U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

Decision

Matter of: Department of Health and Human Services—Medicare Part D Premium Stabilization Demonstration

File: B-336645

Date: May 27, 2025

DIGEST

The Department of Health and Human Services (HHS) has authority to undertake demonstration projects to test certain changes to Medicare payment methodologies. On July 29, 2024, the Centers for Medicare & Medicaid Services (CMS) announced that it is conducting a voluntary Medicare Part D Premium Stabilization Demonstration (Demonstration) under this authority. This legal decision addresses whether the Demonstration is consistent with the Secretary of Health and Human Services' (Secretary) legal authority specified under section 402(a)(1)(A) of the Social Security Amendments of 1967, as amended (Section 402).

We conclude that the Demonstration is consistent with the Secretary's authority under Section 402. Specifically, the Demonstration, as implemented by CMS in 2025, creates additional incentives for participating Part D prescription drug plan sponsors to increase the economy and efficiency of Medicare services and enables the agency to determine whether these changes in payment methods increase the efficiency and economy of Medicare services without adversely affecting quality, consistent with the requirements of Section 402. Although CMS has not yet selected a particular design for its evaluation of the Demonstration, we do not find that fact disqualifying. Rather, we find that CMS has taken initial steps and identified methods that, if implemented appropriately, could enable CMS to determine whether, and if so which, of the Demonstration's payment changes have the effect of increasing the efficiency and economy of Medicare services without adversely affecting quality, thereby satisfying the requirements of Section 402.

DECISION

This responds to an August 5, 2024, congressional request for a legal decision and other information regarding the Department of Health and Human Services' (HHS) Medicare Part D Premium Stabilization Demonstration (Demonstration).[1] This legal decision addresses whether the Demonstration is consistent with the Secretary of Health and Human Services' (Secretary) legal authority specified under section 402(a)(1)(A) of the Social Security Amendments of 1967, as amended (Section 402).[2] We are conducting an audit to address the remaining questions in the request.[3]

As explained below, we conclude that the Demonstration is consistent with the Secretary's authority under Section 402. Specifically, the Demonstration, as implemented by the Centers for Medicare & Medicaid Services (CMS) in 2025, creates additional incentives for participating Part D plan sponsors to increase the economy and efficiency of Medicare services and enables the agency to determine whether these changes in payment methods increase the efficiency and economy of Medicare services without adversely affecting quality, consistent with the requirements of Section 402. Although CMS has not yet selected a particular design for its evaluation of the Demonstration, we do not find that fact disqualifying. Rather, we find that CMS has taken initial steps and identified methods that, if implemented appropriately, could enable CMS to determine whether, and if so which, of the Demonstration's payment changes have the effect of increasing the efficiency and economy of Medicare services without adversely affecting quality, thereby satisfying the requirements of Section 402.

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[1] Letter from Ranking Member Mike Crapo, Senate Committee on Finance, Chair Cathy McMorris Rodgers, House Committee on Energy and Commerce, and Chairman Jason Smith, House Committee on Ways and Means, to the Comptroller General (Aug. 5, 2024). Mr. Crapo and Ms. McMorris Rodgers are no longer serving in the positions they held when they requested our work. Specifically, in January 2025, Mr. Crapo became the chairman of the Senate Committee on Finance, and Ms. McMorris Rodgers retired from Congress. In addition, Representative Bret Guthrie became the chairman of the House Committee on Energy and Commerce and joined the request. Accordingly, we consider Chairman Crapo, Chairman Smith, and Chairman Guthrie to be the requesters of this work.

[2] Social Security Amendments of 1967, Pub. L. No. 90-248, § 402, 81 Stat. 821, 930 –31 (Jan. 2, 1968), *as amended by* the Social Security Amendments of 1972, Pub. L. No. 92-603, § 222, 86 Stat. 1329, 1390 – 93 (Oct. 30, 1972) (*codified at* 42 U.S.C. § 1395b-1).

[3] Our forthcoming audit report will address CMS's design and implementation of the Demonstration, CMS's plans to evaluate the effectiveness of the Demonstration, and comparisons of various aspects of the Demonstration with prior demonstrations implemented under Section 402 authority.

In accordance with our regular practice, we transmitted a letter to HHS on October 25, 2024, to obtain factual information and its legal views on this matter.[4] HHS provided us with information and its legal views on November 22, 2024 (HHS Response).[5]

BACKGROUND

The Medicare Part D prescription drug benefit provides voluntary outpatient prescription drug coverage through private insurance companies, known as sponsors, that contract with CMS. In 2024, Part D provided prescription drug coverage to approximately 54 million Medicare beneficiaries. Of those, 42 percent—or approximately 23 million beneficiaries—were enrolled in standalone prescription drug plans (PDPs).[6]

PDP sponsors are paid based on an annual process specified in federal law and CMS regulations.[7] This process determines the monthly premiums beneficiaries pay and the subsidy and risk corridor amounts CMS pays to PDP sponsors. Annually in June, prospective PDP sponsors submit bids to CMS that reflect their expected costs to provide basic PDP benefits the following year. Under a statutory formula set forth in section 1860D-13 of the Social Security Act (Act), CMS determines the national average bid amount and, from that, the base beneficiary premium (BBP), which is a share of the national average bid amount.[8] The monthly premium that beneficiaries will pay is calculated as the sum of the BBP and other components, including the difference between the plan's bid and the national average bid amount, additional premiums for any supplemental coverage, and late enrollment penalties, as applicable.

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[4] GAO, *GAO's Protocols for Legal Decisions and Opinions*, GAO-24-107329 (Washington, D.C.: Feb. 2024), *available at* https://www.gao.gov/products/gao-24-107329; Letter from Assistant General Counsel, GAO, to General Counsel, HHS (Oct. 25, 2024).

[5] Letter from General Counsel, HHS, to Assistant General Counsel, GAO (Nov. 22, 2024).

[6] In addition, in 2024, 57 percent of Part D beneficiaries were enrolled in Medicare Advantage plans that offer drug coverage (MA-PDs). The remaining Part D beneficiaries (less than 1 percent) were enrolled in other types of plans.

[7] *See generally* 42 U.S.C. §§ 1395w-111–1395w-116; 42 C.F.R. pt. 423, subpts. F, G (2024).

[8] *See* 42 U.S.C. § 1395w-113; 42 C.F.R. § 423.286 (2024).

Subsidy and risk corridor payment amounts are determined under section 1860D-15 of the Act.[9] Specifically, CMS must provide a premium subsidy to PDP sponsors for each enrolled beneficiary in an amount reflecting the plan's bid amount adjusted for certain factors and reduced by the BBP. In addition, CMS must pay reinsurance subsidies, which contribute to an overall direct subsidy generally amounting to 74.5 percent of each plan's bid. After each plan year, CMS must reconcile PDP sponsors' actual drug spending with the expected spending reflected in the PDP sponsor's bid and determine whether any risk corridor payments are due. Risk corridors are risk-sharing arrangements under which the federal government and PDP sponsors share in a PDP's losses or gains when costs are higher or lower than anticipated. Section 1860D-15(e) of the Act and implementing regulations provide for symmetrical risk corridors, meaning the risk-sharing arrangement for losses is the same as the arrangement for gains.

Inflation Reduction Act of 2022

The Inflation Reduction Act of 2022 (IRA) made significant changes to Medicare's prescription drug benefit, which began taking effect in 2023 with certain provisions taking effect in 2024 and 2025.[10] For example, beginning in 2024, the IRA introduced a premium stabilization provision that caps annual growth in the BBP at 6 percent. In 2025, the IRA capped beneficiaries' total Medicare Part D out-of-pocket spending at $2,000. Also beginning in 2025, the IRA made other major changes to Part D's standard benefit design, such as reducing Medicare's share of costs for certain catastrophic expenses from 80 percent to 40 percent for generic drugs and from 80 percent to 20 percent for brand name drugs. Overall, the IRA's Part D changes "shift the upfront cost of providing the standard Part D benefit to plan sponsors while reducing out-of-pocket expenses for enrollees," according to the Congressional Research Service.[11] As a result, the IRA "contributed to a significant rise from 2024 to 2025 in the amounts that [PDP sponsors] bid. Those higher bids increase premiums paid by beneficiaries and the federal cost of the subsidies paid to Part D plans," according to the Congressional Budget Office.[12]

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[9] *See* 42 U.S.C. § 1395w-115 (subsidies and risk corridors); 42 C.F.R. §§ 423.329, 423.336 (2024).

[10] Pub. L. No. 117-169, title I, subtitle B, 136 Stat. 1818, 1833 – 1905 (Aug. 16, 2022).

[11] Library of Congress, Congressional Research Service, *Medicare Part D Premium Stabilization Demonstration*, No. IF12889, (Jan. 30, 2025).

[12] Congressional Budget Office, Letter to Chairman Arrington, *Re: Developments in Medicare's Prescription Drug Benefit*, at 3 (Oct. 2, 2024).

Section 402 Demonstration Authority

Section 402 authorizes HHS to undertake demonstration projects to test certain changes to Medicare payment methodologies. Specifically, section 402(a)(1)(A) authorizes the Secretary to develop and engage in experiments and demonstration projects

> to determine whether, and if so which, changes in methods of payment or reimbursement . . . for health care and services under health programs established by [the Social Security Act] . . . would have the effect of increasing the efficiency and economy of health services under such programs through the creation of additional incentives to these ends without adversely affecting the quality of such services.[13]

Part D Premium Stabilization Demonstration

In a July 29, 2024, memorandum, CMS announced that it is conducting a voluntary demonstration for PDPs under its Section 402 authority (Demonstration Memo).[14] The Demonstration Memo established parameters for 2025, with parameters for at least two subsequent years to be adjusted to reflect market conditions in those years.[15] The Demonstration's parameters for the first year consist of three elements applicable to participating PDPs:[16]

[13] 42 U.S.C. § 1395b-1(a)(1)(A).

[14] CMS, *Voluntary Part D Premium Stabilization Demonstration for Standalone Prescription Drug Plans, Release of the* De Minimis *Amount, and Operational Guidance* (July 29, 2024). The Demonstration Memo required plans opting into the Demonstration to respond in writing within one week, by August 5, 2024.

[15] On April 7, 2025, CMS released its Medicare Advantage and Part D rate announcement for 2026, stating that "CMS anticipates that the factors contributing to the design and magnitude of the [calendar year] 2025 demonstration parameters will be significantly mitigated for [calendar year] 2026," and indicating CMS will announce any additional premium stabilization and narrowed risk corridors no later than summer 2025. *See* CMS, *Announcement of Calendar Year (CY) 2026 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies*, at 6–7 (Apr. 7, 2025).

[16] The Demonstration is for standalone PDPs only; MA-PDs are not eligible to participate in the Demonstration. Only the first element of the Demonstration is applicable to the subset of PDPs known as employer group waiver plans, which provide prescription drug coverage to an employer's Medicare-eligible retirees.

1) A $15 BBP reduction, generally resulting in an equivalent reduction in beneficiaries' monthly premiums;[17]

2) A $35 year-over-year limit on the increase in monthly beneficiary premiums, meaning any plan-specific total Part D premium would not be permitted to increase more than $35 from 2024 to 2025; and

3) Changes to the applicable risk corridors to provide for greater government risk sharing of potential plan losses.

CMS stated that it is conducting the Demonstration to "test whether additional policy changes stabilize year-over-year changes in premiums for participating standalone PDPs, leading to more predictable options for beneficiaries during the initial implementation of the IRA benefit improvements, creating more gradual enrollment changes, and allowing participating Part D sponsors to accumulate the experience necessary for bidding in future years."[18]

CMS has not yet established the parameters for the Demonstration beyond 2025. Accordingly, this legal decision evaluates whether the Demonstration is consistent with the Secretary's authority under Section 402 by analyzing the parameters announced for 2025.

DISCUSSION

We have previously observed that while Section 402 provides the Secretary with broad authority, that authority is not unlimited. In 2012, we examined HHS's Medicare Advantage Quality Bonus Payment Demonstration against the criteria set forth in Section 402. We found that while the payment changes under a demonstration need not actually result in increased efficiency or economy, they must create additional incentives designed to do so and enable the agency to determine whether these changes increase the efficiency and economy of Medicare services without adversely affecting the quality of such services. Because we concluded that CMS had not established that the demonstration in that case satisfied either of those elements, we raised concerns about the agency's legal authority to undertake the demonstration in a letter transmitted to the Secretary on July 11, 2012 (2012 Letter).[19]

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[17] The BBP reduction will be less than this amount if the full reduction would cause the plan-specific premium to be less than $0.

[18] Demonstration Memo, at 8.

[19] GAO, Letter to HHS Management, B-323170 (July 11, 2012). We issued a separate audit report that recommended the Secretary cancel the demonstration. GAO, *Medicare Advantage: Quality Bonus Payment Demonstration Undermined by*

(continued...)

Therefore, following our past approach, we examine two issues to determine whether the Demonstration is consistent with the Secretary's authority under Section 402: (1) whether the Demonstration makes payment changes that create additional incentives to increase efficiency and economy, and (2) whether the Demonstration will enable the agency to determine if its payment changes increase the efficiency and economy of Medicare services without adversely affecting the quality of such services.

Whether the Demonstration Makes Medicare Payment Changes That Create Additional Incentives to Increase Efficiency and Economy

In considering whether the Demonstration makes changes in Medicare methods of payment that create additional incentives to increase efficiency and economy, we analyze each element of Section 402 in turn. We focus on the plain language of the statute, as it is well established that statutory analysis "begins with the plain language of the statute."[20] If the statutory language is clear and unambiguous on its face, then the plain meaning of that language controls.[21] While we also consider applicable precedent, the few court cases that discuss Section 402 relate to the Secretary's ability to waive specified sections of Title XVIII of the Social Security Act and do not address the particular criteria that demonstrations initiated under section 402(a)(1)(A) must meet.[22]

High Estimated Costs and Design Shortcomings, GAO-12-409R (Washington, D.C.: Mar. 21, 2012).

[20] *Jimenez v. Quarterman*, 555 U.S. 113, 118 (2009). *See also Lamie v. United States Trustee*, 540 U.S. 526, 534 (2004) ("The starting point in discerning congressional intent is the existing statutory text . . . .").

[21] *Bostock v. Clayton County*, 590 U.S. 644, 673–74 (2020) ("This Court has explained many times over many years that, when the meaning of the statute's terms is plain, our job is at an end."); *Carcieri v. Salazar*, 555 U.S. 379, 387 (2009) ("[W]e must first determine whether the statutory text is plain and unambiguous. If it is, we must apply the statute according to its terms.") (citations omitted); *United States v. American Trucking Ass'ns*, 310 U.S. 534, 543 (1940) ("There is, of course, no more persuasive evidence of the purpose of a statute than the words by which the legislature undertook to give expression to its wishes.").

[22] We identified only one federal court decision addressing a demonstration initiated under the section 402(a)(1)(A) authority; however, the decision focuses on the Secretary's use of the section 402(b) waiver authority and not on the scope of section 402(a)(1)(A). *American Academy of Ophthalmology, Inc. v. Sullivan,* 998 F.2d 377, 384 (6th Cir. 1993).

Payment Changes

Section 402 authorizes the Secretary to undertake demonstration projects to determine whether, and if so, which changes in Medicare methods of payment or reimbursement increase the efficiency and economy of Medicare services. We first consider whether the Demonstration involves changes in Medicare methods of payment or reimbursement.

The first two elements of the Demonstration—the $15 BBP reduction and $35 year-over-year limit on premium increases—generally reduce the 2025 premium to be paid by PDP enrollees. These premium reductions have a direct impact on CMS's subsidy payments to participating PDP sponsors because they are linked by a statutory formula. Specifically, section 1860D-15(a) of the Act requires the direct subsidy paid to PDP sponsors to be calculated by subtracting the BBP from each plan's bid amount. Therefore, if CMS reduces the BBP by $15, it generally follows that CMS must increase the direct subsidy payment for each PDP sponsor by $15.[23] Similarly, if CMS limits the year-over-year total premium increase to $35, it generally follows that some 2025 premiums will be lower than they otherwise would have been, thereby increasing CMS's direct subsidy for those PDP sponsors. Thus, we find the Demonstration's first two elements generally increase Medicare's direct subsidy by lowering premiums relative to what they would have been absent the Demonstration and thereby constitute changes in Medicare methods of payment to PDP sponsors.

The Demonstration's third element modifies the application of risk corridors to participating PDP sponsors. Under current law, the federal government shares in a PDP sponsor's unanticipated losses and gains through symmetrical risk corridors, meaning the risk-sharing arrangement for losses is the same as the arrangement for gains.[24] In contrast, the Demonstration's risk corridors are not symmetrical. Rather, under the Demonstration, the federal government shares a larger percentage of a PDP sponsor's potential losses and begins to share in those losses at a lower threshold, without a corresponding increase in the government's share of potential

[23] Because a PDP sponsor's total premium may not fall below zero, some PDP sponsors with lower-than-average bids may not receive the full BBP reduction or the full subsidy increase under the Demonstration.

[24] Specifically, under current law, the federal government bears 50 percent of each PDP's actual drug costs that are between 105 and 110 percent of its bid and, beyond that, 80 percent of unexpected costs, while the PDP sponsor bears the remaining costs. Similarly, the federal government shares in a PDP's unexpected gains to the same extent, bearing 50 percent of each PDP's actual gains that are between 105 and 110 percent of its bid and, beyond that, 80 percent of unexpected gains, while the PDP sponsor keeps the remaining gains. 42 U.S.C. § 1395w-115(e); 42 C.F.R. § 423.336 (2024).

gains.[25] By establishing asymmetrical risk corridors for participating PDPs, the Demonstration changes how CMS makes risk corridor payments to PDP sponsors experiencing higher costs than expected, shifting potential costs to the federal government. This constitutes a change in Medicare's method of payment to PDP sponsors compared with current law. Therefore, we find this element of the Demonstration, like the first two elements, involves changes in Medicare's methods of payment as required under Section 402.

Additional Incentives

Under Section 402, a demonstration making changes in Medicare methods of payment must create additional incentives to increase efficiency and economy of Medicare services. Accordingly, we next consider whether the Demonstration creates incentives that are additional to those available under current law.

In our 2012 Letter, we raised concerns that bonus payments made in the first year of the Medicare Advantage Quality Bonus Demonstration rewarding plans for pre-demonstration performance did not create incentives. Specifically, we noted that the payments in the first year of the demonstration were "based on data collected entirely before the demonstration was announced," and that payments were "unlikely to have any impact on plan quality."[26] Because the first year of payments, and some payments in the second year, were not likely to change plans' future behavior, but merely rewarded pre-demonstration performance, we raised concerns that those payments did not constitute an incentive.[27]

In contrast, this Demonstration creates incentives for PDP sponsors and beneficiaries to change future behavior in at least three ways. First, HHS explains that absent the Demonstration, it predicted very large increases in PDP premiums that "would likely cause an unusually high number of beneficiaries to switch plans" in 2025.[28] By lowering premiums overall in the PDP market—with a $15 BBP reduction applicable to all participating PDPs—HHS expected to "mitigate the

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[25] Under the Demonstration, the federal government bears 50 percent of each PDP's actual drug costs that are between 102.5 percent and 105 percent of its bid and, beyond that, 90 percent of unexpected costs, while the PDP sponsor bears the remaining costs. For unexpected gains, the risk-sharing arrangement remains the same as under current law. Demonstration Memo, at 9.

[26] 2012 Letter, at 5, 7. In addition, we noted that Medicare regulations precluded the plans' ability to reinvest bonus payment funds in the quality of care provided to beneficiaries, and the demonstration had not waived the restriction. *See* 2012 Letter, at 6.

[27] 2012 Letter, at 6.

[28] HHS Response, at 4.

incentive for beneficiaries to switch plans in the face of premium increases," such as to lower-cost MA-PDs or otherwise out of the market entirely.[29] Second, HHS determined that beneficiaries enrolled in certain PDPs in 2024 would face significantly higher premiums than others if they remained enrolled in 2025, which would encourage plan switching, such as to lower-cost plans within the PDP market. HHS aimed to mitigate that effect by placing a $35 cap on year-over-year premium increases under the second element of the Demonstration. Third, HHS explains that the third element of the Demonstration, which adjusts risk corridors for participating PDP sponsors, created incentives for PDP sponsors to choose to participate in the Demonstration, in light of plans' inability to adjust bids to account for the Demonstration's parameters before the deadline to opt in. Further, by reducing participating PDP sponsors' risk of losses for 2025, the Demonstration's risk corridors may create incentives for them to remain in the PDP market in 2026, potentially allowing them to provide beneficiaries greater PDP options in the future. In these ways, we find the Demonstration creates incentives for PDP sponsors and beneficiaries to change future behavior, rather than providing a reward for past performance. Therefore, we find the Demonstration creates incentives for the purpose of Section 402.

Moreover, in 2012, we analyzed the size of the bonus payment percentages under the demonstration to determine whether they were *additional* to the bonuses that would have been paid absent the demonstration. We found that in the third year of the demonstration—the only year not rewarding pre-demonstration performance—most plans would have received the same or a smaller annual increase in their bonus payment percentages relative to the bonuses to be paid absent the demonstration. In fact, we noted that "the demonstration may actually reduce incentives for these plans to improve quality" because underlying law provided larger annual bonus increases for certain plans.[30] Therefore, we raised concerns about whether those incentive payments could be considered additional to the payments made absent the demonstration, as contemplated by Section 402.

Here, we find this Demonstration's three elements provide incentives that are additional to the premium stabilization and risk-sharing provisions in current law. For example, the Demonstration's $15 BBP reduction is on top of the IRA's 6 percent premium stabilization provision, not replacing it. Overall, when accounting for all premium subsidies and risk corridor payments that CMS would make due to the Demonstration's changes, the Congressional Budget Office determined federal payments would be greater in amount overall than the payments made to PDP sponsors under current law. Specifically, in October 2024, the Congressional Budget Office calculated that the Demonstration's subsidies and risk corridor

[29] HHS Response, at 5.

[30] 2012 Letter, at 7.

payments would increase federal spending in 2025 alone by an additional $5 billion, relative to prior projections.[31]

Because the Demonstration's changes to subsidy and risk corridor payments incentivize future market behavior, and these incentive payments are generally projected to be greater than the amounts that would be paid under current law, we find the Demonstration has created additional incentives, consistent with Section 402.

Increasing Efficiency and Economy

Section 402 authorizes demonstrations conducted to determine whether and which payment changes would have the effect of increasing the efficiency and economy of health services under Medicare. As we indicated in the 2012 Letter, Section 402 does not require HHS to undertake a demonstration with certainty that it will enhance efficiency or economy, nor does it require that HHS is ultimately successful in doing so.[32] Rather, Section 402 merely requires that payment changes are made *for the purpose of* determining whether the changes would have the effect of increasing the efficiency and economy of Medicare services. Accordingly, we assess whether the Demonstration's intended outcome, if achieved, would increase the efficiency and economy of Medicare services.

Here, HHS articulates an intent to prevent predicted large-scale enrollment shifts that it expected to cause multiple inefficiencies in the Part D market. According to the HHS Response, "the Demonstration is intended to prevent inefficiencies related to administrative, financial, and operational difficulties arising from potentially large and unexpected enrollment shifts due to the wide variation in PDP bids and resulting premium changes."[33] For example, HHS points to potential medication adherence disruptions that could result from beneficiaries enrolling in different plans with benefits that do not meet their needs, which could be avoided through additional market stabilization.

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[31] Congressional Budget Office, Letter to Chairman Arrington, *Re: Developments in Medicare's Prescription Drug Benefit*, at 4 (Oct. 2, 2024). This aligns with the estimated figure the CMS Office of the Actuary provided of $5.2 billion. HHS Response, at 7.

[32] *See* 2012 Letter, at 9.

[33] HHS Response, at 10. Specifically, HHS explains that the IRA's recent policy changes led to substantial and varied transitional issues for PDP sponsors, causing large projected premium increases for certain organizations with large market share, which would likely cause an unusually high number of beneficiaries to switch out of those organizations' plans—and potentially out of the PDP market entirely—disrupting beneficiaries' drug coverage, access, and adherence to medication regimens.

If the Demonstration achieves its intended effects, it would lead to a less inefficient outcome than HHS anticipates under current law, as amended by the IRA, absent the Demonstration. We find that a less inefficient outcome under the Demonstration relative to the outcome anticipated absent the Demonstration is consistent with an increase in efficiency and economy for the purpose of Section 402.

Whether the Demonstration Will Enable the Agency to Determine Whether the Demonstration's Payment Changes Increase Efficiency and Economy Without Adversely Affecting Quality

As noted above, Section 402 authorizes the Secretary to revise Medicare payment methodologies for the purpose of determining "whether, and if so which, changes in methods of payment . . . would have the effect of increasing the efficiency and economy of health services . . . without adversely affecting the quality of such services."[34] In the 2012 Letter, we observed that this determination "involves a comparison of the effect of the payment methodology adopted under the demonstration to the effect of the payment methods in place under current law."[35] In that instance, we raised concerns about the agency's ability to make such a determination with respect to the Medicare Advantage Quality Bonus Payment Demonstration. We concluded that the agency was not likely to be able to isolate the effects of the demonstration from concurrent policy changes, and therefore it was unlikely for the demonstration to produce meaningful results. As a result, we found that CMS had not established that the demonstration would enable the agency to determine whether the payment changes increased the efficiency and economy of Medicare services without adversely affecting the quality of those services, as required under Section 402.

Here, CMS faces similar circumstances, which the agency acknowledges in the HHS Response.[36] Specifically, several provisions of the IRA are being implemented simultaneously in 2025—notably, the IRA's $2,000 cap on beneficiaries' out-of-pocket costs and an increase in plan sponsors' liability for additional costs above the cap—with effects on 2025 plan enrollment and 2026 plan premiums and enrollment still unknown.

[34] 42 U.S.C. § 1395b-1(a)(1)(A).

[35] 2012 Letter, at 8.

[36] For example, HHS states, "CMS expects that the Demonstration impacts will be linked to other changes in Part D policy" and that the evaluation would "work to disentangle the impacts" but "with the understanding that they are related." HHS Response, at 11.

In addition, the vast majority of PDPs offered in 2025 opted to participate in the Demonstration.[37] As a result of these factors, designing an evaluation of the Demonstration to determine its effects on efficiency, economy, and the quality of services may prove challenging due to difficulty isolating the effects of the Demonstration from the IRA's effects on plan liability, bids, and enrollment.

However, the HHS Response describes an approach that CMS plans to use to evaluate the effects of the Demonstration on efficiency, economy, and quality. HHS explains that its evaluation will use a quasi-experimental evaluation design to compare beneficiary premiums, enrollment trends, and economic benefits, among other things, under the Demonstration with the same elements absent the Demonstration. Specifically, HHS tells us the Office of the Assistant Secretary for Planning and Evaluation (ASPE) will work to construct a counterfactual scenario for 2025, reflecting current law as amended by the IRA, but absent the Demonstration. To do so, HHS indicates it could use statistical analysis of historical data from prior to and during the initial implementation of the IRA in 2023, in addition to the actual pre-Demonstration bids for 2025. HHS has not detailed in full the potential methods that could be used to construct the counterfactual, nor has HHS committed to undertaking any of them; rather, HHS states it is working to finalize the evaluation design in 2025 and indicates that it has taken initial steps to do so.[38]

We find this evaluation approach could be used to measure the effects of the Demonstration in comparison to what would have occurred in the absence of the Demonstration, if the evaluation is designed and conducted appropriately. Evaluations of program effects typically involve some version of quasi-experimental designs, which provide a way to isolate changes in an outcome of interest that are due to the program itself from changes in that outcome brought about by other factors. For programs that encompass all relevant participants, and thus lack

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[37] In 2025, 782 out of 818 PDPs are offered by PDP sponsors that opted to participate in the Demonstration. HHS estimates that this means around 99 percent of PDP enrollees in 2025 are covered by plans offered by participating PDP sponsors, with the remaining 1 percent enrolled in employer group waiver plans. *See* HHS Response, at 13.

[38] For example, HHS explains CMS took steps to engage ASPE to develop the design for an independent evaluation with support from a contractor following the conclusion of the Demonstration—which is expected to span at least three years—to "analyze standalone Part D plan benefits, premiums, enrollment trends, profit margins, bid accuracy, and plan availability across at least three to five years before and one year following the Demonstration period." HHS Response, at 10. In addition, HHS states that prior to implementing the Demonstration, CMS consulted various experts, including from ASPE, on the research goals, hypotheses of the Demonstration, and the necessary data sources and analytic approaches to best assess those hypotheses, as well as cost estimates for conducting an evaluation of the Demonstration.

appropriate comparison groups, this can involve single group quasi-experimental designs where the effect of a program change is assessed through a combination of tracking relevant outcomes over time with statistical adjustments to control for the effect of other factors considered likely to affect those outcomes.[39] While the strength of any evaluation's design may depend on how well statistical adjustments address the full range of external factors affecting the observed outcome, this type of quasi-experimental design could enable a meaningful evaluation of the Demonstration.[40]

Although CMS is still working to develop the evaluation design, we do not find that fact disqualifying. We observe that section 402(b) of the Act requires the agency to take certain steps prior to conducting a Section 402 demonstration. Specifically, this provision prohibits HHS from engaging in a demonstration until the Secretary has obtained the advice and recommendations of specialists.[41] Unlike that requirement, section 402(a) does not specify that HHS must articulate its evaluation methods *prior to* conducting a demonstration under Section 402. Rather, as we noted in 2012, the statute merely requires a demonstration to test payment changes in a way that "enabl[es] the agency to determine whether these changes in payment methods increase the efficiency and economy of Medicare services."[42]

Furthermore, the ultimate strength of the future evaluation is not a factor in our legal analysis here. Rather, we find the possibility of a credible evaluation suffices, because it means the Demonstration *enables* the agency to make a determination about the Demonstration's effects. CMS's stated evaluation plans indicate that the agency could make such a determination here and, therefore, the Demonstration is consistent with the Secretary's authority under Section 402.

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[39] *See* GAO, *Designing Evaluations: 2012 Revision*, GAO-12-208G (Washington, D.C.: Jan. 2012), at 39, 44, 47.

[40] Indeed, the objectives of our forthcoming audit report on the Demonstration include an examination of CMS's plans to evaluate the effectiveness of the Demonstration, including methodologies and evaluation timeline.

[41] Section 402(b) provides, in part, "No experiment or demonstration project shall be engaged in or developed under subsection (a) until the Secretary obtains the advice and recommendations of specialists who are competent to evaluate the proposed experiment or demonstration project as to the soundness of its objectives, the possibilities of securing productive results, the adequacy of resources to conduct the proposed experiment or demonstration project, and its relationship to other similar experiments and projects already completed or in process." *See* 42 U.S.C. § 1395b-1(b).

[42] 2012 Letter, at 10.

CONCLUSION

Section 402 provides the Secretary with broad authority to modify methods of payment under Medicare to create additional incentives to increase the economy and efficiency of Medicare services by carrying out experiments and demonstration projects. Payment changes tested under a demonstration need not actually result in increased efficiency or economy. However, demonstrations carried out under Section 402 must create additional incentives to increase the economy and efficiency of Medicare services and enable the agency to determine whether these changes in payment methods increase the efficiency and economy of Medicare services without adversely affecting quality. CMS has established that in 2025, the Demonstration's payment changes create such incentives for participating PDP sponsors and beneficiaries. Further, although CMS is still developing its evaluation plans for the Demonstration, we find the agency has described an approach that could enable the agency to evaluate whether the Demonstration's changes would have the effect of increasing efficiency and economy of Medicare services without adversely affecting quality, consistent with Section 402.

Edda Emmanuelli Perez
General Counsel