Project Report

Part D Senior Savings Model Final Evaluation

Executive Summary

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About This Executive Summary

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

This is the executive summary of *Part D Senior Savings Model Final Evaluation, 2021 to 2023*. It presents an overview of the findings of a mixed-methods evaluation of the three years of the model on various outcomes, including access to insulins, health outcomes, beneficiary costs, progression through the Part D benefit phases, and financial outcomes for plans, manufacturers, and CMS.

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Executive Summary

Overview of Main Findings

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

Consistent with expectations, PDSS:

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

However, PDSS was also associated with:

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

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

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

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

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

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

Approach

Our mixed-methods evaluation of the model combined quantitative data modeling with qualitative data collection and analysis. We used secondary data sources, including the Medicare prescription drug event, Part D plan bid, Payment Reconciliation System, Part D direct and indirect remuneration, fee-for-service medical and service claims, MA encounter, and publicly available Part D formulary data to construct outcome measures. Following a similar approach to that used in producing the evaluation of the first year of the model test,[1] with some revisions to accommodate changes in model participation and advances in methods, we ran difference-in-differences (DD) regression analyses to isolate the association between the PDSS model and the outcome of interest based on pre- and post-model data. Before running the DD regressions, we calculated and applied weights to balance model participants and nonparticipants across various characteristics.

We ran DD regression models at the plan and beneficiary levels, separately for MA-PDs and PDPs, using nonparticipating Part D plans as the comparison group. PDSS was expected to directly impact beneficiaries enrolled in participating plans and using insulin (*insulin users*) by,

[1] Erin Audrey Taylor, Dmitry Khodyakov, Michael Dworsky, Christine Buttorff, Zachary Predmore, Lane F. Burgette, Stacie B. Dusetzina, Preethi Rao, Asa Wilks, Shiyuan Zhang, Jennifer Gildner, Sarah Dalton, Catherine E. Cooke, and Monique Martineau, *Evaluation of the Part D Senior Savings Model: First Year of the Model Test (2021)*, Centers for Medicare & Medicaid Services, 2023.

for example, lowering their insulin out-of-pocket (OOP) costs, while potentially indirectly affecting those beneficiaries enrolled in participating plans and not using insulin (*noninsulin users*) via spillover effects, such as increased plan premiums. We identified comparison beneficiaries as those enrolled in nonparticipating plans who did or did not have any insulin fills in the year before the model began.

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

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

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

Key Findings

Model Participation

The three largest U.S. insulin manufacturers joined the model in 2021, and all five U.S. insulin manufacturers participated in the model test in 2022 and 2023. The number of PDSS-

participating plan sponsors increased over the course of the model, from 75 to 116. They entered an increasing number of MA-PDs into the model in each year, starting with 1,195 in 2021 and ending with 2,339 in 2023. PDP consolidations led to fewer total PDSS-participating PDPs in 2022 compared with 2021, but the number of PDSS-participating PDPs increased to 324 in 2023.

Impact on Insulin Users

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

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

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

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

In particular, we found that PDSS was associated with:

- **Increased 30-day fills for insulin users** enrolled in both PDSS-participating MA-PDs and PDPs. PO survey results supported these findings: Most POs in all three years reported increased insulin use, which they attributed to lower copayments. Consistent with quantitative findings, the percentage of POs reporting an increase in insulin use also declined from 76% in 2021 to 56% in 2023.

- **Increased adherence to both short/rapid-acting insulins and basal insulins** for insulin users enrolled in both plan types. While most POs also reported increased adherence to insulins, some noted that increased insulin utilization was not necessarily always followed by increased insulin adherence because of increased enrollment of insulin users. Moreover, changes in diabetes management guidelines that placed greater emphasis on noninsulin diabetes medications, such as GLP-1 agents, have affected insulin possession rates. Finally, only 13% of interviewed insulin users reported no longer skipping insulin doses and skimming on basic needs to pay for insulin, and 10% reported no longer delaying filling an insulin prescription as a result of PDSS. Most insulin users noted that the lack of opportunities to stay physically active and their inability to follow a healthy diet, rather than high insulin costs, were key barriers to diabetes management.
- **Decreased annual beneficiary Part D OOP drug costs** for insulin users in both PDSS-participating MA-PDs and PDPs. PO survey results supported the decrease in Part D OOP drug costs, which was particularly pronounced for insulin OOP costs and during the coverage gap. Moreover, 42% of interviewed insulin users reported noticing that they had additional funds to spend on other items, such as living expenses, food, and medical expenses, after their insulin copayments decreased.
- **Decreased total Part D costs** for insulin users in both plan types in 2021 and 2022. Total Part D costs were calculated as annual OOP drug costs plus 12 months of the monthly Part D plan premium. However, the effect size decreased for insulin users in MA-PDs and changed to an estimated increase for those in PDPs in 2023.
- **Decreased inpatient stays and ED visits in some years for diabetes-related complications** for insulin users enrolled in PDSS-participating MA-PDs, but increased inpatient stays for uncontrolled diabetes complications for insulin users enrolled in PDSS-participating PDPs in 2022. While most POs did not report changes in inpatient care or ED use, a few that noted changes reported seeing different outcomes. None of the interviewed insulin users reported a change in how often they went to emergency rooms or were admitted to a hospital after their insulin copayments decreased.

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

Impact on Part D Plans, Insulin Manufacturers, and CMS

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

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

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

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

In particular, we found that PDSS was associated with:

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

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

Spillover Effects of the Model

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

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

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

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

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

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

Impact of the IRA Insulin Provision

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

Conclusions

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

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

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

Abbreviations

CMS	Centers for Medicare & Medicaid Services
DD	difference-in-differences
ED	emergency department
IRA	Inflation Reduction Act
LIS	low-income subsidy
MA-PD	Medicare Advantage plan with Part D coverage
OOP	out-of-pocket
Part D	Medicare Prescription Drug Benefit Program
PDP	prescription drug plan
PDSS	Part D Senior Savings
PMPM	per-member per-month
PO	parent organization
R&I	rewards and incentives
SHIP	State Health Insurance Assistance Program