of the PDSS Model. As a PO E representative explained: "If there's increased adherence, [beneficiaries will] be filling more scripts than they would in the absence of this program." Some PO A representatives suggested that the Model test would lead to their plans having more high-cost insulin users and thus more drug spending overall. Other POs posited that drug spending could decrease if targeted beneficiaries were having fewer exacerbations in their symptoms that required additional medication use. A representative for PO B said:

> I'm hoping that because they're taking their insulin on a consistent basis, that they're controlling their diabetic care, which will make it so they don't have to get other drugs, and you start [seeing] the cascading effect. So, they're not going to the ER [emergency room] because they went into a diabetic shock.

Plan Bids, Manufacturer Payments, and Costs to CMS

We estimated the effects of the PDSS Model on plan bids, administrative costs, reinsurance payments, manufacturer rebates, and total Part D costs to CMS. We defined all cost outcomes in our analysis as PMPM amounts to facilitate the analysis of plans with differing levels of enrollment. We do not analyze all components of costs to CMS separately in this report; instead, we focus on the components deemed (in consultation with CMS) to be most directly affected by the PDSS Model.

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

- 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 of the Part D benefit
- 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 understand the timing of plan payments. Many components of plan payments (including reinsurance payments, which we examine here) are

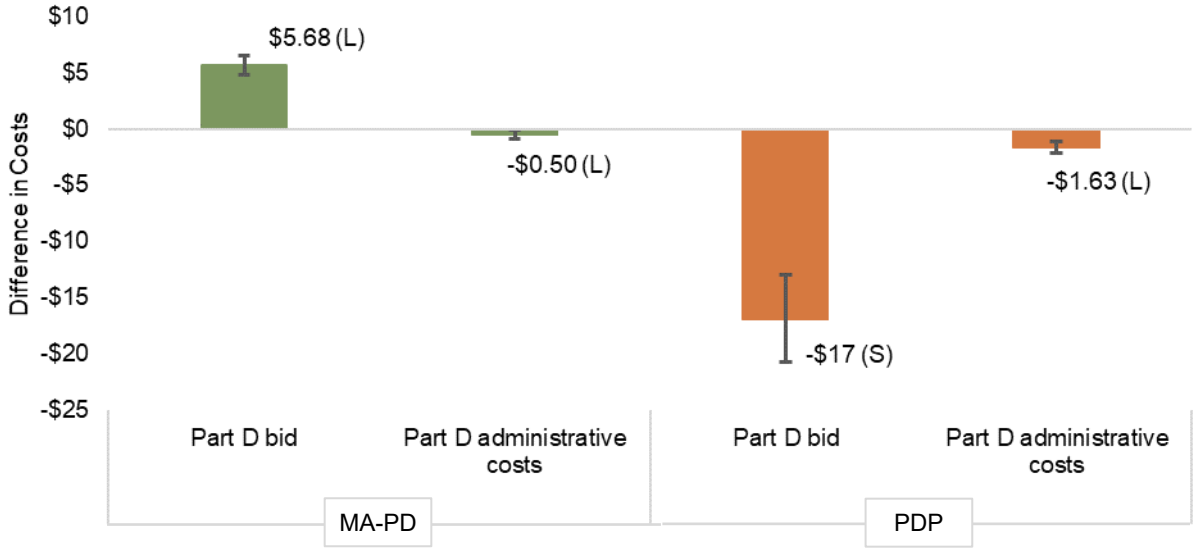
both paid on a prospective basis during the contract year and subject to adjustments through a reconciliation process after the contract year ends. We examined the *final* amounts of reinsurance, DIR, and total costs to CMS, accounting for reconciliation.

Plan bids and administrative costs, in contrast, are 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. See Appendix B for further details.

Plan Bids and Administrative Costs

For MA-PDs, we found limited evidence that the PDSS Model increased Part D bids, and we found limited evidence that the PDSS Model reduced administrative costs (Figure 5.9). The Model test led to a $5.68 (95% CI of $4.79 to $6.56) increase in the Part D bid for MA-PDs, a 14.6% increase relative to the estimated average for MA-PDs of $39, in the absence of the Model test. The Model test also reduced Part D administrative costs by $0.50 PMPM (95% CI of –$0.94 to –$0.06) for MA-PDs, a 3.2% reduction relative to the estimated average administrative costs of $15 for MA-PDs in the absence of the Model test.

Figure 5.9. Estimated Effect of the PDSS Model on Plan Bids and Administrative Costs, by Plan Type



SOURCE: Authors' analysis of Part D plan bids and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTES: (S) = strong evidence; (M) = moderate evidence; (L) = limited evidence; (N/W) = no or weak evidence. This figure shows coefficients on the PDSS Model implementation indicator from the plan-level DD regression model. The comparison groups consisted of eligible nonparticipating plans. The *N*s represent the number of plans included in the analyses across all three years of data. *N* = 7,085 plan-years for MA-PDs and *N* = 1,285 plan-years for PDPs. Error bars indicate 95% Cis based on plan-clustered standard errors. See Appendix A for additional technical details.

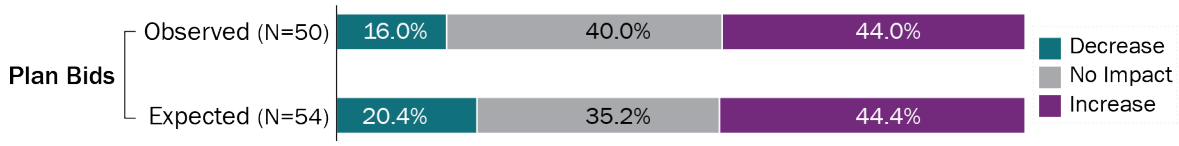
For PDPs, we found strong evidence that the PDSS Model reduced Part D bids and limited evidence that the PDSS Model reduced administrative costs. We estimated an average $17 reduction (95% CI of –$21 to –$13) in the Part D bids for PDPs; this effect represents a 36.6% reduction in the estimated expected average bid of $46 in the absence of the Model test. This estimated decrease in the Part D bids appears to be reflected in the basic and supplemental premium findings shown in Figure 5.1; that is, PDPs reduced their Part D bids and, by extension, their basic premiums, while increasing their supplemental premiums by about the same amount. In the end, the decrease in Part D bids did not flow through to a decrease in the total Part D premium. The effect on administrative costs for PDPs was a $1.63 PMPM reduction (95% CI –$2.16 to –$1.10). In the absence of the PDSS Model, we estimated that average PDP administrative costs would be $15; the DD effect of $1.63 represents a reduction of 10.8% relative to this estimate.

Our finding that the PDSS Model reduced administrative costs may appear surprising since we might have expected the Model test to require greater administrative effort by the plans. In the context of our findings about standardized Part D bids, these findings may suggest that MA-PDs anticipated that the PDSS Model would increase the cost of providing standard coverage even as administrative expenses fell, while PDPs anticipated that both the cost of providing standard coverage and administrative costs would fall with the launch of the PDSS Model. However, we also caution that the administrative cost results were not robust to parallel trends

assumption violations, so less weight should be placed on these findings compared with our findings on the Part D bids for PDPs.

PO survey results showed substantial variation in PO perspectives on the impact of the Model test on bids (Figure 5.10), further supporting our quantitative results. While 44.0% of participants reported that the PDSS Model has already led to and would lead to increases in bids in the future, a larger proportion of POs reported expecting future decreases in plan bids (20.4%) compared with the proportion of POs that reported already having decreased their bids (16%). At the same time, 40.0% of POs reported not seeing any impact, and 35.2% of POs reported not expecting to see any impact on bids in the future.

Figure 5.10. PO Survey Results on PDSS Model Impact on Already Observed and Expected Changes to Plan Bids

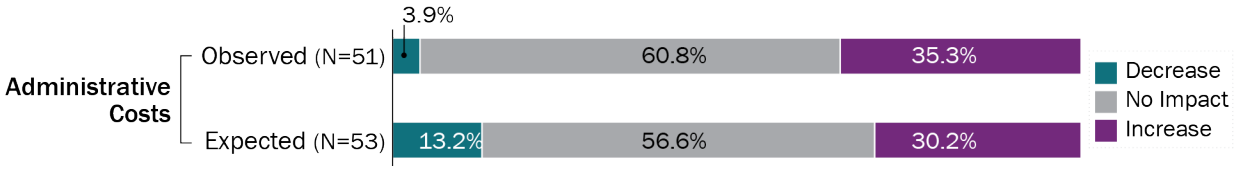


SOURCE: Authors' analysis of response data from 2021 PDSS-participating POs surveyed in 2022.

Interview data provided some additional insights into why most POs increased their bids. Representatives of two POs (A and G) did so because they expected a higher number of beneficiaries with diabetes to enroll in their plans. A PO G representative said: "We anticipated that we would get a larger portion of our population on insulins…. So, we think that a higher portion of members on insulins is going to drive up the overall spend of drugs initially."

The PO survey data, however, contradict the results of our quantitative assessment of the impact of the Model test on plan administrative costs. Only 3.9% of POs reported seeing decreases in their administrative costs, and 13.2% of POs reported expecting to see decreases in their future administrative costs (Figure 5.11). The majority of POs reported neither observing nor expecting to see any impact on their administrative costs, which may partially be attributable to the ease of the PDSS Model implementation from the plan perspective, as well as the absence of major changes in plan formularies and their approaches to negotiations with insulin manufacturers.

Figure 5.11. PO Survey Results on PDSS Model Impact on Already Observed and Expected Changes to Administrative Costs

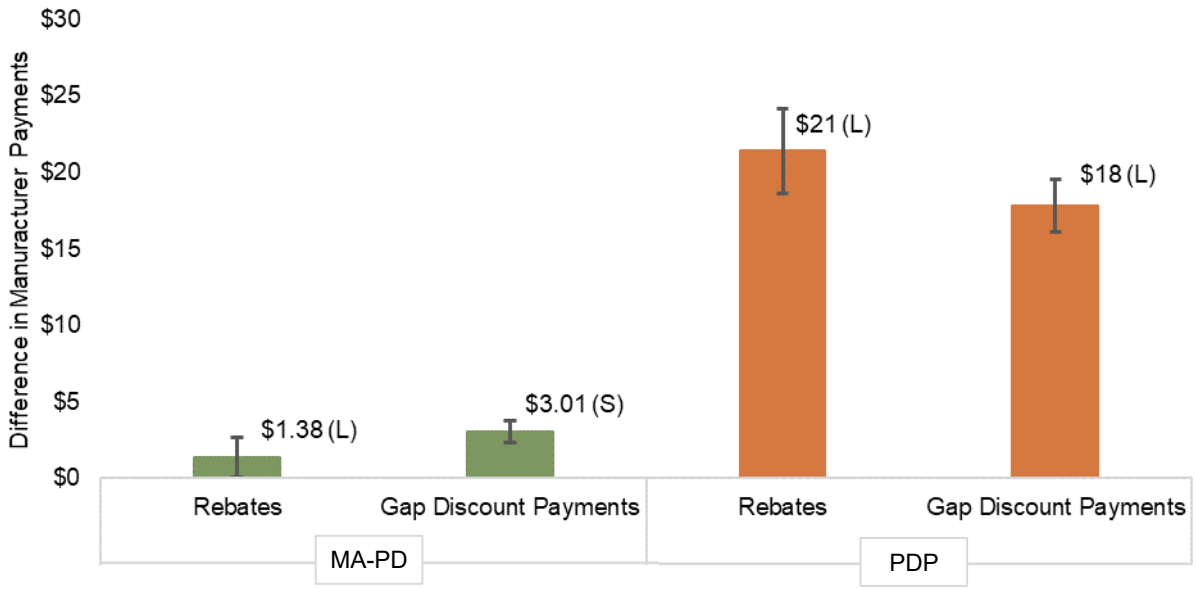


SOURCE: Authors' analysis of response data from 2021 PDSS-participating POs surveyed in 2022.

Manufacturer Rebates and Gap Discount Payments

We found evidence that the PDSS Model increased manufacturer rebates and gap discount payments for both MA-PDs and PDPs (Figure 5.12). For MA-PDs, we found limited evidence that manufacturer rebates increased by $1.38 PMPM (95% CI of $0.06, $2.70), reflecting a 1.9% increase relative to the $73 average estimated for MA-PDs, in the absence of the Model test. For PDPs, we found limited evidence that manufacturer rebates increased by $21 (95% CI of $19 to $24), a 30.7% increase relative to the average manufacturer rebate of $70 estimated for PDPs, expected in the absence of the PDSS Model.

Figure 5.12. Estimated Effect of the PDSS Model on Manufacturer Rebates and Gap Discount Payments, by Plan Type



SOURCE: Authors' analysis of DIR, PDE, and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTES: (S) = strong evidence; (M) = moderate evidence; (L) = limited evidence; (N/W) = no or weak evidence. This figure shows coefficients on the PDSS Model implementation indicator from the plan-level DD regression model. The comparison groups consisted of eligible nonparticipating plans. The *N*s represent the number of plans included in the analyses across all three years of data. *N* = 7,085 plan-years for MA-PDs and *N* = 1,285 plan-years for PDPs. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

Similarly, for manufacturer gap discount payments, we found strong evidence of an estimated $3.01 increase for MA-PDs (95% CI of $2.29 to $3.73), corresponding to a 16.0% increase relative to the $22 estimated average gap discount payment expected in the absence of the PDSS Model. For PDPs, we found limited evidence of an $18 increase (95% CI of $16 to $20) in gap discount payments, corresponding to a 59.1% increase relative to the $48 estimated average gap discount payment expected in the absence of the Model test.

Some insulin manufacturers anticipated increases in manufacturer rebates. For example, Manufacturer C expected that, because the PDSS Model would increase the financial contribution of Part D plans, PBMs and POs would come back to the manufacturers to request additional rebate dollars to pay for the enhanced insulin coverage. Manufacturer C representatives explained that they:

> chose to proceed with the expectation that everybody would kind of do their fair share. [The manufacturer] would incur costs through increased coverage gap discounts. [The PO] would potentially increase costs through lower out-of-pocket costs for patients, capping the out-of-pocket costs for patients, but there was no guarantee of that going into the discussions.

However, our quantitative findings that the PMPM manufacturer rebate increased under the Model test could also be driven by increases in drug volumes or sales that result in higher rebate payments under a given rebate agreement. According to a Manufacturer C representative:

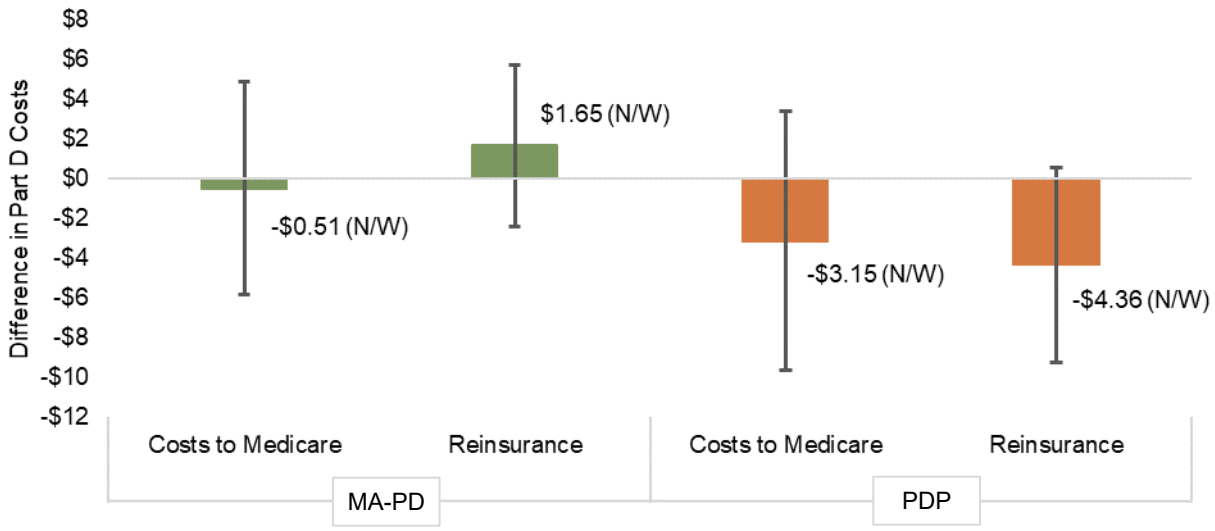
> There are two things that drive our increased costs [associated with the PDSS Model]. [Both are related to the] number of fills that go up in the coverage gap. One is driven by improved adherence. As people can afford their medicines better, they're more likely to be adherent. So that likely results in increased coverage gap payments [or gap discount payments]. And then, two, people stay in the coverage gap longer, paying lower out-of-pocket costs ... [which is] driving up our costs. Those are the two parts that drive our increased financial exposure.

We note that additional analysis using drug-level DIR data, which were not available to the study team, would be needed to distinguish between changes in manufacturer rebates due to manufacturer-PO bargaining outcomes and changes in manufacturer rebates due to increased gross drug costs or sales volumes.

Final Part D Costs to CMS

We found no or weak evidence of an effect of the PDSS Model on final Part D costs to CMS and no or weak evidence on PMPM reinsurance payments for both MA-PDs and PDPs (Figure 5.13).

Figure 5.13. Estimated Effect of the PDSS Model on Part D Costs to Medicare and Reinsurance, by Plan Type



SOURCE: Authors' analysis of Part D plan bid, PDE, and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTES: (S) = strong evidence; (M) = moderate evidence; (L) = limited evidence; (N/W) = no or weak evidence. This figure shows coefficients on the PDSS Model implementation indicator from the plan-level DD regression model. The comparison groups consisted of eligible nonparticipating plans. The *N*s represent the number of plans included in the analyses across all three years of data. *N* = 7,085 plan-years for MA-PDs and *N* = 1,285 plan-years for PDPs. Error bars indicate 95% CIs based on plan-clustered standard errors. See Appendix A for additional technical details.

PO survey findings corroborated the quantitative results on reinsurance payments, which showed that the majority of POs reported that they did not observe any impact of the PDSS Model on reinsurance payments (Figure 5.14). The proportion of POs stating that the Model test will have no impact on reinsurance payments in the longer term decreased from 76.2% to 50.0%.

Figure 5.14. PO Survey Results on PDSS Model Impact on Already Observed and Expected Changes to Reinsurance Payments

SOURCE: Authors' analysis of response data from 2021 PDSS-participating POs surveyed in 2022.

Sensitivity of Quantitative Results to Alternative Comparison Groups

As a sensitivity analysis, we also estimated PDSS Model impacts on MA-PDs and PDPs using all nonparticipating plans as the comparison group. Results from comparing PDSS-participating MA-PDs with all nonparticipating plans were similar in sign and significance to the results reported above for all plan-level outcomes analyzed in this chapter.

However, comparing PDSS-participating PDPs with all nonparticipating plans yielded different results for the PDSS Model impacts on noninsulin OOP costs for insulin users: In this alternate analysis, we found no evidence that the PDSS Model increased noninsulin OOP costs for insulin users. In addition, for other beneficiary-level cost outcomes, we found that the comparison of PDSS-participating PDPs with all nonparticipating plans generally reduced the size of the estimated effect of the Model test, although the results were still statistically significant.

The comparison between PDSS-participating PDPs with all nonparticipating plans also yielded somewhat different results for Model test impacts on two plan-level outcomes: total costs to CMS and reinsurance payments. In this sensitivity analysis, we found moderate evidence that the PDSS Model reduced reinsurance payments and strong evidence that the PDSS Model reduced costs to CMS; in contrast, we found no or weak evidence of a Model test effect on these outcomes when PDSS-participating plans were compared with eligible nonparticipating plans. Results from the comparison of PDSS-participating PDPs to all nonparticipating plans were similar in sign and significance to the results reported above for all other plan-level outcomes analyzed in this chapter. See Appendix D for detailed results.

Summary

By lowering monthly copays for insulin and making them more predictable, the PDSS Model was designed to move risks and costs from CMS to plans and manufacturers and make insulin more affordable to beneficiaries. We found no or weak evidence of an effect of the PDSS Model on Part D premiums for either MA-PDs or PDPs. Furthermore, estimates reported in this chapter show that the PDSS Model led to large reductions in OOP spending on insulin (41.5% for MA-PDs and 56.5% for PDPs) and in total OOP costs (17.1% for MA-PDs and 23.1% for PDPs) for insulin users. POs considered this outcome to be the most significant for their beneficiaries, who generally reported that paying less for their insulins enabled them not only to increase their insulin use but also to skimp less on other necessities, such as utilities, groceries, and gas. We further found strong evidence that total Part D costs declined for insulin users in both MA-PDs and PDPs. However, there may have been a negative spillover effect for noninsulin users enrolled in PDSS-participating PDPs, because we found limited evidence of an average increase of $34 in total beneficiary spending for this group.

We found limited evidence that the PDSS Model increased Part D bids for MA-PDs, but we found strong evidence of a decrease in Part D bids for PDPs. Manufacturer rebates and gap discount payments did increase in both PDSS-participating MA-PDs and PDPs, suggesting that the reduced beneficiary OOP costs were paid for, in part, by manufacturer rebates and increased gap discount payments. Our interviews with manufacturers showed that they were concerned about their contributions to the PDSS Model, relative to those of the plans, and would prefer to see a more equal sharing of financial responsibilities among all stakeholders, as described in

Chapter 2. Our analysis of plan-level cost outcomes found no evidence that reinsurance payments or total Part D costs to CMS changed as a result of the Model test.

The finding of no evidence that CMS reinsurance payments changed as a result of the Model test may be surprising in light of the sizable increases in insulin users' gross drug spending, which was considered by POs as the most significant impact of the Model test on their PDSS-participating plans. Increases in gross drug costs without increases in reinsurance payments might occur if the increases in gross drug costs due to the Model test were driven by spending before the catastrophic phase, as suggested by the finding in Chapter 4 that insulin users spent less time in the catastrophic phase as a result of the PDSS Model. We also note that the PDSS Model effects on reinsurance payments were defined in comparison with eligible nonparticipating plans, which saw rapid growth in PMPM reinsurance payments between 2020 and 2021 (see Appendix D).

Chapter 6. Conclusions

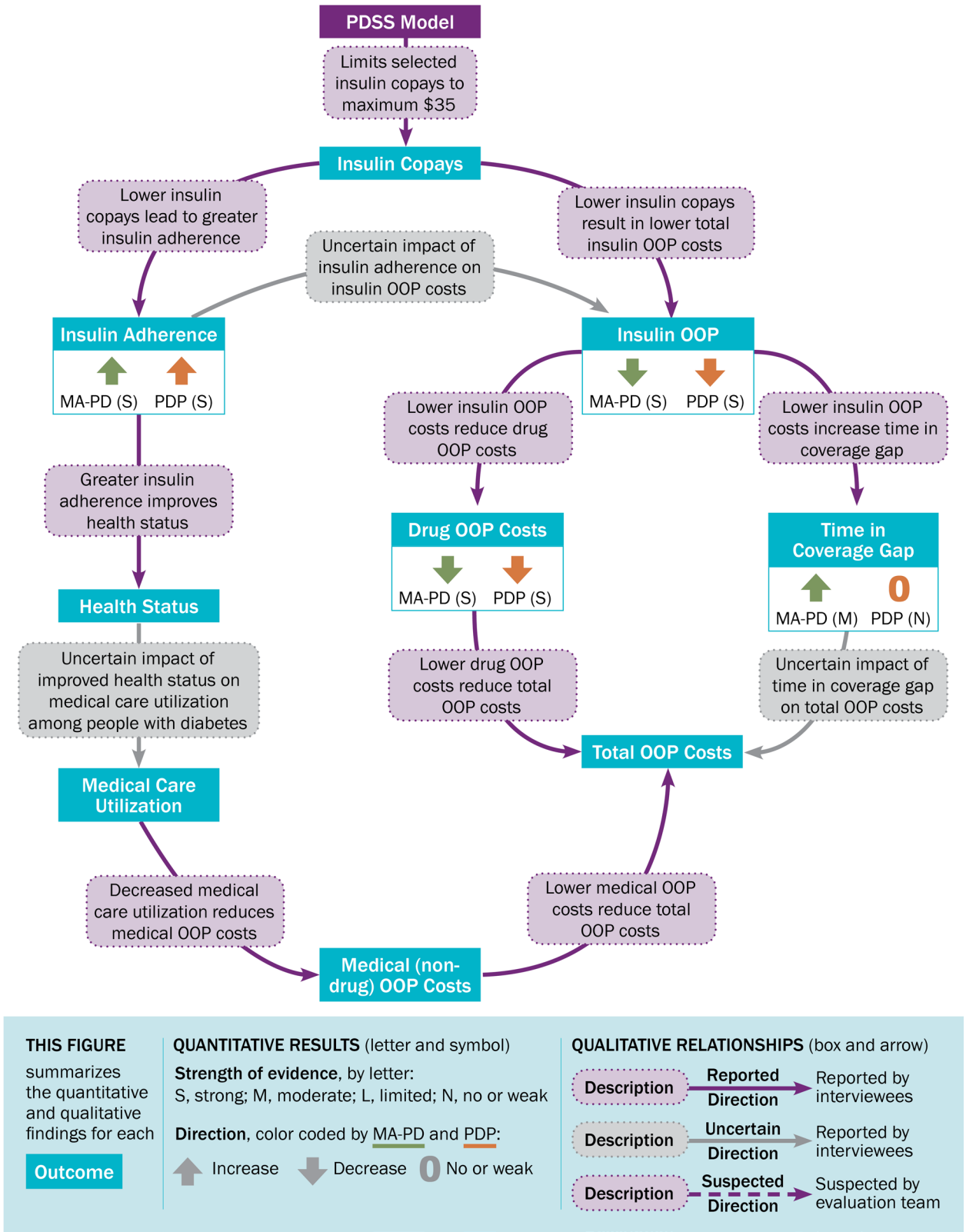
We used a mixed-methods approach that combines statistical modeling and analysis of key stakeholder perspectives to evaluate the early impact of the PDSS Model on a variety of outcomes, including insulin utilization and adherence; plan enrollment and benefits; and plan bids, premiums, and spending. This chapter synthesizes our evaluation results by presenting three diagrams (Figures 6.1–6.3),[2] one each for beneficiaries, plans, and manufacturers; discusses main limitations of our evaluation; and outlines next steps.

Impact on Key Stakeholders

Results of our **beneficiary-level** analyses suggest that there is strong evidence that the PDSS Model had a positive impact on insulin users based on the outcomes of our statistical modeling and key stakeholder perspectives. Figure 6.1 shows that insulin users saved money on their OOP insulin costs, especially in PDPs; increased their insulin use; became more adherent to their insulin regimens; and reduced their overall OOP spending as a result of the PDSS Model. PO and manufacturer representatives we interviewed also expected that increased insulin adherence will help beneficiaries improve their overall health status. Nonetheless, they suggested that the impact of beneficiaries' health status on medical care utilization, as well as the impact of insulin OOP costs and total OOP costs, may depend on the number of co-occurring disorders insulin users have and the extent to which improvements in their diabetes management can improve these other health issues. At the same time, PO and manufacturer representatives reported that if beneficiaries were to see decreased medical care utilization, that would lower beneficiary medical (non-drug) spending and total OOP costs.

[2] Each figure shows key outcomes of the Model test (blue boxes) from the perspective of different stakeholders, as well as the relationships between them (rounded shaded boxes). The outcomes that we assessed quantitatively are indicated by the white boxes; up and down arrows show the direction of the impact of the PDSS Model on a given outcome and strength of evidence, separately, for MA-PDs and PDPs. We note that although the same type of outcome may be present in more than one figure, it may be operationalized differently in qualitative and quantitative analyses, and its impact may vary by stakeholder group. Our quantitative assessments did not focus on capturing the relationships between outcomes included in these figures, such as the impact of insulin adherence on insulin OOP costs; instead, the data modeling assessed how the PDSS Model affected each of these outcomes separately. The arrows linking the outcomes and the descriptions of the relationships between them are based on the qualitative synthesis of the perspectives of all three stakeholder groups. Any major discrepancies within or between the stakeholder groups are marked as an uncertain relationship and shown in gray.

Figure 6.1. Summary of the Impact of the PDSS Model on Beneficiary Outcomes



Our findings also suggest that there were some small negative spillover effects of the Model test on noninsulin users enrolled in PDPs. Specifically, we found limited evidence that PDP noninsulin users had an average $34 increase in total Part D costs as a result of the Model test. With no evidence of a change in total OOP costs, this finding suggests that premium increases drove the increase in total Part D costs. However, we found no or weak evidence of an effect of the PDSS Model on total premiums for either MA-PDs or PDPs. These somewhat contradictory findings may be due to the different enrollment patterns of beneficiaries in our noninsulin user sample, because these beneficiaries may have been disproportionately enrolled in PDPs that increased their premiums. Our total premium regression analyses, by contrast, were conducted at the plan level, and the results reflect the average effect across all unweighted Part D premiums.

The impact of the Model test on **PDSS-participating plan-level** outcomes is somewhat less robust than the impact for beneficiaries and varies by plan type (Figure 6.2). Both MA-PDs and PDPs saw increased gross drug spending for insulin users and a decrease in the time insulin users spent in the catastrophic phase. We found strong evidence of increased enrollment of insulin users in MA-PDs and limited evidence of decreased insulin user enrollment in PDPs. We further found strong evidence of decreased enrollment of LIS-eligible beneficiaries in PDPs, but we found only limited evidence of increased enrollment by LIS-eligible beneficiaries in MA-PDs. There is also limited evidence of an increase in MA-PD bids for basic Part D coverage and strong evidence of a decrease in PDP Part D bids. We found limited evidence that Part D administrative costs declined for both MA-PDs and PDPs as a result of the PDSS Model, but PO representatives generally reported increases or no impact on their administrative costs. They also considered the Model test to have more of an impact on beneficiary outcomes than plan outcomes, although some POs reported increasing or planning to increase their Part D bids. PO representatives with PDSS-participating MA-PDs noted that they were able to absorb the increase in Part D premiums using MA rebate dollars. Their perspectives on the impact on drug spending varied, especially their projections of the Model test's long-term impact. While some POs expected an increase in insulin user enrollment, which would increase drug spending, others anticipated that better insulin adherence would lead to a reduction in costly exacerbations requiring additional medication use or medical expenditures, or both.

Major **insulin manufacturers** reported seeing increased utilization of and adherence to their insulins even in the absence of substantial changes to drug formularies (Figure 6.3). Their profits, however, might have been negatively affected by insulin users staying in the coverage gap phase longer, where manufacturers pay the 70% manufacturer gap discount plus the negotiated manufacturer rebate to plans. However, we did find limited evidence of an increase in total manufacturer rebates to both MA-PDs and PDPs and evidence of an increase in manufacturer gap discount payments as well for both MA-PDs (strong evidence) and PDPs (limited evidence). Manufacturers did not report major changes in formulary coverage of their insulin products by PDSS-participating plans because of the plans' unwillingness to disrupt the medication regimens of their enrollees.

Figure 6.2. Summary of the Impact of the PDSS Model on Plan Outcomes

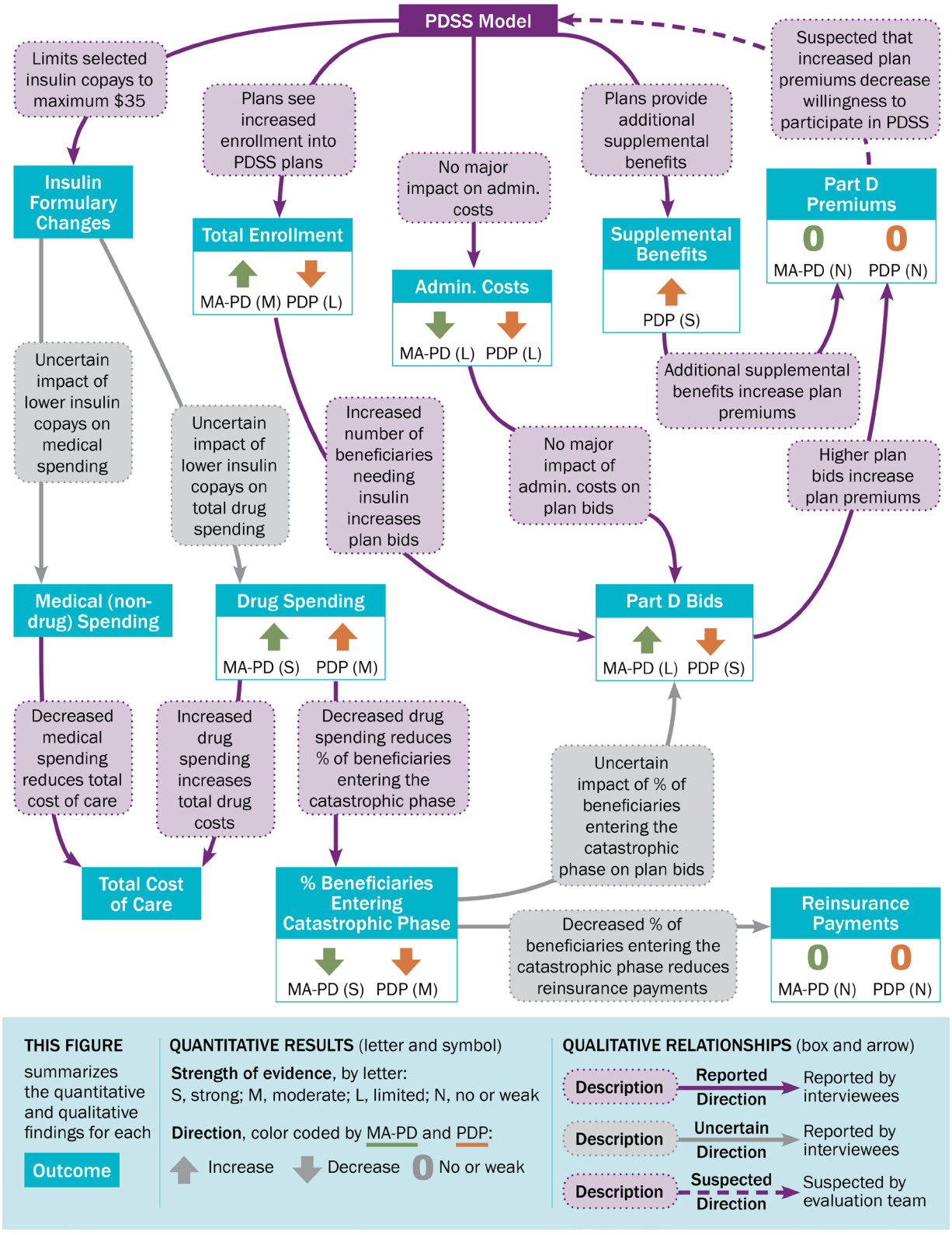
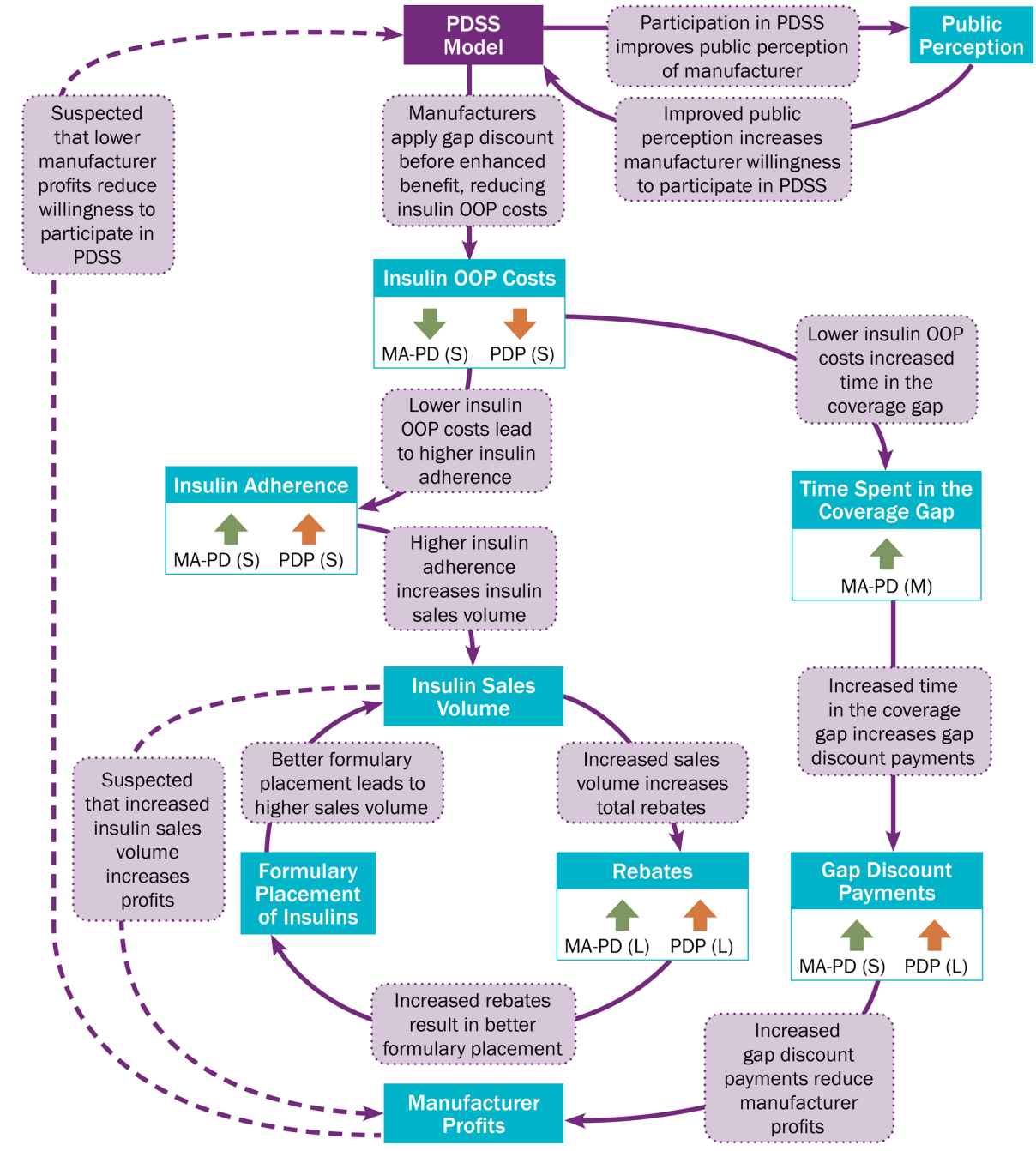


Figure 6.3. Summary of the Impact of the PDSS Model on Manufacturer Outcomes



THIS FIGURE summarizes the quantitative and qualitative findings for each **Outcome**

QUANTITATIVE RESULTS (letter and symbol)

Strength of evidence, by letter:
S, strong; M, moderate; L, limited; N, no or weak

Direction, color coded by MA-PD and PDP:
Increase · Decrease · 0 No or weak

QUALITATIVE RELATIONSHIPS (box and arrow)

- **Description** —**Reported Direction**→ Reported by interviewees
- **Description** —**Uncertain Direction**→ Reported by interviewees
- **Description** —**Suspected Direction**→ Suspected by evaluation team

Finally, we found no or weak evidence that **CMS** experienced any positive or negative cost outcomes attributable to the PDSS Model, as measured by final Part D costs to CMS and reinsurance payments. This finding is likely due to the fact that fewer insulin users reached the catastrophic phase of the benefit, potentially counterbalanced by increased insulin utilization and associated increased drug spending for insulin users.

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 both 2020 and 2021. Therefore, our results do not reflect the effects of the Model test on beneficiaries who elected to enroll in a PDSS-participating plan in 2021. To address this limitation, we compared descriptive statistics for newly enrolled beneficiaries with at least one insulin fill in PDSS-participating plans in 2021 to beneficiaries in the insulin user sample, and we found that the two groups were somewhat different in terms of demographic characteristics (results shown in Table A.9 in Appendix A). As part of the final evaluation report, we will further explore the impact of the Model test on outcomes for this group of beneficiaries. Second, the strength of our findings depends heavily on the parallel trends assumption; these results may be sensitive to violations of the parallel trends assumption similar to those observed in our baseline period for several of our outcome measures. Nonetheless, for some key outcomes (for example, insulin utilization and beneficiary costs), even relatively large violations of the parallel trends assumption are unlikely to substantially affect our conclusions; thus, the strength of our confidence in these effects is high. Third, requiring insulin utilization in the pre-period omits from our analyses beneficiaries who may have delayed or not taken insulin before the PDSS Model began because of costs and beneficiaries who began to take insulin as a result of the Model test. Finally, although we invited all 2021 PDSS-participating POs to complete our survey and interviewed all U.S. insulin manufacturers, not all POs participated in the survey or answered all of the questions. Moreover, our PO and beneficiary interview samples were relatively small and thus not representative.

Next Steps

Regardless of the limitations, the results of our mixed-methods evaluation that triangulated quantitative and qualitative data analysis results provide an early view of the impact of the Model test on a variety of outcomes. In our next evaluation report, we will add 2022 and 2023 data and assess the impact of the PDSS Model on additional outcomes, such as insulin users' health status, utilization of avoidable care, and medical spending outcomes. Doing so will help us determine not only short-term but also longer-term impacts of the Model test.

Appendix A. Overview of Data Sources and Quantitative Methods

This appendix provides an overview of the data sources and methods that we used to estimate the impacts of the PDSS Model on beneficiary and plan outcomes.

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	18 months after 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 (MBISG 2.0)	RAND	Fall of following year	Beneficiary
Risk scores [Hierarchical Condition Categories (HCC), Prescription Drug Hierarchical Condition Code (RxHCC)]	IDR	Fall of the following year	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
Payment Reconciliation System (PRS)	HPMS	September of the following year	Plan
CMS Star ratings	Public	Every fall prior to open enrollment	Contract
PDSS Model application data	Innovation Center	Fall (for upcoming plan year)	PDSS-participating plans and manufacturers

Data Source	Location	Data Considered Final	Unit of Observation
PDSS Model-eligible insulin list	Innovation Center	Fall (for upcoming Model test year)	PDSS-participating manufacturers
Area Health Resources File	HRSA	N/A	County

NOTE: HRSA = Health Resources and Services Administration; IDR = Integrated Data Repository; N/A = not applicable; OACT = CMS Office of the Actuary.

Main Regression Models

Causal Inference and Assumptions

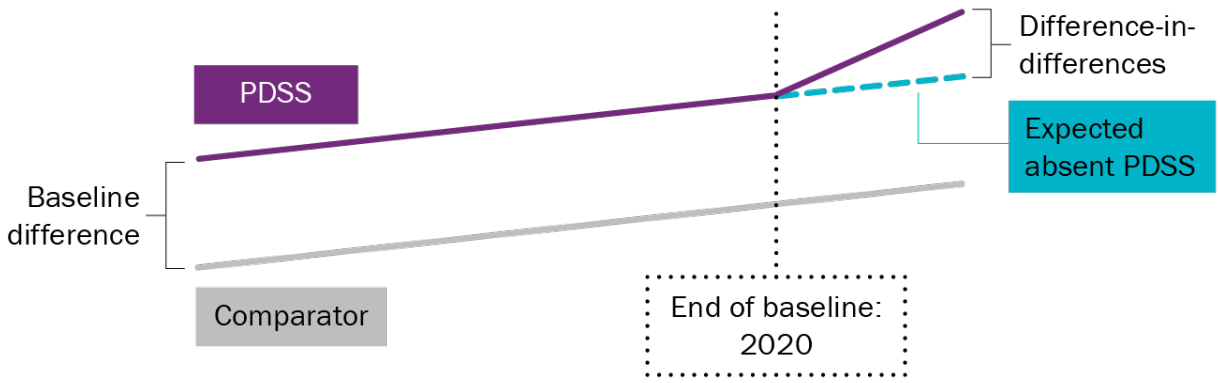
Participation in the Model test was voluntary, and there was no random assignment of plans to the PDSS-participating (treated) or comparison (control) group. Thus, any observed differences in 2021 outcomes may reflect some combination of the differences between the PDSS-participating and comparison groups prior to the start of the PDSS Model, differential changes that would have occurred between 2020 and 2021 in the absence of the PDSS Model, and the causal effect of the PDSS Model. We focus on DD models to estimate causal effects of treatment in this report, which at its essence compares the differences from the pre-treatment period with the post-treatment period for the group that received the treatment (that is, PDSS-participating plans) versus the comparison group that did not.

More precisely, we assume that each unit of observation (in our case, either beneficiary or plan) has two *potential outcomes*; that is, the outcome that would be observed if the unit had been exposed to the treatment ($Y_{i,t}^{1}$) and the outcome that would have been observed if the unit had received the control condition ($Y_{i,t}^{0}$). In this notation, i indexes the observational unit, and t indexes the study period (minimally, pre- and post-period indicators, but there can be multiple time points in the pre- and post-period). Both potential outcomes exist for each member of our study populations, but we can never observe more than one potential outcome in the post-treatment period. Our models estimate the average treatment effect on the treated, which is defined as $E(Y_{i,\text{post}}^{1} - Y_{i,\text{post}}^{0} | \mathsf{A} = 1)$, where $A = 1$ denotes the treated population.

The key assumption that underlies DD is that of *parallel trends*, which states that, if none of the units had been exposed to the treatment, the average of the potential outcomes (Y_{i}^{0}) over time would be parallel when stratified by the units that received the treatment versus those units that did not receive the treatment. In short, we estimate the change from the pre- to post-periods that the treated group *would have experienced had they not received the treatment* by measuring the pre- to post-period change that the control observations actually experienced. Figure A.1 depicts the DD approach graphically. While there may be differences between PDSS-participating and nonparticipating plans before the PDSS Model began (in 2019 and 2020), the DD estimate looks only at differential changes over time for plans that adopted the PDSS Model in 2021 versus

those plans that did not. A key benefit of this DD approach is that it removes time-invariant confounders that may not be observed (i.e., differences in covariates between the intervention and control groups prior to the intervention), because such variables cannot induce a violation of parallel trends if the relationship between the covariates and outcome does not change over time.

Figure A.1. Difference-in-Differences Methodology

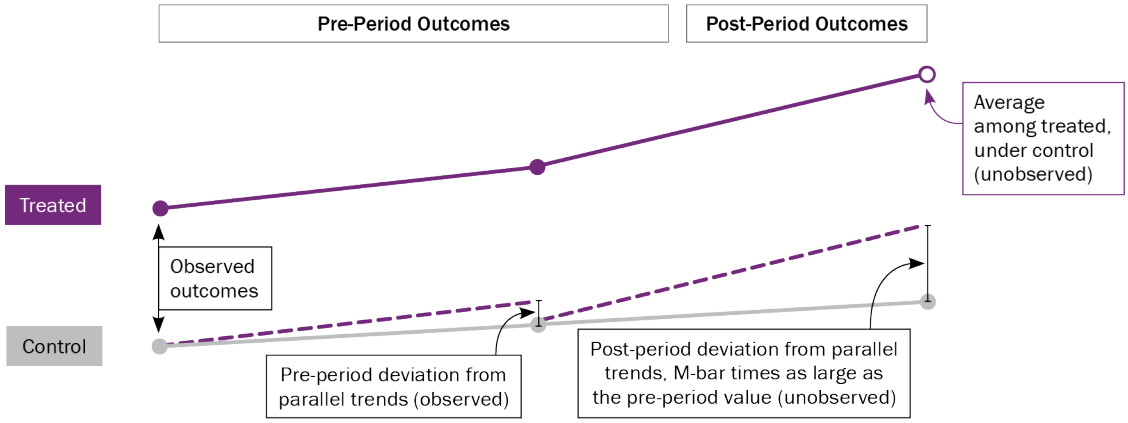


We are unable to observe whether the trends are, in fact, parallel in the post-treatment period because we do not observe $Y^0_{i,\text{post}}$ for the units that receive the active treatment. DD analyses typically assess whether the trends are parallel in the pre-treatment period (where $Y^0_{i,\text{pre}}$ is observed for both the group that receives treatment and the group that receives control in the post-period) under the assumption that parallel trends in the pre-period are likely to carry over into the post-period. This approach can be unsatisfactory for at least two reasons. First, the presence of parallel trends in the pre-period does not guarantee this will hold true in the post-period. Second, as a practical matter, reasonable assumptions about the data-generating process would typically never result in trends that are *exactly* parallel in either the pre- or post-periods. Statistical tests of parallel trends in the pre-period often reflect the available sample size (increases in which result in greater analytical power to detect deviations from parallel trends) as much as the magnitude of observed deviations from parallel trends.

We would argue that a more relevant assessment of parallel trends examines the sensitivity of study findings to potential violations of parallel trends in the post-treatment period, relative to the magnitude of violations that are supported by the data in the pre-period. This is the approach of Rambachan and Roth (2023). In particular, we focus on their "bounds on relative magnitudes" approach which assumes that the unobservable post-period deviation from parallel trends is at most some multiple $\bar{M}$ (M-bar) of the deviation from parallel trends in the pre-period. (In cases where there are more than two pre-period time points, the multiple applies to the largest of the pre-period deviations in parallel trends.) For example, imagine a DD treatment effect estimate that is statistically significant at the 5% level of significance. To provide a concrete but hypothetical example, if a Rambachan and Roth sensitivity analysis with $\bar{M} = 1.5$ retains

statistical significance, we would conclude that the findings are robust to violations of parallel trends up to 1.5 times as large as the largest pre-period trend violation. In Figure A.2, the deviation from parallel trends in the pre-period is observed (up to the sampling error) as the vertical distance from the end of the dashed, purple line segment to the middle gray point. The corresponding quantity is not observed in the post-period because the open purple circle represents the mean of the outcome of the treated group *if it had instead received the control condition*. We are interested in what the outcome would have been for the treated group if it had instead received the control condition because our treatment effect is defined as the difference in outcomes under the treatment versus under the control condition, for those who actually received the treatment. The sensitivity of the results is assessed if the vertical distance between the dashed purple line and the gray point at the right-hand side of the figure is $\bar{M}$ times as large as the analogous vertical distance at the middle point of the figure.

Figure A.2. Depiction of Rambachan and Roth Methodology



NOTE: In this figure, the solid and dashed purple line segments are parallel to one another. The vertical distance from the solid gray to dashed purple line segment in the pre-period is observed (up to the sampling variation). The hollow purple point indicates the unobserved mean of the treated group until the control condition (that is, if those individuals had instead been exposed to the control condition), which implies a deviation from parallel trends equal to the vertical distance from the dashed purple line to the solid gray point in the post-period. As an example, an $\bar{M}$ equal to 2 would assess the sensitivity of the results if the vertical distance between the dashed purple line segment on the right-hand side were twice as large as the vertical distance between the dashed purple line segment and the gray point in the middle of the figure.

Note that the violation from parallel trends in the pre-period is estimated with uncertainty, so two analyses may have the same *point estimate* for the magnitude of the pre-period violation of parallel trends, but if one of them is estimated more precisely, this would be expected to translate into less uncertainty in the treatment effect CI. Note, also, that a transition from significance to statistical insignificance reflects both how far away from the null effect the original interval estimate is (in other words, whether the original treatment effect CI nearly overlaps zero or is far

from it) and the amount of additional uncertainty introduced by the potential violation of parallel trends (as modulated by the value of $\bar{M}$).

Model Implementation

To implement the DD modeling, we had initially planned to use weighting or matching on observed covariates so that the treated and control groups for a given analysis "look more like each other." While DD analyses do not require equal levels for the outcome during the pre-period, we generally expect parallel trends to be improved if the treated and control groups are similar in their covariate distributions. (For example, in the ideal case where treatment is randomly assigned, the distribution of treatment and control group covariates will be the same, up to sampling variation.) However, we found that PDSS-participating and nonparticipating plans were different enough in terms of observed characteristics that it would be difficult or impossible to find satisfactory matches between treated and control groups in some cases. As an alternative to matching or weighting, we instead control for covariates in the beneficiary-level models that may improve the parallel trends between the treated and control groups. In initial analyses, we implemented the "post-double-selection" approach of Belloni, Chernozhukov, and Hansen (2014), which suggested that essentially all the covariates are either imbalanced prior to treatment (and are therefore predictive of participation in the PDSS Model) or are associated with the outcome for the beneficiary-level models, or both. (Covariates that are balanced between the treated and control groups or that are not associated with the beneficiary-level outcomes are not confounders and therefore need not be included in the models.) For consistency across models, we included all covariates described below in each DD model, because the post-double-selection analysis suggested there is little risk of overfitting the data by doing so. To account for correlation of outcomes within plans, we used cluster-robust standard errors at the plan level, in addition to plan-level fixed effects using the "fixest" package in R to estimate the outcomes models using ordinary least squares. We also control for year effects for 2019 and 2021. While there is no mathematical guarantee that adding covariates to a model will improve parallel trends, we generally expect that it will, and in our experience, this seems to be the case (as seen in pre-period trends) for the beneficiary-level outcomes. However, care must be taken to avoid covariates that may be affected by the PDSS Model, because including such covariates in the DD models would be expected to bias treatment effect estimates; we excluded such variables from our analyses. We ran the Rambachan and Roth sensitivity analyses using their "HonestDiD" R package.

Covariates Used in Regression Models

We did not adjust for covariates in the plan-level regression models for two key reasons. First, plan benefit design and enrollment composition are unlikely to change much over time, and any changes may be correlated with implementation of the PDSS Model (in other words, plans

may have changed their benefit designs in response to the PDSS Model). Second, many of the plan-level cost outcomes (Part D bids and premiums, especially) are established before the final composition of a plan is settled. Controlling for plan composition after costs are established would adjust for aspects of the plan that are outside the plans' control when estimating costs. We therefore used an unadjusted DD regression model for all plan-level outcomes included in this report, and we relied on plan-level fixed effects to address any time-invariant variation across plans.

Table A.2 presents the covariates used in the beneficiary-level regression models. In addition to relying on plan-level fixed effects, we also included controls for beneficiary characteristics, including demographics and utilization patterns, to account for differences across beneficiaries in our samples (insulin users and noninsulin users) that may contribute to differences in our outcome measures beyond those attributable to the Model test. We control only for beneficiary characteristics associated with utilization by using pre-period (2020) values. We also removed selected variables from some outcome regression models where the covariate was closely associated with the outcome. For example, we did not control for Part D risk score in beneficiary-level OOP outcome regressions, because Part D risk score is intended to estimate the likelihood of beneficiary spending. We clarify in the table notes which variables were excluded from which outcome models.

Table A.2. Beneficiary-Level Regression Model Covariates

Variable	Insulin Users Only	Pre-Period (2020) Value Only	Source
Beneficiary age	No	No	IDR
Beneficiary gender	No	No	IDR
Original reason for Medicare entitlement	No	No	IDR
Number of 30-day insulin fills[a]	Yes	Yes	PDE
Any use of noninsulin antidiabetic medication	Yes	Yes	PDE
Final benefit phase of year[b]	No	Yes	PDE
Part D risk score (RxHCC)[c]	No	Yes	RxHCC scores
Race/ethnicity	No	No	MBISG 2.0
RxHCC flag for kidney disease	No	Yes	IDR
RxHCC flag for high cholesterol	No	Yes	IDR
RxHCC flag for CHF	No	Yes	IDR
RxHCC flag for hypertension	No	Yes	IDR
Any fill of intermediate-acting insulin[a]	Yes	Yes	PDE
Any fill of long-acting insulin[a]	Yes	Yes	PDE
Any fill of rapid-acting insulin[a]	Yes	Yes	PDE
Any fill of insulin pen[a]	Yes	Yes	PDE
Any fill of insulin vial[a]	Yes	Yes	PDE
Median income for service area	No	No	AHRF
Urbanicity of service area	No	No	AHRF
Drug benefit type[d]	No	No	HPMS

Variable	Insulin Users Only	Pre-Period (2020) Value Only	Source
Plan offers nonzero Part D premium[e]	No	Yes	HPMS
Plan offers nonzero Part D deductible	No	Yes	HPMS
Plan deductible	No	Yes	HPMS
Part D total premium	No	Yes	HPMS
Star Ratings measure: getting needed medications	No	No	CMS Star Ratings
Star Ratings measure: diabetes adherence	No	No	CMS Star Ratings
Does not offer partial coverage in gap	No	No	HPMS
Partial gap coverage for brands only	No	No	HPMS
Partial gap coverage for generics only	No	No	HPMS
Full gap coverage N/A	No	No	HPMS
Does not offer full gap coverage	No	No	HPMS
Full gap coverage of generics	No	No	HPMS
Part C premium[e]	No	No	HPMS
Amount of Part D premium buydown[e]	No	No	Part D bid data
Number of Part D fills per month	No	Yes	PDE
Number of emergency department (ED) visits	No	Yes	FFS claims / MA encounter
Number of hospitalizations	No	Yes	FFS claims / MA encounter

NOTE: AHRF = Area Health Resources File; CHF = Congestive Heart Failure; RxHCC = Prescription Drug Hierarchical Condition Code.
[a] Excluded from analyses of beneficiary adherence to insulin.
[b] Excluded from analyses of benefit phase outcomes.
[c] Excluded from analyses of Part D spending.
[d] All nonparticipating plan comparison group only.
[e] MA-PDs only.

Unlike a model that used covariates to control for beneficiary characteristics, an unadjusted model that used beneficiary-level fixed effects would also have controlled for both unobserved and observed beneficiary characteristics. We ran all beneficiary-level models using this alternative specification and compared our results with the main regression model DD coefficients. Most estimates from models with beneficiary-level fixed effects were not meaningfully different (in terms of sign and significance) from those from our main specification, but estimates for PDSS Model effects on noninsulin users in PDPs were somewhat more sensitive.

Changes in estimated PDSS Model effects for noninsulin users in PDPs were as follows:

- Compared with our main specification, controlling for beneficiary-level fixed effects yields slightly different results for PDSS Model effects on time spent in benefit phases (30-day periods), with larger estimated PDSS Model effects on time spent in the initial coverage phase and smaller estimated PDSS Model effects on time spent in the coverage gap and catastrophic phases.
- Controlling for beneficiary-level fixed effects results in a statistically insignificant negative estimated effect of the PDSS Model on total Part D costs for noninsulin users (DD effect of –$10; 95% CI of –$34 to $13), whereas the estimated effect from our main model was positive and statistically significant.

- The estimated effect of the PDSS Model with beneficiary-level fixed effects on total drug spending was also outside the 95% CI from our main specification, but had the same sign.

Identification of Participating and Comparison Plans

We defined participating plans as those that participated in the PDSS Model in 2021. We defined comparison plans as plans that did not participate in PDSS and categorized them into one of two groups: (1) only Part D plans eligible for the Model test (enhanced), and (2) all Part D plans (both basic and enhanced). The first comparison group comprised enhanced plans that were eligible but did not participate in the PDSS Model in either 2021 or 2022. We included basic plans in the second comparison group because participation in the PDSS Model was high and increasing over time, particularly among PDPs, and the basic plans may form the core of the comparison group in future Model test years. The primary difference between basic and enhanced plans is that basic plans are not able to offer beneficiaries supplemental benefits and, thus, may have different benefit designs when compared with enhanced plans. However, the Medicare Payment Advisory Commission recently highlighted important differences in average premiums among enhanced PDPs (Rollins, 2022), finding that enhanced PDPs fall into two groups—low and high premium. Average basic PDP premiums fall between the average premiums for these two enhanced plan groups. These differences suggest that eligible nonparticipating enhanced PDPs may be substantially different from participating enhanced PDPs, although we maintain them as our main comparison group for this report because they could have participated in the Model test and we would expect the results of our DD regressions to be valid, so long as their trends evolved in parallel to those of PDSS-participating plans. We also ran the DD models using all nonparticipating plans as the comparison group to provide additional information on the effects of the Model test when examining nonparticipating plans overall.

We excluded from both comparison groups 1876 Cost, 1833 Cost, Employer/Union Only Direct Contract PDP, Medicare-Medicaid Plan HMO, National Pace, PFFS, dual eligible Special Needs Plans, and Point-of-Sale Contractor plans because they have different targeted populations or Part D benefit structures compared with Part D plans available to the general Medicare population.

We ran the regression models separately for MA-PDs and PDPs because of differences in plan financing and incentives to manage adherence and medical spending. For example, MA-PDs cover medical services in addition to prescription drugs, while PDPs do not; thus, MA-PDs may face different incentives for increasing the use of chronic maintenance medications that may stave off downstream health care utilization. MA-PDs are also able to buy down the Part D premium and to provide supplemental benefits using rebate dollars received as part of the MA bidding and quality rating processes. Separating the two plan types in analyses enables us to draw conclusions about the effect of the PDSS Model on MA-PDs and PDPs individually.

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 to 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.[3] 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 are due to consolidations, we used the most recent year for the analysis in this report (2021) as the reference year 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 later consolidated.

Table A.3 presents descriptive statistics for the PDSS-participating and eligible nonparticipating MA-PDs for 2020.

Table A.3. MA-PD Participating and Eligible Nonparticipating Plan Descriptive Statistics, 2020

Variable	Eligible Nonparticipating MA-PDs	PDSS-Participating MA-PDs
Full gap coverage–brands and generics	0.0%	0.2%
Full gap coverage–brands only	0.0%	0.0%
Full gap coverage–generics only	53.1%	26.3%***
Partial gap coverage–brands and generics	0.0%	0.2%
Partial gap coverage–brands only	0.0%	1.8%***
Partial gap coverage–generics only	1.3%	0.1%***
Actuarially Equivalent Benefit Type	0.4%	0.0%**
Basic Alternative Benefit Type	1.1%	0.5%*
Defined Standard Benefit Type	0.2%	0.0%*
Enhanced Alternative Benefit Type	98.3%	99.5%***
For profit	79.3%	80.1%
Average enrollee age	71.2 (3.7)	72.1*** (3.4)
American Indian / Alaska Native	0.4%	0.4%
Asian / Pacific Islander	5.0%	3.4%***
Black	13.3%	10.5%***
Hispanic	12.1%	11.2%
Multiracial	2.1%	2.0%***
White	67.1%	72.5%***
Part C risk score	1.1 (0.3)	1.1*** (0.3)
Part D risk score	0.99 (0.3)	0.97** (0.2)
Average area income	$64,334 (15374)	$61,468*** (13399)
Offers nonzero Part D deductible	46.4%	49.8%
Offers nonzero Part D premium	44.1%	43.5%
% enrollees taking noninsulin antidiabetics	21.0%	23.3%***
% insulin users	6.7%	8.1%***
% female	54.6%	54.9%

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

Variable	Eligible Nonparticipating MA-PDs	PDSS-Participating MA-PDs
% originally disabled and end-stage renal disease (ESRD)	0.2%	0.1%***
% originally disabled	27.8%	24.8%***
% originally ESRD	0.3%	0.0%***
Part D deductible	118 (150)	110 (132)
Part C premium	15.37 (36)	14.27 (32)
Star Ratings - diabetes medication adherence (missing)	20.0%	18.6%
Star Ratings - diabetes medication adherence	3.3 (1.8)	3.5*** (1.8)
Star Ratings - getting needed drugs (missing)	25.0%	19.6%***
Star Ratings - getting needed drugs	2.7 (1.8)	2.7 (1.6)
Urbanicity	1.8 (0.3)	1.8 (0.3)

SOURCE: Authors' analysis of Part D plan and other data. For a complete list of datasets, please see Table A.1.
NOTE: Standard deviation shown in parentheses. *** *p*-value < 0.01; ** *p*-value < 0.05; * *p*-value < 0.10; *p*-values are calculated as *t*-tests for the difference in means across groups.

Table A.4 presents descriptive statistics for the PDSS-participating and eligible nonparticipating PDPs for 2020.

Table A.4. PDP Participating and Eligible Nonparticipating Plan Descriptive Statistics, 2020

Variable	Eligible Nonparticipating PDPs	PDSS-Participating PDPs
Full gap coverage - generics only	10.8%	24.9%***
No full gap coverage	89.2%	75.1%***
No partial gap coverage	100.0%	100.0%
Enhanced Alternative Benefit Type	100.0%	100.0%
For profit	92.4%	100.0%***
Average enrollee age	72.62 (1.91)	73.74*** (2.41)
American Indian / Alaska Native	0.4%	0.5%
Asian / PI	2.3%	2.5%*
Black	3.4%	4.3%**
Hispanic	3.1%	4.0%
Multiracial	1.7%	1.8%
White	89.1%	86.9%**
Part C risk score	0.89 (0.16)	1.03*** (0.21)
Part D risk score	0.80 (0.12)	0.90*** (0.15)
Average area income	$63,044 (10682)	$63,050 (10989)
Offers nonzero Part D deductible	89.8%	74.4%
Offers nonzero Part D premium	100.0%	100.0%
% enrollees taking noninsulin antidiabetics	15.3%	19.1%***
% insulin users	3.4%	7.3%***
% female	56.9%	56.6%
% originally disabled and ESRD	0.1%	0.2%***
% originally disabled	11.9%	14.3%***
% originally ESRD	0.3%	0.4%*

Variable	Eligible Nonparticipating PDPs	PDSS-Participating PDPs
Part D deductible	384 (136)	259*** (189)
Star Ratings - diabetes medication adherence (missing)	18.5%	0.0%***
Star Ratings - diabetes medication adherence	2.3 (1.2)	2.6*** (0.5)
Star Ratings - getting needed drugs (missing)	18.5%	0.0%***
Star Ratings - getting needed drugs	2.9 (1.7)	3.1* (0.8)
Urbanicity	1.6 (0.3)	1.6 (0.3)

SOURCE: Authors' analysis of Part D plan and other data. For a complete list of datasets, please see Table A.1.
NOTE: Standard deviation shown in parentheses. *** *p*-value < 0.01; ** *p*-value < 0.05; * *p*-value < 0.10; *p*-values are calculated as *t*-tests for the difference in means across groups.

Identification of Insulin Users and Noninsulin Users

We conducted analyses separately for two groups of beneficiaries that may be affected by the Model test. The first group consists of *insulin users*, defined as those beneficiaries who filled at least one 2021 PDSS Model-eligible insulin in 2020 (before the Model test began). The second group consists of *noninsulin users*, identified as enrollees of the plan who were not in the insulin user group (that is, did not fill at least one 2021 PDSS Model-eligible insulin) in 2020. Beneficiaries who were eligible for the LIS were not eligible to participate in the Model test and, therefore, were not included in either analytic sample.

For the statistical analyses, we included beneficiaries in the analytic sample who were continuously enrolled in the same plan for all of 2020 and 2021. If a beneficiary was also enrolled in the same plan for all of 2019, we included their 2019 data in the analysis, but 2019 enrollment was not a requirement for inclusion in the DD regressions. Thus, our treatment effect estimates correspond to the group of beneficiaries with one or two years of pre-period data, as well as a year of post-period data.

Table A.5 presents descriptive statistics for insulin users for 2020.

Table A.5. Insulin User Descriptive Statistics, 2020

Variable	PDSS-Participating MA-PDs	PDSS-Participating PDPs	Eligible Nonparticipating MA-PDs	Eligible Nonparticipating PDPs
Age	72.9 * (7.7)	75.2 *** (7.0)	73.2 (7.7)	74.4 (6.9)
% female	47.3%	48.0% ***	47.7%	46.0%
Any noninsulin antidiabetic medication	71.4%**	66.5% ***	70.4%	66.9%
Probability American Indian / Alaska Native	0.4%	0.4%	0.4%	0.5%
Probability Asian / Pacific Islander	2.9% ***	2.1%	5.4%	2.5%
Probability Black	12.0%	5.3%	10.5%	3.9%
Probability Hispanic	14.4%	3.8%	13.5%	4.0%
Probability Multiracial	1.8%	1.7%	1.8%	1.6%

Variable	PDSS-Participating MA-PDs	PDSS-Participating PDPs	Eligible Nonparticipating MA-PDs	Eligible Nonparticipating PDPs
Probability White	68.4%	86.6%	68.4%	87.4%
RxHCC kidney disease	0.5% ***	0.5% *	0.4%	0.5%
RxHCC high cholesterol	86.2% *	85.2% ***	85.0%	83.9%
RxHCC CHF	23.5% ***	21.8% ***	19.7%	21.4%
RxHCC hypertension	66.4% ***	68.4%	68.5%	67.0%
Long-acting insulin fills	78.7% ***	82.2%	61.7%	80.2%
Intermediate-acting insulin fills	5.1% ***	4.1%	23.6%	5.5%
Pen fills	73.8% ***	80.8% ***	64.5%	79.8%
Vial fills	29.9% ***	23.9% ***	40.4%	22.5%
Median income for service area	$59,868 *** (12184)	$64,215 (10396)	$67,595 (15503)	$65,051 (9918)
Urbanicity of service area	1.86 (0.21)	1.70 (0.23)	1.87 (0.23)	1.72 (0.22)
Plan deductible	$92.75 (117.23)	$143.25 *** (194.69)	$71.78 (119.42)	$276.87 (205.24)
Inpatient stays (*n*)	0.27 ** (0.69)	0.36 (0.84)	0.25 (0.67)	0.37 (0.86)
ED visits (*n*)	0.57 (1.12)	0.64 ** (1.19)	0.57 (1.14)	0.65 (1.19)

SOURCE: Authors' analysis of Part D beneficiary and other data. For a complete list of datasets and covariates, please see Tables A.1 and A.2.
NOTE: Standard deviations are shown in parentheses. *** *p*-value < 0.01; ** *p*-value < 0.05; * *p*-value < 0.10; *p*-values are calculated as *t*-tests for the difference in means across groups clustering by plan.

Table A.6 presents descriptive statistics for noninsulin users for 2020.

Table A.6. Noninsulin User Descriptive Statistics, 2020

Variable	PDSS-Participating MA-PDs	PDSS-Participating PDPs	Eligible Nonparticipating MA-PDs	Eligible Nonparticipating PDPs
Age	73.91 (7.88)	76.04 *** (7.53)	74.02 (7.81)	73.79 (6.70)
% female	54.6%	58.4% ***	54.7%	57.5%
Any noninsulin antidiabetic medication	17.5% ***	15.3% ***	15.3%	12.8%
Probability American Indian / Alaska Native	0.3%	0.3%	0.3%	0.3%
Probability Asian / Pacfic Islander	3.4% ***	1.8%	5.8%	2.1%
Probability Black	8.0%	3.1%	7.2%	2.4%
Probability Hispanic	10.9%	2.8%	9.0%	2.7%
Probability Multiracial	1.6%	1.5%	1.6%	1.5%
Probability White	75.7%	90.4%	76.1%	91.0%
RxHCC kidney disease	0.1% ***	0.1% ***	0.1%	0.1%
RxHCC high cholesterol	65.6% ***	66.2% ***	62.9%	62.5%
RxHCC CHF	11.1% ***	10.2% ***	8.6%	7.2%
RxHCC hypertension	56.0% ***	59.3% ***	54.6%	54.6%
Median income for service area	$61,520 *** (12384)	$64,696 (10499)	$67,817 (15490)	$65,212 (10110)
Urbanicity of service area	1.87 (0.20)	1.69 (0.25)	1.87 (0.23)	1.71 (0.24)
Plan deductible	$105.27 (123.50)	$225.41 *** (214.42)	$91.77 (131.99)	$387.60 (131.03)

Variable	PDSS-Participating MA-PDs	PDSS-Participating PDPs	Eligible Nonparticipating MA-PDs	Eligible Nonparticipating PDPs
Inpatient stays	0.11 ***	0.16 ***	0.10	0.13
	(0.41)	(0.52)	(0.39)	(0.47)
ED visits	0.30 ***	0.35 ***	0.28	0.29
	(0.76)	(0.84)	(0.75)	(0.75)

SOURCE: Authors' analysis of Part D beneficiary and other data. For a complete list of datasets and covariates, please see Tables A.1 and A.2.
NOTE: Standard deviations are shown in parentheses. *** *p*-value < 0.01; ** *p*-value < 0.05; * *p*-value < 0.10; *p*-values are calculated as *t*-tests for the difference in means across groups clustering by plan.

Overview of Regression Models and Sample Size

Tables A.7 and A.8 provide the sample sizes for the plan- and beneficiary-level regression models, respectively.

Table A.7. Plan-Level Regression Models and Sample Sizes

Comparison Group	Number of Participating Plans	Number of Comparison Plans	Number of Plan-Year Observations
Main quantitative results			
Eligible Nonparticipating MA-PDs	1,184	1,700	7,085
Eligible Nonparticipating PDPs	310	208	1,285
Sensitivity analysis			
All Nonparticipating MA-PDs	1,184	1,887	7,565
All Nonparticipating PDPs	310	594	2,400

SOURCE: Authors' analysis of Part D beneficiary and other data. For a complete list of datasets and covariates, please see Tables A.1 and A.2.

Table A.8. Beneficiary-Level Regression Models and Sample Sizes

Plan Type	Comparison Group	Beneficiary Sample	Number of Beneficiaries in Participating Plans	Number of Beneficiaries in Comparison Plans	Number of Beneficiary-Year Observations
Main quantitative results					
MA-PD	Eligible Nonparticipating	Insulin Users	181,456	125,712	857,912
MA-PD	Eligible Nonparticipating	Noninsulin Users	3,797,207	2,924,550	18,834,729
PDP	Eligible Nonparticipating	Insulin Users	151,566	30,825	521,270
PDP	Eligible Nonparticipating	Noninsulin Users	3,158,789	1,313,054	12,709,421
Sensitivity analysis					
MA-PD	All Nonparticipating	Insulin Users	181,456	127,454	862,719
MA-PD	All Nonparticipating	Noninsulin Users	3,797,207	2,958,669	18,928,906
PDP	All Nonparticipating	Insulin Users	151,566	149,301	857,053
PDP	All Nonparticipating	Noninsulin Users	3,158,789	3,998,124	20,381,963

SOURCE: Authors' analysis of Part D beneficiary and other data. For a complete list of datasets and covariates, please see Tables A.1 and A.2.

Characteristics of Beneficiaries Who Switched Plans

Beneficiaries who switched into PDSS-participating plans in 2021 and utilized insulin in 2021 may have different characteristics from the beneficiaries included in the insulin users sample for the DD regression models. To assess the extent to which these samples differed, we identified beneficiaries who were not LIS-eligible, who were enrolled in a PDSS-participating plan as of July 1, 2021, who were enrolled in a different plan in December 2020, and who had at least one insulin fill in 2021. We compared their characteristics to beneficiaries in our MA-PD and PDP insulin user samples.

Table A.9 shows the characteristics of beneficiaries with at least one insulin fill in 2021 who switched into PDSS-participating MA-PDs or PDPs in 2021 (who we refer to as "switchers"), along with beneficiaries in the insulin user samples. We found that 66,667 beneficiaries switched into PDSS-participating MA-PDs and 55,709 beneficiaries switched into PDSS-participating PDPs, compared with 181,456 and 151,566 beneficiaries in our insulin user MA-PD and PDP samples, respectively. Insulin users were older on average than beneficiaries who switched into PDSS-participating plans, and PDP switchers were less likely to be female. Fewer insulin users in MA-PDs were originally entitled to Medicare due to disability, compared with the switchers. While switchers had similar average Part D risk scores, we did find differences by race/ethnicity and similar rates of chronic conditions, and switchers were less likely to have high cholesterol compared with insulin users. We found higher average numbers of monthly Part D fills for MA-PD switchers and lower average fills for PDP switchers, and higher average number of ED visits for switchers in both MA-PDs and PDPs.

These findings suggest that the sample of switchers who used insulin in 2021 may have differed from beneficiaries previously enrolled in the plan and who used insulin in 2020. We will explore PDSS Model outcomes for switchers in greater detail in the final evaluation report.

Table A.9. Sample Characteristics of Switchers Versus Insulin Users

Characteristic	MA-PD Switchers	MA-PD Insulin Users	PDP Switchers	PDP Insulin Users
N	66,667	181,456	55,709	151,566
Age (average years)	71.7 ***	74.9	72.7 ***	77.2
Female	48.5% ***	47.3%	44.5% ***	48.0%
Originally entitled to Medicare due to disability	31.5% ***	25.9%	15.3%	15.3%
Part D risk score	1.3 ***	1.3	1.2 ***	1.3
Race/ethnicity				
American Indian	0.4% *	0.4%	0.3% ***	0.4%
Asian / Pacific Islander	3.1%	2.9%	1.9%	2.1%
Black	14.0% ***	12.0%	3.4% ***	5.3%
White	66.6%	68.4%	89.8% ***	86.6%
Hispanic	13.8%	14.4%	3.0% **	3.8%
Multiracial	2.0% ***	1.8%	1.6%	1.7%
Chronic conditions				
Kidney disease	0.6% **	0.5%	0.6% **	0.5%
High cholesterol	83.4% ***	86.2%	82.5% ***	85.2%
Congestive Heart Failure	22.6% ***	23.5%	19.0% ***	21.8%
Hypertension	65.1% ***	66.4%	67.6% **	68.4%
Utilization of Part D drugs and health care services				
Average number of monthly Part D fills	3.9 ***	3.8	4.1	4.2
Number of inpatient stays	0.4 ***	0.3	0.4 ***	0.4
Number of ED visits	0.9 ***	0.6	0.7 ***	0.6

SOURCE: Authors' analysis of Medicare enrollment and other data. Please see Appendix Table A.2 for further details on variables.

NOTE: Switchers are beneficiaries who were not LIS-eligible, who switched into PDSS-participating plans in 2021, and had at least one insulin fill in 2021. *** *p*-value < 0.01; ** *p*-value < 0.05; * *p*-value < 0.10; *p*-values are calculated as *t*-tests for the difference in means across groups clustering by plan.

Appendix B. Outcome Measures

This appendix describes the methods of quantitative data collection and analysis used in this report. We analyzed secondary data on plan and beneficiary 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 and Medicare.

Access Measures

We have 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 the 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 first 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 may use more than one type of insulin. We think this measure is likely the most sensitive to changes in cost sharing for insulin.

Medication possession ratios. We calculated a MPR measure within specific insulin types: rapid- and short-acting (rapid/short), mixed, and concentrated. The MPR calculates the total days supplied and divides 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). Once a user has initiated a fill of the given insulin type, we treat them as an existing user both for the remainder of the current calendar year and for the following calendar year. We used the MPR because we wanted to see whether the Model test influences the total days supplied for the type of insulin; more-conservative measures, such as 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 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.

Persistence to basal insulin. The most complex measure we use is the Pharmacy Quality Alliance's Persistence to Basal Insulin measure (PST-INS; Pharmacy Quality Alliance, 2022).

The PST-INS focuses on intermediate- and long-acting insulins only, because these types of insulins are more commonly used on a regular basis than rapid/short insulins. It 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.

Enrollment and Benefit Phase Measures

We assessed the effect of the Model test on a plan's total enrollment and on the number of beneficiaries newly enrolling in the plan. We also assessed changes in enrollment by insulin users and noninsulin users separately. We also examined PDSS Model 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 considered LIS-eligible).

Enrollment. We calculated our enrollment measures using enrollment as of July 1st 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 insulin users and noninsulin users within each calendar year and separate from our beneficiary-level regression model samples, because we wished to identify insulin use (and nonuse) within the calendar year itself and not only in 2020, 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. We defined *new enrollment* as beneficiaries enrolled on July 1st who were enrolled in a different plan as of December of the preceding year.

Benefit phase progression. We also evaluated the effect of the PDSS Model on beneficiary progression through the different phases of the Part D benefit: deductible, initial coverage, coverage gap, and catastrophic. Progression through the benefit phases is determined by different cost measures for different phases. Beneficiary spending determines when a beneficiary exits the deductible. 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 is in the catastrophic phase, costs for each fill are split between the beneficiary, plans, and CMS.

Reducing beneficiary OOP costs for insulins through the first three benefit phases may increase utilization of insulins, as well as possibly other prescription drugs. Increased utilization may move the beneficiary 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 the beneficiary spends in the gap and may reduce the time the beneficiary spends in the

catastrophic phase. Changes in the time spent in each benefit phase has cost implications for beneficiaries, plans, manufacturers, and CMS.

The PDE data provide information on which benefit phase the beneficiary was in at the beginning of the fill and in which benefit phase the beneficiary was after accounting for the costs of the specific fill. 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 the beneficiary spent in each phase. Beneficiaries with no fills spent zero 30-day periods in each benefit phase. In addition to evaluating the amount of time spent in the benefit phases, we also constructed separate measures of whether the beneficiary ended the year in the coverage gap or catastrophic phase. An increase in the likelihood of ending the year in the coverage gap implies a reduction in reinsurance costs, incurred in the catastrophic phase, for CMS.

Bids, Premiums, and Spending Measures

These outcome measures capture different aspects of costs associated with Part D coverage that are paid by different parties, including OOP spending by beneficiaries, gross drug spending (which is split between plans, beneficiaries, manufacturers, and CMS), and costs to CMS.

Beneficiary spending comprises both OOP spending on prescription drugs and premiums paid by beneficiaries. Other cost measures are defined and modeled at the plan level (rather than the beneficiary level). Gross drug costs reflect the total amount of spending on prescription drugs (including both plan payments and beneficiary cost sharing) prior to manufacturer rebates or reinsurance payments from CMS. Other cost measures are defined and modeled at the plan level (rather than the beneficiary level). Plan bids for Part D coverage play an important role in determining the monthly capitation payment that plans receive during the coverage year. Plan bids also have a major influence on beneficiary premiums, which affect plan choice and are an important component of overall beneficiary cost sharing. Manufacturer rebates and other forms of DIR are negotiated payments from manufacturers to plans. Rebates and other DIR payments can be substantial and, thus, have an important impact on the net cost to plans in providing Part D coverage. Examining these outcomes jointly allows us to describe how plans and manufacturers have responded to the PDSS Model, while also characterizing the implications for beneficiary premiums and the net effect of PDSS Model changes on gross drug costs.

We also examined final Part D costs to CMS. Final costs to CMS reflect not only the prospectively determined capitation payments provided to plans during the coverage year but also reconciliation payments that account for the actual (ex post) values of beneficiary risk scores, for reinsurance of prescription drug costs in the catastrophic benefit phase, and for risk corridor payments through which plans shared the risk of excess profits or losses with CMS.

Units of Observation and Interpretation of PDSS Model Impacts on Bid, Premium, and Spending Outcomes

We analyzed PDSS Model impacts on OOP costs using beneficiary-level regression models (see Appendix A for details) in which an observation corresponds to a beneficiary-year.

Estimated PDSS Model impacts on OOP cost measures therefore reflect changes in the annual amount of OOP costs owed by beneficiaries. Gross drug costs (defined below) are also analyzed using the beneficiary-year as the unit of observation.

We analyzed plan-level measures, which we observed at the plan-year level, using the plan-year as the unit of observation. To facilitate the comparison of bid and cost results across models, we define all plan-level bid and cost outcomes on a PMPM basis.

In some places, we discuss how changes in beneficiaries' annual gross drug spending and annual OOP costs (estimated using beneficiary-level models) compare with PDSS Model impacts on plan-level outcomes. However, we caution that there are differences in the population of interest between plan-level and beneficiary-level analyses. In particular, we estimated regression results for PDSS Model impacts on premiums—which are of interest both as a plan-level outcome and as a component of beneficiary OOP spending—at the *plan* level, while estimating impacts on OOP costs at the *beneficiary* level.

Beneficiary Spending

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 2021 plan for all 24 months from 2020 to 2021. We excluded LIS-eligible beneficiaries from our analysis of OOP costs because they were not eligible for the PDSS Model.

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 PDSS Model-eligible insulins, and OOP costs for all noninsulin drugs.

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 plans' Part D bids) and a supplemental premium that pays for enhanced coverage, which can be expressed as:

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

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 analyze Part D premiums for MA-PDs after rebates have been applied. This premium measure captures the premium that is owed by beneficiaries who are ineligible for LIS. We do not incorporate premium reductions due to LIS because LIS-eligible beneficiaries are not targeted by the PDSS Model.

Total Part D Costs

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 we use (as described above) accounts for reductions in the premium for MA-PDs that use the MA rebate to lower Part D premiums.

Gross Drug Costs

In addition to beneficiary OOP spending, we also examined gross drug costs, which we defined as total annual spending on Part D-covered prescription drugs before manufacturer rebates or federal reinsurance are received. 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 Model impacts on OOP spending.

The PDSS Model 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 non-catastrophic benefit phases. By making beneficiary cost sharing for insulin more predictable and affordable, the PDSS Model is expected to increase adherence, which in turn may 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 may also be shaped by changes in plans' benefit design made in response to the PDSS Model, while negotiations with manufacturers over discounts, rebates, and formulary placement of noninsulin drugs could also potentially be affected by the Model test.

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.

Reinsurance

We used the final reinsurance payment amounts from the Payment Reconciliation System (PRS) data, calculated as a plan-level measure of PMPM reinsurance rates. Final reinsurance payments to plans are calculated 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 plan DIR received by a plan, and *GDCB* is gross drug spending below the catastrophic phase.

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 (for example, 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 copays). 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 the PDSS Model on manufacturer rebates is thus an outcome of interest for our evaluation.

The likely impact of the PDSS Model on rebates for noninsulin drugs sold by PDSS-participating manufacturers, or on rebates from other manufacturers, is unclear, because the utilization impacts of the PDSS Model 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 provided to the study team 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 test 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 test continue to pay 70% of insulin costs in the coverage gap while beneficiary OOP costs are capped at $35 per one-month supply. The PDSS Model might increase the number of insulin fills in the coverage gap and might 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 the PDSS Model 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) to eligible nonparticipating plans.

Plan Bids and Administrative Costs

The CMS Office of the Actuary (OACT) provided data on plan bids to the study team. We extracted bids and other related variables from the Part D Bid Pricing Tool, an 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.

In order to capture the PDSS Model's 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.

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 ends. 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 Model 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 Model 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:

- 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 (discussed above) 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 reinsurance payment amounts reported in the PRS data in our analysis.

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. LIPS payments for each plan were derived 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. These counts of LIS member-months were then multiplied by plan-level LIPS payment amounts reported in HPMS and aggregated to the plan level to obtain the total LIPS payment for each plan.

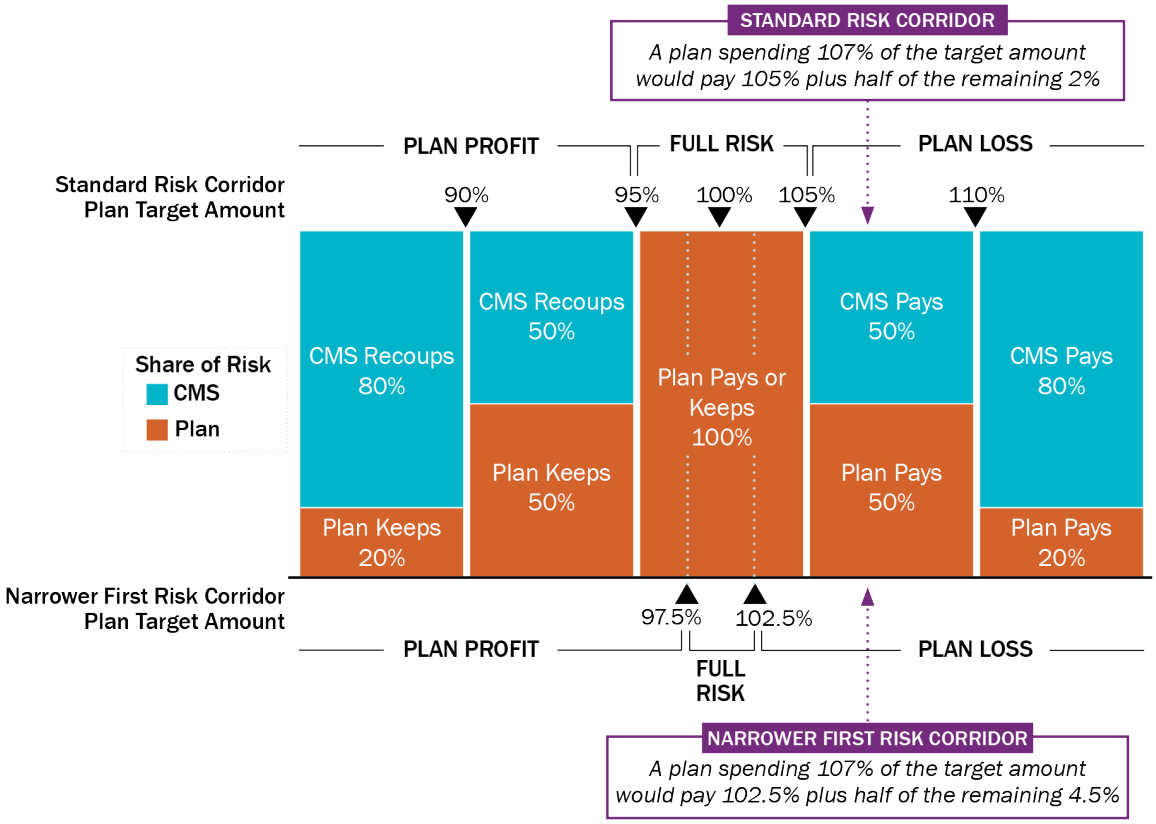
Risk corridor payments are made to share unanticipated plan profits and losses with CMS. The risk corridor involves comparison of allowed costs (drug costs paid by the plan, net of federal reinsurance and DIR, and subject to an adjustment for induced utilization) to a target amount (the risk-adjusted 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 Model evaluation report, illustrates the structure of the risk corridor in Part D and the optional narrower first risk corridor component of the PDSS Model.

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 test 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:

Allowed Costs = (CPP – Reinsurance – Total DIR) / 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.

Appendix C. Detailed Regression Results for Main Models

This appendix reports DD regression estimates for the models that we present in Chapters 3, 4, and 5. Each section shows a full regression table (including all covariates other than plan fixed effects), followed by a series of shorter tables reporting only the DD estimate of the Model test effect. Beneficiary-level models in this appendix compare beneficiaries in PDSS-participating plans (either insulin users or noninsulin users, depending on the outcome) with a comparably defined population of beneficiaries in plans that were eligible to participate in the PDSS Model but chose not to. Models for MA-PDs and PDPs are estimated separately. Similar regression results for sensitivity analyses that use a less narrowly defined group of comparison plans (that is, all nonparticipating plans) are presented in Appendix D.

Access Regression Results

Regression results reported in Chapter 3 are from beneficiary-level regression models in which an observation is a beneficiary-year and beneficiaries in PDSS-participating plans are compared with beneficiaries in eligible nonparticipating plans. See Appendix A for details on sample definition and model specification.

Table C.1. shows the full set of regression coefficients for one of the access outcomes, number of 30-day insulin fills, for MA-PDs.

Table C.1. Detailed Regression Results for Number of 30-Day Insulin Fills, MA-PDs

Variable	Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Year 2021 indicator	–0.57	0.03	0.00	–0.62	–0.51
DD effect	0.89	0.04	0.00	0.81	0.97
Age	0.01	0.00	0.00	0.00	0.02
Female	0.05	0.02	0.01	0.01	0.09
Originally entitled due to disability and ESRD	0.20	0.23	0.38	–0.25	0.65
Originally entitled due to disability	–0.65	0.02	0.00	–0.70	–0.61
Originally entitled due to ESRD	0.26	0.24	0.27	–0.21	0.73
Reached catastrophic phase in 2020	5.78	0.06	0.00	5.65	5.91
Reached coverage gap phase in 2020	2.91	0.04	0.00	2.84	2.98
RxHCC score	–0.44	0.02	0.00	–0.47	–0.40
American Indian / Alaska Native	0.02	0.39	0.95	–0.74	0.79
Asian / Pacific Islander	0.04	0.07	0.56	–0.10	0.18
Black	–0.69	0.04	0.00	–0.77	–0.60
Hispanic	–0.42	0.04	0.00	–0.50	–0.34
Multiracial	–3.39	0.78	0.00	–4.92	–1.86
RxHCC flag - kidney disease	–0.21	0.11	0.06	–0.43	0.01
RxHCC flag - high cholesterol	0.31	0.03	0.00	0.25	0.37
RxHCC flag - CHF	–0.25	0.05	0.00	–0.33	–0.16

Variable	Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
RxHCC flag - hypertension	0.31	0.04	0.00	0.24	0.39
Average area income	0.00	0.00	0.01	0.00	0.00
Urbanicity	0.22	0.41	0.59	–0.59	1.03
Star Ratings - getting needed drugs	–0.07	0.02	0.00	–0.12	–0.03
Star Ratings - getting needed drugs (missing)	–0.32	0.15	0.03	–0.61	–0.03
Star Ratings - diabetes medication adherence	0.02	0.03	0.47	–0.04	0.09
Star Ratings–diabetes medication adherence (missing)	–0.01	0.20	0.96	–0.40	0.38
Number of Part D fills per month (2020)	0.27	0.01	0.00	0.24	0.30
Number of inpatient stays (2020)	–0.54	0.02	0.00	–0.58	–0.50
Number of ED visits (2020)	–0.31	0.01	0.00	-0.34	–0.29
Any use of noninsulin antidiabetic medications (2020)	–2.09	0.03	0.00	–2.15	–2.04
Year 2019 indicator	–0.95	0.03	0.00	–1.01	–0.90

SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources and variables.
NOTES: 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 eligible nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021. *N* = 848,830 for MA-PDs. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Table C.2 shows all regression coefficients for the number of 30-day insulin fills for PDPs.

Table C.2. Detailed Regression Results for Number of 30-Day Insulin Fills, PDPs

Variable	Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Year 2021 indicator	–0.92	0.09	0.00	–1.10	–0.73
PDSS implementation indicator	0.95	0.10	0.00	0.75	1.15
Age	0.01	0.00	0.00	0.00	0.01
Female	–0.03	0.02	0.27	–0.07	0.02
Originally entitled due to disability and ESRD	–0.06	0.20	0.76	–0.46	0.33
Originally entitled due to disability	–0.62	0.04	0.00	–0.71	–0.54
Originally entitled due to ESRD	0.13	0.18	0.45	–0.21	0.48
Reached catastrophic phase in 2020	6.25	0.05	0.00	6.15	6.34
Reached coverage gap phase in 2020	3.22	0.03	0.00	3.16	3.28
RxHCC score	–0.41	0.02	0.00	–0.45	–0.37
American Indian / Alaska Native	–0.75	0.38	0.05	–1.49	0.00
Asian / Pacific Islander	0.16	0.09	0.09	–0.02	0.34
Black	–0.81	0.07	0.00	–0.95	–0.67
Hispanic	–0.40	0.09	0.00	–0.58	–0.23
Multiracial	–1.01	0.97	0.30	–2.91	0.89
RxHCC flag - kidney disease	–0.11	0.14	0.43	–0.39	0.17
RxHCC flag - high cholesterol	0.28	0.04	0.00	0.21	0.35
RxHCC flag - CHF	–0.46	0.05	0.00	–0.56	–0.37
RxHCC flag - hypertension	0.18	0.04	0.00	0.10	0.25
Average area income	0.00	0.00	0.05	0.00	0.00
Urbanicity	2.25	1.31	0.08	–0.31	4.82
Star Ratings - getting needed drugs	0.21	0.03	0.00	0.15	0.28

Variable	Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Star Ratings - diabetes medication adherence	0.13	0.03	0.00	0.06	0.19
Number of Part D fills per month (2020)	0.15	0.01	0.00	0.13	0.16
Number of inpatient stays (2020)	–0.50	0.02	0.00	–0.54	–0.46
Number of ED visits (2020)	–0.23	0.01	0.00	–0.26	–0.20
Year 2019 indicator	–2.32	0.04	0.00	–2.39	–2.25

SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources and variables.
NOTES: 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 eligible nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021. *N* = 509,662 for PDPs. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Table C.3 shows the full set of DD coefficients from all access outcome models for MA-PDs, which are the same as those presented in Chapter 3.

Table C.3. Difference-in-Differences Coefficients for Access Models, MA-PDs

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Number of 30-day insulin fills	0.89	0.04	0.00	0.81	0.97
Rapid/short MPR	0.03	0.00	0.00	0.03	0.04
Mixed MPR	0.03	0.01	0.00	0.02	0.04
Concentrated MPR	0.01	0.02	0.65	–0.02	0.04
Persistence to basal insulin	0.02	0.00	0.00	0.02	0.03

SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table shows coefficients on the DD effect from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in eligible nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021. *N* = 848,830 for MA-PDs. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Similarly, Table C.4 shows the full set of DD coefficients from all access outcome models for PDPs, which are the same as those presented in Chapter 3.

Table C.4. Difference-in-Differences Coefficients for Access Models, PDPs

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Number of 30-day insulin fills	0.95	0.10	0.00	0.75	1.15
Rapid/short MPR	0.05	0.01	0.00	0.04	0.07
Mixed MPR	0.07	0.01	0.00	0.05	0.09
Concentrated MPR	–0.01	0.02	0.69	–0.05	0.03
Persistence to basal insulin	0.01	0.00	0.00	0.00	0.02

SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table shows coefficients on the DD effect from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in eligible nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021. *N* = 509,662 for PDPs. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Enrollment and Benefit Phase Regression Results

Chapter 4 includes our plan-level analyses of enrollment and our beneficiary-level analyses of how much time beneficiaries spent in different phases of the Part D benefit.

Enrollment

Regression results for plan enrollment reported in Chapter 4 are from plan-level regression models, in which an observation is a plan-year and PDSS-participating plans are compared with eligible nonparticipating plans. Because enrollment varies widely across plans, we analyzed outcome variables in the enrollment analyses on a logarithmic scale, with one added to accommodate zero values. That is, for an outcome variable of interest *y*, the outcome used in the regression model is *ln(1+y)*. See Appendix A for additional details on sample definition and model specification.

Table C.5 shows the full set of DD coefficients from all enrollment outcome models for MA-PDs.

Table C.5. Difference-in-Differences Coefficients for Enrollment Models, MA-PDs

Enrollment Outcome	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Total enrollment	0.10	0.02	0.00	0.05	0.14
New enrollees	0.23	0.04	0.00	0.14	0.31
Insulin users	0.24	0.02	0.00	0.19	0.29
Noninsulin users	0.08	0.02	0.00	0.03	0.13
LIS eligible	0.07	0.02	0.00	0.02	0.12
Dually eligible	0.05	0.02	0.03	0.01	0.10
Below age 65	0.07	0.02	0.00	0.03	0.12
Ages 65 to 74	0.10	0.03	0.00	0.05	0.15
Ages 75 to 84	0.09	0.02	0.00	0.04	0.14
Ages 85 and over	0.07	0.02	0.00	0.02	0.12
American Indian / Alaska Native	0.07	0.02	0.00	0.03	0.10
Asian / Pacific Islander	0.09	0.02	0.00	0.04	0.13
Black	0.07	0.02	0.00	0.03	0.12
Hispanic	0.08	0.02	0.00	0.04	0.13
Multiracial	0.08	0.02	0.00	0.04	0.12
White	0.10	0.02	0.00	0.05	0.14
Diabetic (based on RxHCC)	0.10	0.02	0.00	0.06	0.15

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

NOTES: This table shows coefficients on the PDSS Model implementation indicator from the plan-level DD regression model. The comparison groups consisted of eligible nonparticipating plans. The *N* represents the number of plans included in the analyses across all three years of data. *N* = 7,085 plan-years for MA-PDs. 95% CIs are based on plan-clustered standard errors. See Appendix A for additional technical details.

Table C.6 shows the full set of DD coefficients from all enrollment outcome models for PDPs.

Table C.6. Difference-in-Differences Coefficients for Enrollment Models, PDPs

Enrollment Outcome	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Total enrollment	–0.55	0.06	0.00	–0.66	–0.44
New enrollees	0.23	0.09	0.01	0.05	0.40
Insulin users	–0.16	0.07	0.03	–0.30	–0.01
Noninsulin users	–0.57	0.06	0.00	–0.68	–0.45
LIS	–0.56	0.05	0.00	–0.66	–0.46
Dually eligible	–0.56	0.05	0.00	–0.66	–0.46
Below age 65	–0.51	0.05	0.00	–0.62	–0.40
Non-LIS eligible	–0.59	0.06	0.00	–0.70	–0.47
Ages 65 to 74	–0.53	0.06	0.00	–0.64	–0.42
Ages 75 to 84	–0.54	0.05	0.00	–0.65	–0.44
Ages 85 and over	–0.48	0.05	0.00	–0.57	–0.38
American Indian / Alaska Native	–0.49	0.05	0.00	–0.60	–0.39
Asian / Pacific Islander	–0.50	0.05	0.00	–0.60	–0.39
Black	–0.49	0.05	0.00	–0.59	–0.39
Hispanic	–0.53	0.05	0.00	–0.63	–0.42
Multiracial	–0.55	0.06	0.00	–0.66	–0.44
White	–0.47	0.06	0.00	–0.58	–0.36
Diabetic (based on RxHCC)	0.23	0.09	0.01	0.05	0.40

SOURCE: Authors' analysis of Part D enrollment and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTES: This table shows coefficients on the PDSS Model implementation indicator from the plan-level DD regression model. The comparison groups consisted of eligible nonparticipating plans. The *N* represents the number of plans included in the analyses across all three years of data. *N* = 1,285 plan-years for PDPs. 95% CIs are based on plan-clustered standard errors. See Appendix A for additional technical details.

Benefit Phases

Regression results for benefit phase outcomes reported in Chapter 4 are from beneficiary-level regression models in which an observation is a beneficiary-year and beneficiaries in PDSS-participating plans are compared with beneficiaries in eligible nonparticipating plans. See Appendix A for additional details on sample definition and model specification.

Table C.7 shows the full set of regression coefficients for one of the benefit phase outcomes, the number of 30-day periods spent in the coverage gap, for insulin users in MA-PDs.

Table C.7. Detailed Regression Results for Number of 30-Day Periods Spent in the Coverage Gap, Insulin Users in MA-PDs

Variable	Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Year 2021 indicator	0.04	0.01	0.00	0.03	0.06
DD effect	0.05	0.01	0.00	0.03	0.08
Age	–0.01	0.00	0.00	–0.01	–0.01
Female	–0.09	0.01	0.00	–0.10	–0.07

Variable	Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Originally entitled due to disability and ESRD	–0.26	0.06	0.00	–0.37	–0.15
Originally entitled due to disability	–0.24	0.01	0.00	–0.26	–0.22
Originally entitled due to ESRD	–0.10	0.06	0.10	–0.21	0.02
RxHCC score	0.00	0.00	0.41	–0.01	0.01
American Indian / Alaska Native	0.53	0.12	0.00	0.29	0.77
Asian / Pacific Islander	–0.15	0.02	0.00	–0.19	–0.11
Black	–0.25	0.01	0.00	–0.28	–0.23
Hispanic	–0.20	0.02	0.00	–0.25	–0.16
Multiracial	–0.59	0.21	0.01	–1.01	–0.17
RxHCC flag - kidney disease	–0.03	0.04	0.40	–0.11	0.04
RxHCC flag - high cholesterol	0.08	0.01	0.00	0.06	0.10
RxHCC flag - CHF	0.11	0.01	0.00	0.09	0.14
RxHCC flag - hypertension	0.00	0.01	0.68	–0.02	0.02
Average area income	0.00	0.00	0.90	0.00	0.00
Urbanicity	0.00	0.10	0.97	–0.20	0.21
Star Ratings - getting needed drugs	0.01	0.01	0.08	0.00	0.02
Star Ratings - getting needed drugs (missing)	0.07	0.05	0.11	–0.02	0.16
Star Ratings - diabetes medication adherence	0.01	0.01	0.29	–0.01	0.03
Star Ratings - diabetes medication adherence (missing)	–0.02	0.07	0.70	–0.15	0.10
Number of Part D fills per month (2020)	0.17	0.00	0.00	0.17	0.18
Number of inpatient stays (2020)	–0.02	0.01	0.00	–0.03	–0.01
Number of ED visits (2020)	–0.05	0.00	0.00	–0.05	–0.04
Number of 30-day insulin fills (2020)	0.06	0.00	0.00	0.06	0.07
Any use of noninsulin antidiabetic medication (2020)	0.31	0.01	0.00	0.29	0.33
Number of rapid-acting insulin fills (2020)	0.19	0.01	0.00	0.17	0.21
Number of long-acting insulin fills (2020)	–0.09	0.01	0.00	–0.11	–0.06
Number of intermediate-acting insulin fills (2020)	–0.33	0.02	0.00	–0.37	–0.29
Number of pen insulin fills (2020)	0.20	0.01	0.00	0.18	0.23
Number of vial insulin fills (2020)	0.02	0.01	0.16	–0.01	0.04
Year 2019 indicator	0.01	0.01	0.01	0.00	0.03

SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources.

NOTES: 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 eligible nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021. Beneficiaries eligible for the LIS were excluded from the analysis. *N* = 848,830 for MA-PDs. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Table C.8 shows the full set of regression coefficients for one of the benefit phase outcomes, the number of 30-day periods spent in the coverage gap, for insulin users in PDPs.

Table C.8. Detailed Regression Results for Number of 30-Day Periods Spent in the Coverage Gap, Insulin Users in PDPs

Variable	Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Year 2021 indicator	0.05	0.01	0.00	0.03	0.08
DD effect	0.02	0.01	0.20	–0.01	0.04
Age	–0.03	0.00	0.00	–0.03	–0.02

Variable	Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Female	–0.17	0.01	0.00	–0.19	–0.15
Originally entitled due to disability and ESRD	–0.30	0.07	0.00	–0.43	–0.16
Originally entitled due to disability	–0.38	0.01	0.00	–0.40	–0.35
Originally entitled due to ESRD	–0.27	0.06	0.00	–0.38	–0.16
RxHCC score	0.00	0.01	0.88	–0.01	0.01
American Indian / Alaska Native	0.47	0.16	0.00	0.15	0.78
Asian / Pacific Islander	–0.24	0.03	0.00	–0.29	–0.19
Black	–0.35	0.02	0.00	–0.40	–0.30
Hispanic	–0.39	0.03	0.00	–0.45	–0.34
Multiracial	–0.87	0.34	0.01	–1.55	–0.19
RxHCC flag - kidney disease	–0.08	0.06	0.17	–0.20	0.04
RxHCC flag - high cholesterol	0.17	0.01	0.00	0.14	0.19
RxHCC flag - CHF	0.22	0.02	0.00	0.18	0.25
RxHCC flag - hypertension	0.06	0.01	0.00	0.03	0.09
Average area income	0.00	0.00	0.67	0.00	0.00
Urbanicity	0.69	0.36	0.06	–0.02	1.40
Star Ratings - getting needed drugs	0.01	0.01	0.10	0.00	0.02
Star Ratings - diabetes medication adherence	–0.01	0.01	0.59	–0.03	0.02
Number of Part D fills per month (2020)	0.18	0.00	0.00	0.18	0.19
Number of inpatient stays (2020)	–0.02	0.01	0.02	–0.03	0.00
Number of ED visits (2020)	–0.05	0.00	0.00	–0.06	–0.04
Number of 30-day insulin fills (2020)	0.08	0.00	0.00	0.08	0.09
Number of rapid-acting insulin fills (2020)	0.45	0.01	0.00	0.43	0.47
Number of long-acting insulin fills (2020)	0.13	0.02	0.00	0.10	0.16
Number of intermediate-acting insulin fills (2020)	–0.17	0.02	0.00	–0.21	–0.13
Number of pen insulin fills (2020)	–0.56	0.02	0.00	–0.61	–0.51
Number of vial insulin fills (2020)	0.32	0.03	0.00	0.27	0.37
Year 2019 indicator	0.10	0.02	0.00	0.05	0.15

SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources and variables.
NOTES: 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 eligible nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021. Beneficiaries eligible for the LIS were excluded from the analysis. *N* = 509,662 for PDPs. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Table C.9 shows the full set of DD coefficients from all benefit phase outcome models for MA-PDs, which are the same as those presented in Chapter 4.

Table C.9. Difference-in-Differences Coefficients for Beneficiary-Level Benefit Phase Models, MA-PDs

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Insulin users					
Number of 30-day periods in initial coverage	0.03	0.02	1.24	0.22	–0.02
Number of 30-day periods in coverage gap	0.05	0.01	4.02	0.00	0.03
Number of 30-day periods in catastrophic	–0.08	0.01	–7.21	0.00	–0.10
Ended year in coverage gap	0.03	0.00	0.00	0.02	0.03
Ended year in catastrophic	–0.01	0.00	0.00	–0.01	0.00

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Noninsulin users					
Number of 30-day periods in initial coverage	0.02	0.01	2.35	0.02	0.00
Number of 30-day periods in coverage gap	0.00	0.00	0.67	0.50	0.00
Number of 30-day periods in catastrophic	0.00	0.00	0.01	0.99	0.00
Ended year in coverage gap	0.00	0.00	0.00	0.00	0.01
Ended year in catastrophic	0.00	0.00	0.69	0.00	0.00

SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table shows coefficients on the PDSS Model implementation indicator from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in eligible nonparticipating plans. Insulin users and noninsulin users must have been continuously enrolled in the same plan for all of 2020 and 2021. Beneficiaries eligible for the LIS were excluded from the analysis. *N* = 848,830 for insulin users and *N* = 17,219,502 for noninsulin users. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Table C.10 shows the full set of DD coefficients from all benefit phase outcome models for PDPs, which are the same as those presented in Chapter 4.

Table C.10. Difference-in-Differences Coefficients for Beneficiary-Level Benefit Phase Models, PDPs

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Insulin users					
Number of 30-day periods in initial coverage	0.01	0.03	0.79	–0.05	0.06
Number of 30-day periods in coverage gap	0.02	0.01	0.20	–0.01	0.04
Number of 30-day periods in catastrophic	–0.16	0.02	0.00	–0.20	–0.13
Ended year in coverage gap	0.04	0.01	0.00	0.03	0.05
Ended year in catastrophic	–0.02	0.00	0.00	–0.03	–0.02
Noninsulin users					
Number of 30-day periods in initial coverage	0.04	0.01	0.00	0.02	0.05
Number of 30-day periods in coverage gap	0.01	0.00	0.00	0.01	0.01
Number of 30-day periods in catastrophic	0.00	0.00	0.00	0.00	0.01
Ended year in coverage gap	0.00	0.00	0.96	0.00	0.00
Ended year in catastrophic	0.00	0.00	0.00	0.00	0.00

SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table shows coefficients on the PDSS Model implementation indicator from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in eligible nonparticipating plans. Insulin users and noninsulin users must have been continuously enrolled in the same plan for all of 2020 and 2021. Beneficiaries eligible for the LIS were excluded from the analysis. *N* = 509,662 for insulin users and *N* = 11,470,769 for noninsulin users. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Bids, Premiums, and Spending Regression Results

Chapter 5 includes our plan-level analyses of bid, premium, and cost outcomes and our beneficiary-level analyses of OOP spending and beneficiary costs.

Beneficiary Costs

Regression results for beneficiary cost outcomes reported in Chapter 5 are from beneficiary-level regression models in which an observation is a beneficiary-year and beneficiaries in PDSS-participating plans are compared with beneficiaries in eligible nonparticipating plans. See Appendix A for details on sample definition and model specification.

Table C.11 shows the full set of regression coefficients for one of the beneficiary cost outcomes, OOP costs, for insulin users in MA-PDs.

Table C.11. Detailed Regression Results for Beneficiary OOP Costs, Insulin Users Enrolled in MA-PDs

Variable	Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Year 2021 indicator	–42.41	11.26	0.00	–64.49	–20.34
DD effect	–197.85	13.76	0.00	–224.83	–170.88
Age	–1.60	0.26	0.00	–2.10	–1.10
Female	–23.96	2.31	0.00	–28.49	–19.43
Originally entitled due to disability and ESRD	–41.46	23.46	0.08	–87.46	4.54
Originally entitled due to disability	–41.21	3.55	0.00	–48.18	–34.24
Originally entitled due to ESRD	–26.01	31.36	0.41	–87.52	35.49
Reached catastrophic phase in 2020	1309.69	13.45	0.00	1283.31	1336.07
Reached coverage gap phase in 2020	384.57	6.61	0.00	371.60	397.54
RxHCC score	–57.42	64.32	0.37	–183.56	68.71
American Indian / Alaska Native	–33.14	5.36	0.00	–43.65	–22.64
Asian / Pacific Islander	–49.16	4.55	0.00	–58.08	–40.25
Black	–78.95	4.65	0.00	–88.07	–69.83
Hispanic	–107.68	73.82	0.14	–252.44	37.09
Multiracial	–14.53	13.15	0.27	–40.31	11.25
RxHCC flag - kidney disease	7.97	2.83	0.00	2.41	13.53
RxHCC flag - high cholesterol	6.29	4.26	0.14	–2.06	14.64
RxHCC flag - CHF	–16.52	3.56	0.00	–23.51	–9.54
RxHCC flag - hypertension	0.01	0.01	0.08	0.00	0.03
Average area income	–207.63	89.09	0.02	–382.33	–32.92
Urbanicity	10.61	4.37	0.02	2.05	19.17
Star Ratings - getting needed drugs	11.99	44.31	0.79	–74.90	98.88
Star Ratings - getting needed drugs (missing)	–19.72	7.14	0.01	–33.72	–5.73
Star Ratings - diabetes medication adherence	–23.18	44.59	0.60	–110.62	64.25
Star Ratings - diabetes medication adherence (missing)	81.32	1.80	0.00	77.79	84.85
Number of Part D fills per month (2020)	7.19	1.99	0.00	3.28	11.10
Number of inpatient stays (2020)	–8.13	1.50	0.00	–11.07	–5.19
Number of ED visits (2020)	8.76	0.51	0.00	7.76	9.76
Number of 30-day insulin fills (2020)	–29.64	2.74	0.00	–35.01	–24.26
Number of rapid-acting insulin fills (2020)	45.12	4.77	0.00	35.78	54.47
Number of long-acting insulin fills (2020)	28.23	4.70	0.00	19.01	37.44
Number of intermediate-acting insulin fills (2020)	-30.93	5.44	0.00	-41.60	-20.25

Variable	Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Number of pen insulin fills (2020)	35.18	5.42	0.00	24.55	45.80
Number of vial insulin fills (2020)	-26.18	4.39	0.00	-34.79	-17.57
Year 2019 indicator	-91.10	5.66	0.00	-102.20	-79.99

SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources and variables.
NOTES: 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 eligible nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021. *N* = 848,830 for MA-PDs. 95% confidence intervals are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Table C.12 shows the full set of regression coefficients for one of the beneficiary cost outcomes, OOP costs for insulin users in PDPs.

Table C.12. Detailed Regression Results for Beneficiary OOP Costs, Insulin Users Enrolled in PDPs

Variable	Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Year 2021 indicator	107.38	33.76	0.00	41.02	173.74
DD effect	–441.33	35.47	0.00	–511.06	–371.60
Age	–1.24	0.37	0.00	–1.98	-0.51
Female	–35.23	4.74	0.00	–44.55	–25.92
Originally entitled due to disability and ESRD	–49.51	40.03	0.22	–128.19	29.16
Originally entitled due to disability	–36.46	6.23	0.00	–48.71	–24.21
Originally entitled due to ESRD	52.79	19.01	0.01	15.43	90.14
Reached catastrophic phase in 2020	1443.26	20.35	0.00	1403.27	1483.24
Reached coverage gap phase in 2020	524.20	8.02	0.00	508.45	539.96
RxHCC score	–806.43	236.48	0.00	–1271.23	–341.63
American Indian/Alaska Native	1.77	10.50	0.87	–18.87	22.41
Asian / Pacific Islander	–34.92	11.37	0.00	–57.27	–12.57
Black	–101.58	12.44	0.00	–126.02	–77.13
Hispanic	–225.57	264.62	0.39	–745.69	294.54
Multiracial	25.68	17.60	0.15	–8.91	60.28
RxHCC flag - kidney disease	5.23	4.78	0.27	–4.16	14.62
RxHCC flag - high cholesterol	–5.79	6.89	0.40	–19.33	7.74
RxHCC flag - CHF	–28.12	5.62	0.00	–39.16	–17.09
RxHCC flag - hypertension	0.04	0.02	0.02	0.01	0.07
Average area income	1012.68	477.88	0.03	73.40	1951.96
Urbanicity	–20.23	11.65	0.08	–43.12	2.67
Star Ratings - getting needed drugs	–42.79	9.78	0.00	–62.01	–23.57
Star Ratings - diabetes medication adherence	103.02	2.52	0.00	98.07	107.97
Number of Part D fills per month (2020)	10.13	2.23	0.00	5.73	14.52
Number of inpatient stays (2020)	–7.26	1.65	0.00	–10.50	–4.01
Number of ED visits (2020)	4.20	0.52	0.00	3.17	5.22
Number of 30-day insulin fills (2020)	–11.73	3.00	0.00	–17.63	–5.84
Number of rapid-acting insulin fills (2020)	32.52	4.24	0.00	24.18	40.86
Number of long-acting insulin fills (2020)	10.93	4.77	0.02	1.56	20.30
Number of intermediate-acting insulin fills (2020)	-2.78	7.87	0.72	-18.25	12.69

Variable	Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Number of pen insulin fills (2020)	71.92	7.16	0.00	57.84	86.00
Number of vial insulin fills (2020)	-0.68	7.29	0.93	-15.00	13.65
Year 2019 indicator	-217.77	13.29	0.00	-243.89	-191.65

SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources and variables.
NOTES: 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 eligible nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021. *N* = 509,662 for PDPs. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Table C.13 shows the full set of DD coefficients from all beneficiary-level spending outcome models for MA-PDs, which are the same as those presented in Chapter 5.

Table C.13. Difference-in-Differences Coefficients for Beneficiary-Level Cost Models, MA-PDs

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Insulin users					
Total OOP	–197.85	13.76	0.00	–224.83	–170.88
Total OOP for insulin	–223.95	9.05	0.00	–241.69	–206.21
Total OOP for noninsulin	25.91	9.61	0.01	7.05	44.76
Total Part D costs	–197.97	15.52	0.00	–228.41	–167.54
Gross drug costs	500.73	35.08	0.00	431.93	569.53
Gross drug costs for insulin	562.58	19.65	0.00	524.04	601.12
Noninsulin users					
Total OOP	4.66	4.31	0.28	–3.78	13.10
Total Part D costs	8.45	8.09	0.30	–7.42	24.32
Gross drug costs	–22.93	9.58	0.02	–41.72	–4.13

SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table shows coefficients on PDSS implementation indicator from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in eligible nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021. *N* = 848,830 for insulin users and *N* = 17,219,502 for noninsulin users. 95% confidence intervals are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Table C.14 shows the full set of difference-in-differences coefficients from all beneficiary-level spending outcome models for PDPs, which are the same as those presented in Chapter 5.

Table C.14. Difference-in-Differences Coefficients for Beneficiary-Level Cost Models, PDPs

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Insulin users					
Total OOP	–441.33	35.47	0.00	–511.06	–371.60
Total OOP for insulin	–486.60	49.22	0.00	–583.35	–389.86
Total OOP for noninsulin	44.39	18.11	0.01	8.80	79.98
Total beneficiary costs	–417.39	36.25	0.00	–488.64	–346.14
Gross drug costs	546.41	57.58	0.00	433.25	659.58
Gross drug costs for insulin	589.71	46.88	0.00	497.56	681.85

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Noninsulin users					
Total OOP	–8.12	9.31	0.38	–26.41	10.18
Total beneficiary costs	34.12	9.75	0.00	14.96	53.29
Gross drug costs	41.38	18.59	0.03	4.84	77.91

SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table shows coefficients on the PDSS Model implementation indicator from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in eligible nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021. *N* = 509,662 for insulin users and *N* = 11,470,769 for noninsulin users. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Plan-Level Spending Outcomes

Regression results for plan-level spending outcomes reported in Chapter 5 are from plan-level regression models in which an observation is a plan-year and PDSS-participating plans are compared with eligible nonparticipating plans. See Appendix A for details on sample definition and model specification.

Table C.15 shows the full set of DD coefficients from all plan-level spending outcome models for MA-PDs, which are the same as those presented in Chapter 5.

Table C.15. Difference-in-Differences Coefficients for Plan-Level Spending Models, MA-PDs

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Total Part D premium	0.41	0.37	0.27	–0.31	1.13
Basic Part D premium	0.64	0.33	0.05	0.00	1.28
Supplemental Part D premium	–0.24	0.18	0.19	–0.59	0.12
Administrative costs	–0.50	0.23	0.03	–0.94	–0.06
Manufacturer rebates	1.38	0.67	0.04	0.06	2.70
Manufacturer gap discount payments	3.01	0.37	0.00	2.29	3.73
Part D standardized bid	5.68	0.45	0.00	4.79	6.56
Part D costs to Medicare	–0.51	2.74	0.85	–5.88	4.87
Reinsurance	1.65	2.07	0.43	–2.40	5.70

SOURCE: Authors' analysis of Part D bids and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTES: This table shows coefficients on the PDSS Model implementation indicator from the plan-level DD regression model. The comparison groups consisted of eligible nonparticipating plans. The *N* represents the number of plans included in the analyses across all three years of data. *N* = 7,085 plan-years for MA-PDs. 95% CIs are based on plan-clustered standard errors. See Appendix A for additional technical details.

Table C.16 shows the full set of DD coefficients from all plan-level spending outcome models for PDPs, which are the same as those presented in Chapter 5.

Table C.16. Difference-in-Differences Coefficients for Plan-Level Spending Models, PDPs

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Total Part D premium	–1.00	0.74	0.18	–2.46	0.46
Basic Part D premium	–16.91	1.98	0.00	–20.79	–13.03
Supplemental Part D premium	15.91	1.49	0.00	12.98	18.84
Administrative costs	–1.63	0.27	0.00	–2.16	–1.10
Manufacturer rebates	21.41	1.42	0.00	18.62	24.20
Manufacturer gap discount payments	17.80	0.87	0.00	16.02	19.52
Part D standardized bid	–16.91	1.97	0.00	–20.79	–13.04
Part D costs to Medicare	–3.15	3.32	0.34	–9.68	3.38
Reinsurance	–4.36	2.50	0.08	–9.27	0.55

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

NOTES: This table shows coefficients on the PDSS Model implementation indicator from the plan-level DD regression model. The comparison groups consisted of eligible nonparticipating plans. The *N* represents the number of plans included in the analyses across all three years of data. *N* = 1,285 plan-years for PDPs. 95% CIs are based on plan-clustered standard errors. See Appendix A for additional technical details.

Appendix D. Sensitivity Analyses

In this appendix, we report statistics that provide information about the plausibility of the parallel trends assumption (discussed in Chapter 1 and Appendix A) needed for our DD regression models to capture the policy impacts of the PDSS Model. We also report DD regression estimates from models that use an alternative comparison group (that is, all nonparticipating plans) and, thus, provide a sensitivity analysis for the main quantitative results discussed in the body of this report.

Group-Year Means and Robustness to Parallel Trends Violations

Tables in this appendix present summary statistics on outcomes stratified by participant status (PDSS-participating plans versus eligible nonparticipating plans, which we refer to in the tables as "PDSS Participants" and "Eligible Nonparticipants," respectively, for convenience) and by year. The group-year means of the outcomes provide context for interpreting the magnitudes of estimated PDSS Model effects. The tables can also be used to provide interested readers with an informal evaluation of how unadjusted group mean outcomes were changing prior to the PDSS Model.

For each outcome, the tables also report results from our analysis of robustness to parallel trends violations. As we discussed in Appendix A, we used the methods developed by Rambachan and Roth (2023) to characterize how the CI around our estimated PDSS Model impact would be affected by parallel trends violations in the post-implementation period. Specifically, we calculated CIs for our estimates under a range of potential parallel trends violations, where the magnitude of the violation relative to the largest observed pre-implementation parallel trends violation is denoted by an M-bar ($\bar{M}$).

To summarize robustness to parallel trends violations, we report the largest value of $\bar{M}$ under which our estimated effect remains statistically significant at the 5% level. A value of "N/A" indicates that our estimated effect is statistically insignificant at 5% even before allowing for parallel trends violations; a value of 2 (the maximum value examined) indicates that our estimated effect is robust to parallel trends violations twice as large as the largest pre-period violation.

Access Measures

In looking across all insulins covered by plans, we found that descriptive trends in the number of 30-day insulin fills show slight increases in the first year of the PDSS Model implementation (2021) among insulin users in PDSS-participating plans. Table D.1 shows the average number of 30-day fills for insulin-using beneficiaries in PDSS-participating and eligible

nonparticipating groups for MA-PDs. Table D.1 also shows the average MPRs for each insulin type and the percentage of beneficiaries persistent to basal insulin.

Table D.1. Access Outcome Measure Means and M-bar Results, MA-PDs

Outcome Measure	Group	2019	2020	2021	Max. $\bar{M}$
Number of 30-day insulin fills	Eligible Nonparticipants	11.22	10.72	11.23	> 2.0
	PDSS Participants	10.43	10.07	11.40	
Rapid/short MPR	Eligible Nonparticipants	0.71	0.56	0.44	1.1
	PDSS Participants	0.66	0.54	0.45	
Mixed MPR	Eligible Nonparticipants	0.80	0.67	0.55	0.9
	PDSS Participants	0.77	0.65	0.55	
Concentrated MPR	Eligible Nonparticipants	0.79	0.65	0.50	N/A
	PDSS Participants	0.74	0.58	0.45	
Persistence to basal insulin	Eligible Nonparticipants	0.73	0.69	0.68	> 2.0
	PDSS Participants	0.68	0.64	0.66	

SOURCE: Authors' analysis of PDE and other data. See Tables A.1 and A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table reports unadjusted means of outcomes by year for PDSS-participating plans and eligible nonparticipating plans. *N* = 848,830 insulin users enrolled in MA-PDs. Max. M-bar = maximum value of Rambachan and Roth's (2023) M-bar at which the PDSS Model effect remains statistically significant at the 5% level. We tested robustness to parallel trends violations for a grid of M-bar values from 0 to 2 in increments of 0.1. A value of "N/A" for M-bar indicates that the DD estimate was not statistically significant at 5%.

Table D.2 shows the same set of outcomes for PDPs.

Table D.2. Access Outcome Measure Means and M-bar Results, PDPs

Outcome Measure	Group	2019	2020	2021	Max. $\bar{M}$
Number of 30-day insulin fills	Eligible Nonparticipants	11.81	11.06	11.56	> 2.0
	PDSS Participants	11.59	11.18	12.23	
Rapid/short MPR	Eligible Nonparticipants	0.66	0.54	0.45	> 2.0
	PDSS Participants	0.69	0.55	0.47	
Mixed MPR	Eligible Nonparticipants	0.80	0.66	0.51	> 2.0
	PDSS Participants	0.78	0.64	0.56	
Concentrated MPR	Eligible Nonparticipants	0.80	0.62	0.48	N/A
	PDSS Participants	0.78	0.63	0.49	
Persistence to basal insulin	Eligible Nonparticipants	0.76	0.71	0.71	0.2
	PDSS Participants	0.71	0.67	0.68	

SOURCE: Authors' analysis of PDE and other data. See Tables A.1 and A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table reports unadjusted means of outcomes by year for PDSS-participating plans and eligible nonparticipating plans. *N* = 509,662 insulin users enrolled in PDPs. Max. M-bar = maximum value of Rambachan and Roth's (2023) M-bar at which the PDSS Model effect remains statistically significant at the 5% level. We tested robustness to parallel trends violations for a grid of M-bar values from 0 to 2 in increments of 0.1. A value of "N/A" for M-bar indicates that the DD estimate was not statistically significant at 5%.

Enrollment and Benefit Phase Measures

Table D.3 shows enrollment outcomes for MA-PDs.

Table D.3. Enrollment Outcome Measure Means and M-bar Results, MA-PDs

Outcome Measure	Group	2019	2020	2021	Max. $\bar{M}$
Total enrollment	Eligible Nonparticipants	5422.9	4585.7	4026.3	1.6
	PDSS Participants	8774.5	7779.9	7205.3	
New enrollees	Eligible Nonparticipants	651.3	629.8	569.3	1.8
	PDSS Participants	986.5	975.0	988.5	
Insulin users	Eligible Nonparticipants	204.0	170.1	139.9	> 2.0
	PDSS Participants	366.9	328.0	329.5	
Noninsulin users	Eligible Nonparticipants	4061.2	3433.1	3035.0	1.2
	PDSS Participants	6797.7	6053.8	5648.4	
Dually eligible	Eligible Nonparticipants	824.5	694.2	621.3	0.8
	PDSS Participants	1059.3	911.7	827.4	
LIS eligible	Eligible Nonparticipants	1102.7	929.8	804.5	0.9
	PDSS Participants	1509.1	1304.9	1138.2	

SOURCE: Authors' analysis of Part D Enrollment and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTES: This table reports unadjusted means of outcomes by year for PDSS-participating plans and eligible nonparticipating plans. The *N* represents the number of plans included in the analyses across all three years of data. *N* = 7,085 plan-years for MA-PDs. Max. M-bar = maximum value of Rambachan and Roth's (2023) M-bar at which the PDSS Model effect remains statistically significant at the 5% level. We tested robustness to parallel trends violations for a grid of M-bar values from 0 to 2 in increments of 0.1. A value of "N/A" for M-bar indicates that the DD estimate was not statistically significant at 5%.

Table D.4 shows enrollment outcomes for PDPs.

Table D.4. Enrollment Outcome Measure Means and M-bar Results, PDPs

Outcome Measure	Group	2019	2020	2021	Max. $\bar{M}$
Total enrollment	Eligible Nonparticipants	13332.3	14832.2	17797.0	0.6
	PDSS Participants	26922.6	20705.1	17422.6	
New enrollees	Eligible Nonparticipants	1573.5	6066.2	5366.4	0.4
	PDSS Participants	2467.7	2392.1	1359.4	
Insulin users	Eligible Nonparticipants	455.7	395.2	347.1	0.0
	PDSS Participants	1120.1	918.7	971.2	
Noninsulin users	Eligible Nonparticipants	12321.6	13937.9	16850.3	0.6
	PDSS Participants	23824.4	18341.5	15387.7	
Dually eligible	Eligible Nonparticipants	372.4	328.9	396.6	> 2.0
	PDSS Participants	1467.0	1067.3	787.5	
LIS eligible	Eligible Nonparticipants	463.3	416.0	471.5	> 2.0
	PDSS Participants	1820.3	1315.1	940.1	

SOURCE: Authors' analysis of Part D Enrollment and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTES: This table reports unadjusted means of outcomes by year for PDSS-participating plans and eligible nonparticipating plans. The *N* represents the number of plans included in the analyses across all three years of data. *N* = 1,285 plan-years for PDPs. Max. M-bar = maximum value of Rambachan and Roth's (2023) M-bar at which the PDSS Model effect remains statistically significant at the 5% level. We tested robustness to parallel trends violations for a grid of M-bar values from 0 to 2 in increments of 0.1. A value of "N/A" for M-bar indicates that the DD estimate was not statistically significant at 5%.

Table D.5. shows benefit phase outcomes for insulin users in MA-PDs.

Table D.5. Benefit Phase Outcome Measure Means and M-bar Results, Insulin Users in MA-PDs

Outcome Measure	Group	2019	2020	2021	Max. $\bar{M}$
Number of 30-day periods in initial coverage	Eligible Nonparticipants	2.98	3.03	2.94	N/A
	PDSS Participants	3.63	3.74	3.66	
Number of 30-day periods in coverage gap	Eligible Nonparticipants	0.80	0.78	0.80	1.9
	PDSS Participants	0.96	0.93	1.01	
Number of 30-day periods in catastrophic	Eligible Nonparticipants	0.79	0.69	0.73	1.1
	PDSS Participants	0.93	0.80	0.77	
Percentage ended year in coverage gap	Eligible Nonparticipants	33.0%	36.9%	35.7%	0.4
	PDSS Participants	42.4%	48.6%	49.2%	
Percentage ended year in catastrophic	Eligible Nonparticipants	18.6%	16.4%	17.1%	> 2.0
	PDSS Participants	22.0%	19.2%	19.3%	

SOURCE: Authors' analysis of PDE and other data. See Tables A.1 and A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table reports unadjusted means of outcomes by year for PDSS-participating plans and eligible nonparticipating plans. *N* = 848,830 for MA-PDs. Max. M-bar = maximum value of Rambachan and Roth's (2023) M-bar at which the PDSS Model effect remains statistically significant at the 5% level. We tested robustness to parallel trends violations for a grid of M-bar values from 0 to 2 in increments of 0.1. A value of "N/A" for M-bar indicates that the DD estimate was not statistically significant at 5%.

Table D.6 shows benefit phase outcomes for insulin users in PDPs.

Table D.6. Benefit Phase Outcome Measure Means and M-bar Results, Insulin Users in PDPs

Outcome Measure	Group	2019	2020	2021	Max. $\bar{M}$
Number of 30-day periods in initial coverage	Eligible Nonparticipants	3.67	3.69	3.50	N/A
	PDSS Participants	3.82	3.85	3.69	
Number of 30-day periods in coverage gap	Eligible Nonparticipants	1.37	1.39	1.41	N/A
	PDSS Participants	1.55	1.54	1.59	
Number of 30-day periods in catastrophic	Eligible Nonparticipants	1.47	1.31	1.34	> 2.0
	PDSS Participants	1.73	1.50	1.37	
Percentage ended year in coverage gap	Eligible Nonparticipants	38.4%	41.9%	38.4%	> 2.0
	PDSS Participants	38.4%	43.8%	44.6%	
Percentage ended year in catastrophic	Eligible Nonparticipants	30.7%	30.0%	30.7%	1.8
	PDSS Participants	37.4%	33.5%	32.0%	

SOURCE: Authors' analysis of PDE and other data. See Tables A.1 and A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table reports unadjusted means of outcomes by year for PDSS-participating plans and eligible nonparticipating plans. *N* = 509,662 insulin users enrolled in PDPs. Max. M-bar = maximum value of Rambachan and Roth's (2023) M-bar at which the PDSS Model effect remains statistically significant at the 5% level. We tested robustness to parallel trends violations for a grid of M-bar values from 0 to 2 in increments of 0.1. A value of "N/A" for M-bar indicates that the DD estimate was not statistically significant at 5%.

Table D.7 shows benefit phase outcomes for noninsulin users in MA-PDs.

Table D.7. Benefit Phase Outcome Measure Means and M-bar Results, Noninsulin Users in MA-PDs

Outcome Measure	Group	2019	2020	2021	Max. $\bar{M}$
Number of 30-day periods in initial coverage	Eligible Nonparticipants	1.11	1.22	1.24	0.0
	PDSS Participants	0.99	1.14	1.26	
Number of 30-day periods in coverage gap	Eligible Nonparticipants	0.05	0.05	0.06	N/A
	PDSS Participants	0.06	0.06	0.07	
Number of 30-day periods in catastrophic	Eligible Nonparticipants	0.09	0.09	0.11	N/A
	PDSS Participants	0.10	0.09	0.11	
Percentage ended year in coverage gap	Eligible Nonparticipants	7.0%	7.8%	8.9%	0.1
	PDSS Participants	8.4%	9.7%	11.1%	
Percentage ended year in catastrophic	Eligible Nonparticipants	1.7%	1.6%	1.9%	N/A
	PDSS Participants	1.8%	1.7%	2.0%	

SOURCE: Authors' analysis of PDE and other data. See Tables A.1 and A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table reports unadjusted means of outcomes by year for PDSS-participating plans and eligible nonparticipating plans. *N* = 6,721,757 noninsulin users enrolled in MA-PDs. Max. M-bar = maximum value of Rambachan and Roth's (2023) M-bar at which the PDSS Model effect remains statistically significant at the 5% level. We tested robustness to parallel trends violations for a grid of M-bar values from 0 to 2 in increments of 0.1. A value of "N/A" for M-bar indicates that the DD estimate was not statistically significant at 5%.

Table D.8 shows benefit phase outcomes for noninsulin users in PDPs.

Table D.8. Benefit Phase Outcome Measure Means and M-bar Results, Noninsulin Users in PDPs

Outcome Measure	Group	2019	2020	2021	Max. $\bar{M}$
Number of 30-day periods in initial coverage	Eligible Nonparticipants	0.91	0.58	0.65	0.4
	PDSS Participants	1.21	1.19	1.25	
Number of 30-day periods in coverage gap	Eligible Nonparticipants	0.07	0.06	0.07	0.7
	PDSS Participants	0.14	0.13	0.15	
Number of 30-day periods in catastrophic	Eligible Nonparticipants	0.11	0.11	0.13	0.4
	PDSS Participants	0.19	0.18	0.20	
Percentage ended year in coverage gap	Eligible Nonparticipants	6.4%	6.9%	7.8%	N/A
	PDSS Participants	12.3%	13.2%	14.1%	
Percentage ended year in catastrophic	Eligible Nonparticipants	2.1%	1.9%	2.3%	0.6
	PDSS Participants	3.9%	3.4%	3.9%	

SOURCE: Authors' analysis of PDE and other data. See Tables A.1 and A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table reports unadjusted means of outcomes by year for PDSS-participating plans and eligible nonparticipating plans. *N* = 4,471,843 noninsulin users enrolled in PDPs. Max. M-bar = maximum value of Rambachan and Roth's (2023) M-bar at which the PDSS Model effect remains statistically significant at the 5% level. We tested robustness to parallel trends violations for a grid of M-bar values from 0 to 2 in increments of 0.1. A value of "N/A" for M-bar indicates that the DD estimate was not statistically significant at 5%.

Beneficiary Cost Measures

Table D.9 shows beneficiary cost outcomes for insulin users in MA-PDs.

Table D.9. Beneficiary Cost Outcome Measure Means and M-bar Results, Insulin Users in MA-PDs

Outcome Measure	Group	2019	2020	2021	Max. $\bar{M}$
Gross drug costs	Eligible Nonparticipants	6,163	6,777	7,038	> 2.0
	PDSS Participants	7,169	7,929	8,646	
Total OOP	Eligible Nonparticipants	1,018	1,092	1,062	> 2.0
	PDSS Participants	1,104	1,201	960	
Gross drug costs for insulins	Eligible Nonparticipants	3,075	3,264	3,096	> 2.0
	PDSS Participants	3,806	4,096	4,463	
Total OOP for insulins	Eligible Nonparticipants	468	511	470	> 2.0
	PDSS Participants	539	587	315	
Total OOP for noninsulins	Eligible Nonparticipants	550	581	593	> 2.0
	PDSS Participants	566	615	645	
Total Part D costs	Eligible Nonparticipants	1,188	1,288	1,268	> 2.0
	PDSS Participants	1,224	1,344	1,109	

SOURCE: Authors analysis of PDE and other data. See Tables A.1 and A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table reports unadjusted means of outcomes by year for PDSS-participating plans and eligible nonparticipating plans. *N* = 848,830 insulin users enrolled in MA-PDs. Max. M-bar = maximum value of Rambachan and Roth's (2023) M-bar at which the PDSS Model effect remains statistically significant at the 5% level. We tested robustness to parallel trends violations for a grid of M-bar values from 0 to 2 in increments of 0.1. A value of "N/A" for M-bar indicates that the DD estimate was not statistically significant at 5%.

Table D.10 shows beneficiary cost outcomes for insulin users in PDPs.

Table D.10. Beneficiary Cost Outcome Measure Means and M-bar Results, Insulin Users in PDPs

Outcome Measure	Group	2019	2020	2021	Max. $\bar{M}$
Gross drug costs	Eligible Nonparticipants	8,668	9,646	9,725	1.7
	PDSS Participants	9,735	10,432	11,171	
Total OOP	Eligible Nonparticipants	1,463	1,689	1,758	> 2.0
	PDSS Participants	1,622	1,809	1,469	
Gross drug costs for insulins	Eligible Nonparticipants	4,223	4,492	4,198	> 2.0
	PDSS Participants	4,688	4,851	5,151	
Total OOP for insulins	Eligible Nonparticipants	635	762	792	> 2.0
	PDSS Participants	685	799	375	
Total OOP for noninsulins	Eligible Nonparticipants	829	930	969	0.9
	PDSS Participants	939	1,012	1,095	
Total Part D costs	Eligible Nonparticipants	1,863	2,512	2,624	> 2.0
	PDSS Participants	2,297	2,604	2,337	

SOURCE: Authors' analysis of PDE and other data. See Tables A.1 and A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table reports unadjusted means of outcomes by year for PDSS-participating plans and eligible nonparticipating plans. *N* = 509,662 insulin users enrolled in PDPs. Max. M-bar = maximum value of Rambachan and Roth's (2023) M-bar at which the PDSS Model effect remains statistically significant at the 5% level. We tested robustness to parallel trends violations for a grid of M-bar values from 0 to 2 in increments of 0.1. A value of "N/A" for M-bar indicates that the DD estimate was not statistically significant at 5%.

Table D.11 shows beneficiary cost outcomes for noninsulin users in MA-PDs.

Table D.11. Beneficiary Cost Outcome Measure Means and M-bar Results, Noninsulin Users in MA-PDs

Outcome Measure	Group	2019	2020	2021	Max. $\bar{M}$
Gross drug costs	Eligible Nonparticipants	1,414	1,529	1,742	0.5
	PDSS Participants	1,557	1,715	1,896	
Total OOP	Eligible Nonparticipants	309	305	311	N/A
	PDSS Participants	320	323	331	
Total Part D costs	Eligible Nonparticipants	475	467	481	N/A
	PDSS Participants	450	458	473	

SOURCE: Authors' analysis of PDE and other data. See Tables A.1 and A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table reports unadjusted means of outcomes by year for PDSS-participating plans and eligible nonparticipating plans. *N* = 17,219,502 noninsulin users enrolled in MA-PDs. Max. M-bar = maximum value of Rambachan and Roth's (2023) M-bar at which the PDSS Model effect remains statistically significant at the 5% level. We tested robustness to parallel trends violations was tested for a grid of M-bar values from 0 to 2 in increments of 0.1. A value of "N/A" for M-bar indicates that the DD estimate was not statistically significant at 5%.

Table D.12 shows beneficiary cost outcomes for noninsulin users in PDPs.

Table D.12. Beneficiary Cost Outcome Measure Means and M-bar Results, Noninsulin Users in PDPs

Outcome Measure	Group	2019	2020	2021	Max. $\bar{M}$
Gross drug costs	Eligible Nonparticipants	1,518	1,631	1,771	0.3
	PDSS Participants	2,348	2,482	2,680	
Total OOP	Eligible Nonparticipants	390	394	438	N/A
	PDSS Participants	578	587	619	
Total Part D costs	Eligible Nonparticipants	612	821	897	0.7
	PDSS Participants	1,143	1,241	1,343	

SOURCE: Authors' analysis of PDE and other data. See Tables A.1 and A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table reports unadjusted means of outcomes by year for PDSS-participating plans and eligible nonparticipating plans. *N* = 11,470,769 noninsulin users enrolled in PDPs. Max. M-bar = maximum value of Rambachan and Roth's (2023) M-bar at which the PDSS Model effect remains statistically significant at the 5% level. We tested robustness to parallel trends violations for a grid of M-bar values from 0 to 2 in increments of 0.1. A value of "N/A" for M-bar indicates that the DD estimate was not statistically significant at 5%.

Bids, Premiums, and Costs to Medicare Measures

Table D.13 shows plan cost outcomes for MA-PDs.

Table D.13. Plan Cost Outcome Measure Means and M-bar Results, MA-PDs

Outcome Measure	Group	2019	2020	2021	Max. $\bar{M}$
Standardized Part D bid	Eligible Nonparticipants	54.11	44.18	40.24	0.2
	PDSS Participants	45.52	44.52	44.47	
Manufacturer rebates	Eligible Nonparticipants	51.56	58.71	65.56	0.4
	PDSS Participants	56.92	64.36	74.38	

Outcome Measure	Group	2019	2020	2021	Max. $\bar{M}$
Manufacturer gap discount payments	Eligible Nonparticipants	9.57	12.28	13.75	> 2
	PDSS Participants	13.14	16.98	21.79	
Part D administrative costs	Eligible Nonparticipants	14.16	14.06	14.35	0.5
	PDSS Participants	13.22	14.63	14.98	
Part D basic premium	Eligible Nonparticipants	15.45	12.66	12.17	N/A
	PDSS Participants	13.61	12.90	12.53	
Part D supplemental premium	Eligible Nonparticipants	1.47	1.36	0.95	N/A
	PDSS Participants	1.27	1.23	0.76	
Part D total premium	Eligible Nonparticipants	16.92	14.02	13.12	N/A
	PDSS Participants	14.88	14.13	13.29	
Part D costs to Medicare	Eligible Nonparticipants	131.66	130.10	130.33	N/A
	PDSS Participants	101.02	98.76	93.85	
Reinsurance	Eligible Nonparticipants	74.27	71.89	76.72	N/A
	PDSS Participants	56.86	56.73	58.51	

SOURCE: Authors' analysis of plan bids, HPMS, summary DIR, PDE, and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTES: This table reports unadjusted means of outcomes by year for PDSS-participating plans and eligible nonparticipating plans. The *N* represents the number of plans included in the analyses across all three years of data. *N* = 7,085 plan-years for MA-PDs. Max. M-bar = maximum value of Rambachan and Roth's (2023) M-bar at which the PDSS Model effect remains statistically significant at the 5% level. We tested robustness to parallel trends violations for a grid of M-bar values from 0 to 2 in increments of 0.1. A value of "N/A" for M-bar indicates that the DD estimate was not statistically significant at 5%.

Table D.14 shows plan cost outcomes for PDPs.

Table D.14. Plan Cost Outcome Measure Means and M-bar Results, PDPs

Outcome Measure	Group	2019	2020	2021	Max. $\bar{M}$
Standardized Part D bid	Eligible Nonparticipants	45.29	34.82	27.95	> 2
	PDSS Participants	56.73	50.23	29.33	
Manufacturer rebates	Eligible Nonparticipants	40.32	34.77	39.07	0.7
	PDSS Participants	67.01	71.41	91.14	
Manufacturer gap discount payments	Eligible Nonparticipants	16.06	19.20	22.80	0.8
	PDSS Participants	23.52	35.16	47.92	
Part D administrative costs	Eligible Nonparticipants	12.73	12.08	11.28	0.8
	PDSS Participants	13.02	13.13	13.49	
Part D basic premium	Eligible Nonparticipants	27.21	19.97	17.93	> 2.0
	PDSS Participants	38.64	35.38	19.32	
Part D supplemental premium	Eligible Nonparticipants	18.26	15.21	12.51	> 2.0
	PDSS Participants	14.27	15.60	30.16	
Part D total premium	Eligible Nonparticipants	45.46	35.19	30.44	N/A
	PDSS Participants	52.91	50.98	49.48	
Part D costs to Medicare	Eligible Nonparticipants	91.99	78.12	75.36	0.1
	PDSS Participants	121.03	117.84	115.44	
Reinsurance	Eligible Nonparticipants	61.94	52.36	54.23	0.3
	PDSS Participants	80.74	80.72	81.86	

SOURCE: Authors' analysis of plan bids, HPMS, summary DIR, PDE, and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTES: This table reports unadjusted means of outcomes by year for PDSS-participating plans and eligible nonparticipating plans. The *N* represents the number of plans included in the analyses across all three years of data.

N = 1,285 plan-years for PDPs. Max. M-bar = maximum value of Rambachan and Roth's (2023) M-bar at which the PDSS Model effect remains statistically significant at the 5% level. We tested robustness to parallel trends violations for a grid of M-bar values from 0 to 2 in increments of 0.1. A value of "N/A" for M-bar indicates that the DD estimate was not statistically significant at 5%.

Alternative Comparison Group Results: All Nonparticipating Plans

For all outcomes examined in the report, we also estimated DD regression models that used all nonparticipating plans as an alternative comparison group (as we discussed in Appendix A). This subsection presents regression estimates for these models.

Access Measures

Table D.15 shows DD estimates of the PDSS Model impact for the full set of access measures for MA-PDs and PDPs using the alternative comparison group (that is, all nonparticipating plans). The results are similar in magnitude and significance to the results when we used the primary comparison group (of eligible nonparticipating plans) in most cases. The main quantitative results can be found in Chapter 3.

Table D.15. Beneficiary Access Measures Sensitivity Analysis Results, Insulin Users

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
MA-PD					
Number of 30-day insulin fills	0.89	0.04	0.00	0.81	0.97
Rapid/short MPR	0.03	0.00	0.00	0.03	0.04
Mixed MPR	0.03	0.01	0.00	0.02	0.04
Concentrated MPR	0.01	0.02	0.67	–0.02	0.04
Persistence to basal insulin	0.02	0.00	0.00	0.02	0.03
PDP					
Number of 30-day insulin fills	0.86	0.04	0.00	0.79	0.93
Rapid/short MPR	0.04	0.00	0.00	0.03	0.05
Mixed MPR	0.06	0.00	0.00	0.05	0.07
Concentrated MPR	0.02	0.01	0.16	–0.01	0.05
Persistence to basal insulin	0.01	0.00	0.00	0.00	0.01

SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table shows coefficients on the PDSS Model implementation indicator from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in all nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021. *N* = 862,719 insulin users enrolled in nonparticipating MA-PDs; *N* = 857,053 insulin users enrolled in nonparticipating PDPs. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Enrollment and Benefit Phase Measures

Table D.16 shows DD estimates of the PDSS Model impact for the full set of enrollment measures for MA-PDs using all nonparticipating MA-PDs as the comparison group. The results are similar in magnitude and significance to the results for the eligible nonparticipant comparison group in most cases. The main quantitative results can be found in Chapter 4.

Table D.16. Enrollment Outcome Measures Sensitivity Analysis Results, MA-PDs

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Total enrollment	0.09	0.02	0.00	0.04	0.14
New enrollees	0.21	0.04	0.00	0.12	0.29
LIS eligible	0.06	0.02	0.02	0.01	0.10
Dually eligible	0.05	0.02	0.05	0.00	0.09
Insulin users	0.23	0.02	0.00	0.18	0.28
Noninsulin users	0.08	0.02	0.00	0.03	0.12

SOURCE: Authors' analysis of Part D Enrollment and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTES: This table shows coefficients on the PDSS Model implementation indicator from the plan-level DD regression model. The comparison groups consisted of all nonparticipating plans. The *N* represents the number of plans included in the analyses across all three years of data. *N* = 7,565 plan-years for MA-PDs. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Table D.17 shows DD estimates of the PDSS Model impact for the full set of enrollment measures for PDPs. The results are different in magnitude and significance to the results for the eligible nonparticipant comparison group in most cases. The main quantitative results can be found in Chapter 4.

Table D.17. Enrollment Outcome Measures Sensitivity Analysis Results, PDPs

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Total enrollment	–0.12	0.03	0.00	–0.19	–0.06
New enrollees	0.51	0.09	0.00	0.34	0.68
LIS eligible	–0.29	0.03	0.00	–0.35	–0.23
Dually eligible	–0.29	0.03	0.00	–0.35	–0.23
Insulin users	0.34	0.04	0.00	0.26	0.43
Noninsulin users	–0.12	0.04	0.00	–0.19	–0.05

SOURCE: Authors' analysis of Part D Enrollment and other data. See Table A.1 in Appendix A for the complete list of data sources.
NOTES: This table shows coefficients on the PDSS Model implementation indicator from the plan-level DD regression model. The comparison groups consisted of all nonparticipating plans. The *N* represents the number of plans included in the analyses across all three years of data. The *N* represents the number of plans included in the analyses across all three years of data. *N* = 2,400 plan-years for PDPs. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Table D.18 shows DD estimates of the PDSS Model impact for the full set of benefit phase measures for MA-PDs using all nonparticipating plans as the comparison group. The results are similar in magnitude and significance to the results for the eligible nonparticipant comparison group in most cases. The main quantitative results can be found in Chapter 4.

Table D.18. Benefit Phase Outcome Measures Sensitivity Analysis Results, Insulin Users

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
MA-PD					
Number of 30-day periods in initial coverage	0.03	0.02	0.19	–0.02	0.08
Number of 30-day periods in coverage gap	0.05	0.01	0.00	0.03	0.08
Number of 30-day periods in catastrophic	–0.08	0.01	0.00	–0.10	–0.06
Ended year in coverage gap	0.03	0.00	0.00	0.02	0.03
Ended year in catastrophic	–0.01	0.00	0.00	–0.01	0.00
PDP					
Number of 30-day periods in initial coverage	0.05	0.02	0.00	0.02	0.08
Number of 30-day periods in coverage gap	0.02	0.01	0.11	0.00	0.03
Number of 30-day periods in catastrophic	–0.21	0.01	0.00	–0.23	–0.19
Ended year in coverage gap	0.04	0.00	0.00	0.03	0.04
Ended year in catastrophic	–0.03	0.00	0.00	–0.03	–0.02

SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table shows coefficients on the PDSS Model implementation indicator from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in all nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021. *N* = 862,719 insulin users enrolled in MA-PDs; *N* = 857,053 insulin users enrolled in PDPs. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Table D.19 shows DD estimates of the PDSS Model impact for the full set of benefit phase measures for PDPs using all nonparticipating plans as the comparison group. The results are similar in magnitude and significance to the results for the eligible nonparticipant comparison group in most cases. The main quantitative results can be found in Chapter 4.

Table D.19. Benefit Phase Outcome Measures Sensitivity Analysis Results, Noninsulin Users

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
MA-PD					
Number of 30-day periods in initial coverage	0.03	0.01	0.01	0.01	0.05
Number of 30-day periods in coverage gap	0.00	0.00	0.49	0.00	0.00
Number of 30-day periods in catastrophic	0.00	0.00	0.92	0.00	0.00
Ended year in coverage gap	0.00	0.00	0.00	0.00	0.01
Ended year in catastrophic	0.00	0.00	0.71	0.00	0.00
PDP					
Number of 30-day periods in initial coverage	0.08	0.01	0.00	0.07	0.10
Number of 30-day periods in coverage gap	0.00	0.00	0.00	–0.01	0.00
Number of 30-day periods in catastrophic	–0.01	0.00	0.00	–0.01	0.00
Ended year in coverage gap	0.00	0.00	0.00	0.00	0.00
Ended year in catastrophic	0.00	0.00	0.00	0.00	0.00

SOURCE: Authors' analysis of PDE and other data. The complete list of data sources and variables is in Table A.2 in Appendix A.
NOTES: Table shows coefficients on PDSS implementation indicator from beneficiary-level DD regression model estimated for sample of insulin users. Comparison groups consisted of insulin users enrolled in nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021. *N* = 18,928,906 noninsulin users for MA-PDs; *N* = 20,381,963 noninsulin users for PDPs. 95% confidence intervals are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Beneficiary Cost Measures

Table D.20 shows DD estimates of the PDSS Model impact for the full set of beneficiary cost measures for insulin users in MA-PDs using all nonparticipating plans as the comparison group. The results are similar in magnitude and significance to the results for the eligible nonparticipant comparison group in most cases. The main quantitative results can be found in Chapter 5.

Table D.20. Beneficiary Cost Outcome Measure Sensitivity Analysis Results, Insulin Users in MA-PDs

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Total OOP	–198.55	13.68	0.00	–225.38	–171.72
Total OOP for insulins	–224.23	9.03	0.00	–241.94	–206.52
Total OOP for noninsulins	25.50	9.54	0.01	6.80	44.20
Total Part D costs	–199.42	15.45	0.00	–229.72	–169.11
Gross drug costs	505.17	34.82	0.00	436.89	573.45
Gross drug costs for insulin	563.72	19.63	0.00	525.23	602.21

SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table shows coefficients on the PDSS Model implementation indicator 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. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021. *N* = 862,719 insulin users enrolled in MA-PDs. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Table D.21 shows DD estimates of the PDSS Model impact for the full set of beneficiary cost measures for insulin users in PDPs using all nonparticipating plans as the comparison group. The results are similar in magnitude and significance to the results for the eligible nonparticipant comparison group in most cases. The main quantitative results can be found in Chapter 5.

Table D.21. Beneficiary Cost Outcome Measure Sensitivity Analysis Results, Insulin Users in PDPs

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Total OOP	–387.37	12.39	0.00	–411.68	–363.06
Total OOP for insulins	–380.45	15.46	0.00	–410.81	–350.10
Total OOP for noninsulins	–7.92	6.88	0.25	–21.44	5.59
Total Part D costs	–295.33	16.41	0.00	–327.54	–263.12
Gross drug costs	292.84	41.09	0.00	212.19	373.49
Gross drug costs for insulin	407.16	22.13	0.00	363.73	450.60

SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table shows coefficients on the PDSS Model implementation indicator from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in all nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021. *N* = 857,053 insulin users enrolled in PDPs. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Table D.22 shows DD estimates of the PDSS Model impact for the full set of beneficiary cost measures for noninsulin users in PDPs using all nonparticipating plans as the comparison group. The results are similar in magnitude and significance to the results for the eligible nonparticipant comparison group in most cases. The main quantitative results can be found in Chapter 5.

Table D.22. Beneficiary Cost Outcome Measure Sensitivity Analysis Results, Noninsulin Users in MA-PDs

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Total OOP	4.34	4.29	0.31	–4.08	12.76
Total Part D costs	7.58	8.06	0.35	–8.23	23.39
Gross drug costs	–21.24	9.51	0.03	–39.89	–2.59

SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table shows coefficients on the PDSS Model implementation indicator from the beneficiary-level DD regression model estimated for our sample of noninsulin users. The comparison groups consisted of insulin users enrolled in all nonparticipating plans. Noninsulin users must have been continuously enrolled in the same plan for all of 2020 and 2021. *N* = 18,928,906 noninsulin users enrolled in MA-PDs. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Table D.23 shows DD estimates of the PDSS Model impact for the full set of beneficiary cost measures for noninsulin users in PDPs using all nonparticipating plans as the comparison group. The results are similar in magnitude and significance to the results for the eligible nonparticipant comparison group in most cases. The main quantitative results can be found in Chapter 5.

Table D.23. Beneficiary Cost Outcome Measure Sensitivity Analysis Results, Noninsulin Users in PDPs

Outcome Measure	DD Coefficient	St. Error	P-Value	95% CI - Low	95% CI - High
Total OOP	–23.41	4.50	0.00	–32.24	–14.58
Total Part D costs	67.34	8.98	0.00	49.72	84.97
Gross drug costs	–0.52	16.81	0.98	–33.52	32.47

SOURCE: Authors' analysis of PDE and other data. See Table A.2 in Appendix A for the complete list of data sources and variables.
NOTES: This table shows coefficients on the PDSS Model implementation indicator from the beneficiary-level DD regression model estimated for our sample of insulin users. The comparison groups consisted of insulin users enrolled in all nonparticipating plans. Insulin users must have been continuously enrolled in the same plan for all of 2020 and 2021. *N* = 20,381,963 insulin users enrolled in PDPs. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Bid, Premiums, and Costs to Medicare Measures

Table D.24 shows DD estimates of the PDSS Model impact for the full set of plan cost measures in PDPs using all nonparticipating plans as the comparison group. The results are

similar in magnitude and significance to the results for the eligible nonparticipant comparison group in most cases. The main quantitative results can be found in Chapter 5.

Table D.24. Plan-Level Cost Outcome Measures Sensitivity Analysis Results, MA-PDs

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Total premium	0.49	0.30	0.10	–0.09	1.07
Basic premium	0.68	0.29	0.02	0.10	1.25
Supplemental premium	–0.19	0.17	0.28	–0.52	0.15
Administrative costs	–1.39	0.29	0.00	–1.97	–0.81
Manufacturer rebates	1.51	0.72	0.04	0.10	2.91
Manufacturer gap discount payments	3.31	0.36	0.00	2.61	4.01
Part D standardized bid	4.50	0.43	0.00	3.65	5.35
Part D costs to Medicare	–2.57	2.68	0.34	–7.82	2.68
Reinsurance	1.53	2.01	0.45	–2.42	5.48

SOURCE: Authors' analysis of plan bids, HPMS, summary DIR, PDE, and other data. See Table A.1 in Appendix A for the complete list of data sources and variables.
NOTES: This table shows coefficients on the PDSS Model implementation indicator from the plan-level DD regression model. The comparison groups consisted of all nonparticipating plans. The *N* represents the number of plans included in the analyses across all three years of data. *N* = 7,565 plan-years for MA-PDs. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Table D.25 shows DD estimates of the PDSS Model impact for the full set of plan cost measures in PDPs using all nonparticipating plans as the comparison group. The results are similar in magnitude and significance to the results for the eligible nonparticipant comparison group in most cases. The main quantitative results can be found in Chapter 5.

Table D.25. Plan-Level Cost Outcome Measures Sensitivity Analysis Results, PDPs

Outcome Measure	DD Coefficient	Standard Error	P-Value	95% CI - Low	95% CI - High
Total premium	2.74	0.60	0.00	1.55	3.92
Basic premium	–4.31	1.17	0.00	–6.61	–2.01
Supplemental premium	7.05	0.88	0.00	5.31	8.78
Administrative costs	–1.20	0.24	0.00	–1.67	–0.74
Manufacturer rebates	1.24	0.69	0.07	–0.11	2.59
Manufacturer gap discount payments	15.93	0.91	0.00	14.15	17.71
Part D standardized bid	–4.31	1.17	0.00	–6.61	–2.01
Part D costs to Medicare	–17.23	3.07	0.00	–23.26	–11.20
Reinsurance	–10.60	2.20	0.00	–14.91	–6.28

SOURCE: Authors' analysis of plan bids, HPMS, summary DIR, PDE, and other data. See Table A.1 in Appendix A for the complete list of data sources and variables.
NOTES: This table shows coefficients on the PDSS Model implementation indicator from the plan-level DD regression model. The comparison groups consisted of all nonparticipating plans. The *N* represents the number of plans included in the analyses across all three years of data. The *N* represents the number of plans included in the analyses across all three years of data. The *N* represents the number of plans included in the analyses across all three years of data. *N* = 2,400 plan-years for PDPs. 95% CIs are based on plan-clustered standard errors. See Appendix A for covariates and additional technical details.

Appendix E. Qualitative Data Collection and Analysis Methods

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

In 2022, we fielded an online survey to all PDSS-participating POs, conducted semistructured interviews with a sample of POs that completed the survey, and interviewed all five PDSS Model-participating insulin manufacturers, as well as a sample of insulin-using beneficiaries who were enrolled in PDSS-participating plans to better understand their experiences with the Model test and perspectives on its outcomes. Below, we provide further details about each data collection and analysis activity.

Participating Parent Organizations

Survey Data Collection

We obtained a list of and contact information for all 75 POs that participated in the PDSS Model in 2021. Because of mergers and acquisitions that took place after POs submitted their 2021 Model test applications, we merged several entities together to reflect their updated PO status. Our final sample of POs consisted of 73 organizations. We invited all PDSS-participating POs to complete the survey.

We developed survey questions based on our previous experiences conducting PO surveys as part of a similar evaluation of a Model test (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 test (for example, types of plans entered, all plans or a subset of plans), relationship with PBMs, perceived ease of implementation, barriers to beneficiaries' insulin use, observed impacts of the PDSS Model on both plans and beneficiaries using insulin, and potential longer-term impacts of the Model test. POs that entered only PDPs into the Model test received a shorter version of the survey that excluded certain outcomes of the PDSS Model that PDPs are not directly responsible for, such as beneficiary health status.

In January 2022, we programmed the questionnaire into SelectSurvey and invited all 73 POs to complete it. The questionnaire included a consent form as the first screen, which POs reviewed and agreed 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 survey in April 2022. Of the 73 POs contacted, 67 provided consent to be surveyed and completed at least half of the survey (92% response rate). Of the six POs that did not

complete the survey, five were state-based POs and one was regional; five had entered MA-PDs only, and one had entered both PDPs and MA-PDs; and four had higher-than-median enrollment in PDSS-participating plans, while two had enrollments that were lower than the median.

Survey Data Analysis

We cleaned and recoded survey data to prepare for analysis. For example, we asked PO respondents what outcomes their organization had already seen in 2021 that could be attributed to the PDSS Model. 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. We also explored differences in survey responses across different groupings of POs, including those that entered MA-PDs in the Model test compared with POs that did not, those that had more than the median number of PDSS Model-eligible beneficiaries compared with POs whose enrollments were below the median, and those that owned their own PBM compared with POs that did not. Because we did not identify any major differences in responses through these analyses, we reported the results only for the overall sample.

There were several questions on the survey where respondents could write in free-text responses to explain their numeric responses or to provide additional input. We reviewed all survey free-text responses to identify common themes or unique insights. For example, we provided PO respondents the opportunity to write in any additional outcomes they had already seen as a result of the Model test. Almost all respondents who provided information stated that the data on outcomes were preliminary or that the plan had not had a chance to evaluate any PDSS Model effects yet. Several POs stated that member satisfaction had increased; one said that members "are very happy with the reduced co-pay/out of pocket cost." Another PO provided a quantitative assessment of "member cost share per insulin utilizer [that] decreased by 52%" for the first three quarters of 2021.

Interview Sampling

We used a purposive sampling strategy to select POs for in-depth interviews to further explore topics covered in the questionnaire. We first excluded all POs with fewer than 100 beneficiaries in PDSS-participating plans, which left 66 eligible POs. We then used two PO characteristics—the plan type entered into the Model test (MA-PDs, PDPs, or both) and whether the PO participated in the narrower first risk corridor component—to categorize POs into one of five categories:

- Category 1: POs that entered only MA-PDs and did not choose the narrower first risk corridor component (n = 18)
- Category 2: POs that entered only MA-PDs and chose the narrower first risk corridor component (n = 40)
- Category 3: POs that entered only PDPs and chose the narrower first risk corridor component (n = 3)
- Category 4: POs that entered MA-PDs and PDPs and did not choose the narrower first risk corridor component (n = 1)
- Category 5: POs that entered MA-PDs and PDPs and chose the narrower first risk corridor component (n = 4).

Within each category, we sorted POs by the number of enrolled beneficiaries and sampled the smallest PO (with enrollment above 100 beneficiaries) and largest PO within the category, except for Categories 3–5, where there were very few POs. We also sought to include POs that participated in the Part D R&I programs component, which all happened to be part of Category 2. Taking all these factors into account, we invited 15 POs to participate in interviews as follows:

- the largest and smallest POs in Category 1 (n = 2)
- the largest and smallest POs in Category 2 (n = 2)
- the three largest POs offering the Part D R&I programs component in Category 2 (n = 3)
- the two largest POs in Category 3 (n = 2)
- all POs in Category 4 (n = 1)
- all POs in Category 5 (n = 4)
- one of the largest POs by overall beneficiary enrollment outside the Model test with the smallest PDSS Model plan enrollment (n = 1).

Our goal was to interview representatives, including C-level executives, from approximately ten POs from our sample of 15 invited POs. Between March and April 2022, we interviewed 46 representatives of nine 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 the PDSS Model. We encouraged POs to invite representatives of their PBMs to attend the interviews; three POs invited PBMs to share their experiences with the PDSS Model. Our final sample of nine POs included:

- the largest and smallest POs in Category 1 (n = 2)
- two POs offering the R&I programs component in Category 2 (n = 2)
- the two largest POs in Category 3 (n = 2)
- all POs in Category 4 (n = 1)
- one PO in Category 5 (n = 1)
- one of the largest POs by overall beneficiary enrollment with the smallest PDSS enrollment (n = 1).

Interview Process

We developed a semistructured interview guide for PO interviews to better understand PO survey responses about the Model test and its outcomes and to ask additional questions about the process of formulary development and negotiations with insulin manufacturers. Therefore, the interview guide covered such topics as background information about the PO, formulary development, negotiations with insulin manufacturers, PDSS Model impacts (including both expected outcomes and drivers of change), barriers to insulin adherence, and trends in insulin use among beneficiaries in PDSS-participating plans. 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

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," "Negotiation Process with Manufacturers," "Expected Model Outcomes," and "Beneficiary Outcomes." Researchers used these memos to develop a set of initial codes for a code book. The researchers independently coded the same transcript in Dedoose with the initial code book. Once that transcript was coded, they met to discuss any modification 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 as a way to ensure intercoder reliability. Each of these two researchers then coded half of the remaining transcripts. We have successfully used a similar approach to qualitative data coding in previous 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). In analyzing POs' perspectives of the impact of the PDSS Model, we not only looked for their explanations of survey responses but also for the mechanisms through which the Model test might be affecting key outcomes of interest. We prepared a summative memo containing all themes with illustrative quotes, focusing on similarities and differences in PO perspectives. The memo was reviewed by other researchers on the team, including clinicians, to ensure the trustworthiness of our interpretation of the results, including their credibility, validity, and likely transferability to other POs (Patton, 1999).

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. We also compared PO perspectives with those of insulin manufacturers and beneficiaries who use insulin to triangulate our findings. Finally, we incorporated key themes and quotes describing PO perspectives throughout the main body of this report.

Manufacturers

Sampling

Because there were only five manufacturers participating in the Model test in 2022, we included all manufacturers in our sample, regardless of whether they joined the Model test in 2021 or 2022. All five manufacturers agreed to participate in our study, and each identified the appropriate representatives for the interview. We interviewed 16 manufacturer representatives, including a CEO, vice presidents for Government Affairs, and directors of Public Affairs, as well as staff from government strategy, pricing, market access, policy, and finance departments. Each manufacturer was represented by between one and six people.

Data Collection

We developed a semistructured interview protocol that included open-ended questions and probes covering such topics as the reasons for joining the Model test, barriers to insulin affordability, negotiations with PBMs and PDSS-participating plans, expected Model test outcomes, feedback on the Model test, and suggestions for policy options to address drug affordability.

All interviews with manufacturers were conducted virtually, took place between April and May 2022, and followed the same protocol we used for PO interviews. Manufacturer interviews also lasted approximately one hour, were audio-recorded, and were professionally transcribed.

Data Analysis

The manufacturer interviews were coded using the same analytic approach described above for PO interview coding. Briefly, the same two members of the qualitative research team read each of the five transcripts and summarized key themes in a memo (Birks, Chapman and Francis, 2008), which covered key topics discussed during the interviews. They used the key themes from these memos to develop an initial code book. Once developed, one researcher applied the code book to all five transcripts using Dedoose. New codes were added throughout this process to identify emerging subcategories of relevant information. The team members used qualitative content analysis to analyze the coded transcripts to identify key themes and quotes illustrating

them (Graneheim and Lundman, 2004; Hsieh and Shannon, 2005). A second researcher reviewed all coded transcripts for accuracy and consistency.

We created a document summarizing manufacturer perspectives on the Model test, which the project team reviewed to ensure credibility, validity, and transferability of our results. As with the PO interview analyses, we identified manufacturer perspectives on the mechanisms through which the PDSS Model affects key outcomes for beneficiaries, manufacturers, plans, and CMS. We included relevant themes and quotes from manufacturer interviews throughout this report, focusing specifically on the differences and similarities between manufacturer and PO perspectives on the Model test and its outcomes.

Beneficiaries

Sampling and Data Collection

To explore beneficiary perspectives on the Model test, we interviewed insulin users from the PDSS-participating plans ("targeted beneficiaries"). To identify potential interviewees, we created a list of targeted beneficiaries who filled at least one plan-specified Model insulin between January and May 2022 and were enrolled in PDSS-participating plans as of May 31, 2022.

We excluded LIS-eligible beneficiaries from this list because they were not eligible to receive PDSS Model benefits. To reduce the possibility of sampling individuals with cognitive impairments related to old age, we only included beneficiaries 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 3,000 beneficiaries who met all inclusion criteria described above. To ensure diversity of our sample, we used a stratified random sample to include beneficiaries from all PDSS-participating POs. We also sampled the same number of beneficiaries enrolled in MA-PDs and PDPs, male and female beneficiaries, and younger (between 65 and 74 years of age) and older (between 75 and 80 years of age) beneficiaries.

Recruitment Methods

We divided our recruitment activities into three waves to facilitate recruitment. On August 15, 2022, we mailed a one-page letter to one-third of randomly 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 $40 payment by check, and asked beneficiaries who were interested in participating to call a toll-free number to schedule an appointment. To augment our recruitment approach, we identified landline or cell phone numbers of 740 out of the 1,000 beneficiaries included in the first wave of recruitment.

Approximately a week after mailing the interview invitation letter, we began making outgoing calls. After attempting to contact 335 beneficiaries (45% of the beneficiaries for whom we had a telephone number), we were able to schedule eight interview appointments (2% of those contacted by telephone).

Because we received only 37 calls into the toll-free number within a month after mailing the initial interview invitations, we opted to proceed to the second recruitment wave and mailed an invitation letter to an additional sample of 2,004 beneficiaries on September 22, 2022. We mailed the third wave of 500 invitations on October 18, 2022.

In total, we sent invitation letters to 3,504 beneficiaries, received 121 calls from beneficiaries interested in participating in our study, and completed interviews with 100 beneficiaries. 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, work status, occupation, race/ethnicity, and insulin type.

Data Collection

Drawing from our prior experiences interviewing Medicare beneficiaries (Eibner et al., 2020), the literature on barriers to care in patients with diabetes (McBrien et al., 2017; Sina, Graffy, and Simmons, 2018), and input from clinicians on our team, 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 the PDSS Model and its benefits, experiences paying for insulin, barriers to diabetes management, and the impact of the Model test. The protocol was pilot tested with a sample of five beneficiaries. As a result of the pilot, we made slight wording changes to several interview questions and added additional interviewer instructions.

All interviewers were trained by the study's co-director prior to the start of the first interview to ensure that all interviewers understood the basics of the Part D benefit design, the PDSS Model benefits, and insulin types, as well as the intent of all interview questions so that they could paraphrase them if needed.

Between August and November 2022, a team of six interviewers completed 100 telephone interviews with beneficiaries. All interviews were conducted after the IRA legislation was announced on August 16, 2022. Before the start of each interview, interviewers introduced themselves, reviewed the informed consent statement, and confirmed that the participant was willing to participate. We used digital recorders to record the interviews, and the audio recording did not begin until we received the participant's consent to be recorded. Interviewers used the same scripted interview guide to conduct the interviews. On average, the interviews lasted for 30

minutes, with many of the interviews lasting for 40–45 minutes. All audio recordings were professionally transcribed.

Data Analysis

Interviewers took detailed notes during the interview and entered their notes into an Excel data matrix, which included beneficiaries as rows, interview questions as columns, and interviewer notes summarizing beneficiary responses to questions in the appropriate cells. 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 identified exemplar quotes that could be used to illustrate key sentiments expressed by beneficiaries.

Using the data matrix, we developed a series of binary indicators describing beneficiary awareness of the PDSS Model and its benefits (for example, Have you heard about the PDSS? Have you noticed that your insulin copays have recently become $35 or less for a month supply?), the types of insulin they were taking, and whether or not they confused a noninsulin diabetes medication with insulin, among others. To assess the impact of the Model test on different outcomes, we asked beneficiaries a series of binary questions about their behaviors before and after the PDSS Model 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 test 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 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 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 test addressed the most pressing barriers to insulin adherence.

Sample Description

Most of our interviewed beneficiaries were White (87%); three-fifths (61%) were female (Table E.1). The majority of participants had obtained at least a high school diploma or equivalent (96%) and were retired (87%). We achieved comparable representation of beneficiaries enrolled in MA-PDs (52%) and PDPs (48%).

Most interviewed beneficiaries rated their health as "good" (49%) or "fair" (27%); 20% of beneficiaries described their health as "very good." On average, participants reported taking eight different medications (mean 8.17, range 2–20).

Table E.1. Beneficiary Interview Sample Descriptive Statistics

Characteristic	N
Sex	
Female	61
Male	39
Race	
White	87
Black or African American	6
Asian	3
Other	3
Hispanic or Latino	1
Level of education	
Eighth grade or less	2
Some high school	2
High school or GED	23
Some college or two-year degree	29
Four years of college	21
Greater than four years of college	23
Work status	
Retired	87
Working for pay	9
Other	3
Volunteering	1
Part D plan type	
MA-PD	52
PDP	48
Self-rated health status	
Very good	20
Good	49
Fair	27
Poor	4
Number of insulins used	
One	52
Two	46
Three	2
Insulin type(s) used	
Long-acting only	41
Rapid- and long-acting	40
Mixed only	11

Characteristic	N
Rapid-acting only	5
Rapid- and intermediate-acting	1
Rapid-acting and combination	1
Concentrate only	1
Primary insulin delivery device	
Pen	76
Vial	22
Pump	2
Mentioned noninsulin diabetes medication	
No	73
Yes	27
Number of prescription medications (mean)	8.17

SOURCE: Authors' analysis of interviews with 100 insulin users from PDSS-participating plans conducted in 2022.

Almost all interviewed beneficiaries reported taking one or two insulins; only two beneficiaries reported taking three different insulins. Of those taking only one insulin, long-acting insulin was the most common type (41% of the overall sample). Beneficiaries taking two insulins most frequently reported using both rapid- and long-acting insulins (40% of the overall sample). Eleven percent of beneficiaries reported taking mixed insulins. When asked about their primary mode of insulin delivery, most beneficiaries reported using pens (76%). Although beneficiaries were not asked specifically about noninsulin diabetes medication, 27% of participants brought up these medications during our interview, often confusing them with insulins. These medications included Jardiance, Metformin, Ozempic, Trulicity, and Victoza.

Triangulation of Results Using Mixed-Methods Analysis

To synthesize the results of our data modeling and primary data collection and to explain the mechanisms through which the Model test might have affected key outcomes of interest for beneficiaries, manufacturers, and plans, we created three diagrams (see Figures 6.1—6.3). To develop them, we first reviewed the coded interview transcripts for excerpts where interviewees described a mechanism or relationship between two PDSS Model outcomes (for instance, a PO representative noting that increased insulin adherence was associated with improved beneficiary health outcomes). We grouped these mechanisms by the affected outcome and noted the direction of the relationship. We then depicted the outcomes as nodes in the diagrams, connecting nodes with arrows to indicate the mechanisms that interviewees identified and annotating each arrow to explain the mechanisms. We used arrows of different colors to indicate whether interviewees agreed on the direction of the relationship or if the relationship was uncertain, meaning that there was no consensus among interviewees. The research team reviewed the diagrams and added several suspected relationships not specifically discussed by interviewees (denoted by dashed lines in the diagrams). We then overlaid the quantitative results

on the diagrams and used up and down arrow icons to indicate the impact of the PDSS Model on outcomes included in the quantitative data modeling. We presented the results separately for MA-PDs and PDPs and added the strength of the evidence for each quantitative outcome.

Abbreviations

CHF	congestive heart failure
CI	confidence interval
CMS	Centers for Medicare & Medicaid Services
COVID-19	coronavirus disease 2019
DD	difference-in-differences
DIR	direct and indirect remuneration
DME	durable medical equipment
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
HPMS	Health Plan Management System
IDR	Integrated Data Repository
IRA	Inflation Reduction Act
LICS	Low-Income Cost-Sharing Subsidy
LIPS	Low-Income Premium Subsidy
LIS	low-income subsidy
MA	Medicare Advantage
MA-PD	Medicare Advantage Prescription Drug plan
MBISG	Medicare Bayesian-Improved Surname Geocoding
MPR	medication possession ratio
OACT	CMS Office of the Actuary
OOP	out-of-pocket
Part D	Medicare Prescription Drug Benefit Program
PBM	pharmacy benefit manager
PDE	Part D Prescription Drug Event
PDP	Prescription Drug Plan
PDSS	Part D Senior Savings
PMPM	per-member per-month
PO	parent organization
PRS	Payment Reconciliation System
R&I	Rewards and Incentives
RxHCC	Prescription Drug Hierarchical Condition Code

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