NATIONAL TAXPAYERS UNION

# Center for Medicare and Medicaid Innovation: 12 Years into the Game, Taxpayers Still Don't Know the Score

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## Introduction

Congress established the Center for Medicare and Medicaid Innovation (CMMI) as part of the Affordable Care Act (ACA) in 2010.[1] After more than a decade in operation, CMMI is still struggling to justify its benefits to taxpayers.

Before the passage of ACA, the Medicare and Medicaid programs could conduct demonstration projects – and they did.[2] They had about 30 projects on the books when the ACA was being debated, many of them undertaken pursuant to previous statute.

The ACA created one hub for these projects at CMMI and established a more expansive legislative vision for what these projects could accomplish. The ACA also gave the Secretary of Health and Human Services (HHS) and CMMI unique powers to propose and expand demonstration projects, insulated vast portions of CMMI decision-making from judicial review and congressional oversight, and funded CMMI at a level of $10 billion every 10 years.

Proponents of the legislation that created CMMI invested considerable hope in the agency's potential to transform health care delivery and reduce its costs. A Senate Finance Committee report on their version of the ACA said CMMI would pilot models that would "encourage evidence-based, coordinated care for Medicare, Medicaid, and CHIP."[3] The report also said that CMMI would "encourage greater collaboration among health care providers."[4] The Obama administration called CMMI the "centerpiece of the Administration's strategic initiative to drive breakthrough innovations in health care."[5]

The Congressional Budget Office (CBO) was among CMMI's greatest enthusiasts, forecasting that it would reduce Medicare spending by tens of billions of dollars.

CMMI has fallen far short of this promise. The demonstration projects it has conducted over more than a decade have neither transformed health care nor saved the government money. On net, Medicare spending is higher than it would have been without CMMI, despite CBO's optimistic projections.

Although CMMI has disappointed expectations, it continues to wield broad powers. It can create programs that are unlimited in duration and unbounded in scope. Congress has, in effect, invested legislative authority in CMMI, allowing it to determine how much Medicare pays for medical goods and services in ways that deviate from reimbursement schedules established by law and to impose its alternative methodology nationally.

A 2018 National Taxpayers Union (NTU) Foundation study criticized CBO's methodology for forecasting that CMMI would reduce Medicare spending.[6] Building on that previous work, this study finds that those forecasted savings have not materialized. It also renews a call to Congress to reform CMMI by curtailing its powers.

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[1] 42 USC §1315a. Retrieved from: https://uscode.house.gov/view.xhtml?req=(title:42%20section:1315a%20edition:prelim)%20OR%20(granuleid:USC-prelim-title42-section1315a)&f=treesort&edition=prelim&num=0&jumpTo=true (Accessed February 16, 2022.)

[2] Congress granted the HHS Secretary the authority to conduct Medicare demonstration projects through section 402 of the Social Security Act of 1967; see 42 USC §1395b-1. Retrieved from: https://uscode.house.gov/view.xhtml?req=(title:42%20section:1395b-1%20edition:prelim)%20OR%20(granuleid:USC-prelim-title42-section1395b-1)&f=treesort&edition=prelim&num=0&jumpTo=true (Accessed February 16, 2022.)

[3] Senate Committee on Finance. "Report to Accompany S. 1796." October 19, 2009. Retrieved from: https://www.finance.senate.gov/imo/media/doc/prb102109a3.pdf#page=20 (Accessed February 16, 2022.)

[4] *Ibid*.

[5] National Economic Council and Office of Science and Technology Policy. "A Strategy for American Innovation." October 2015. Retrieved from: https://obamawhitehouse.archives.gov/sites/default/files/strategy_for_american_innovation_october_2015.pdf#page=92 (Accessed February 16, 2022.)

[6] Badger, Doug. "Resetting the Scoreboard: Why CBO Should Abandon Its Flawed Analysis of the Center for Medicare and Medicaid Innovation." NTU Foundation, February 8, 2018. Retrieved from: https://www.ntu.org/foundation/detail/resetting-the-scoreboard (Accessed February 16, 2022.)

## Summary of 2018 Paper and Findings

NTU Foundation's Taxpayers' Budget Office published a paper in February 2018 examining the Congressional Budget Office's assumption that CMMI would produce net Medicare savings of $34 billion over ten years (2017-2026).

The paper challenged CBO's methodology and conclusions. It noted that in estimating that CMMI would reduce Medicare spending, CBO departed from its customary concrete, fact-based approach. Instead, its budgetary assumptions rested on faith in the CMMI process. In response to questions raised at an October 2016 House Budget Committee hearing, CBO made it clear that it based its estimate neither on an analysis of ongoing demonstration projects nor expected results.

Instead, the estimates were "primarily based on judgments about the effectiveness of CMMI's process, not on judgments about the expected results of particular demonstrations."[7]

Then-Deputy Director Mark Hadley succinctly captured CBO's methodology in his Budget Committee testimony. "The savings that CBO expects to result from the center's activities," he told the panel, "stem largely from the judgment that successful demonstrations will be expanded and achieve savings."[8]

The paper noted the statement's circularity: CBO "expects" CMMI to achieve savings because CMMI will "achieve savings."

According to the agency, the savings from these projects "will never be observed." Instead, "they will always be estimated in relation to what overall Medicare spending would have been had CMMI never been established."[9]

[7] Hadley, Mark. "CBO's Estimates of the Budgetary Effects of the Center for Medicare and Medicaid Innovation," Congressional Budget Office (CBO), September 7, 2016. Retrieved from: https://www.cbo.gov/publication/51921 (Accessed February 16, 2022; Table 2, p. 6.)

[8] *Ibid*, p. 2. In the testimony, for example, Hadley states that CBO's belief that CMMI will achieve savings "is primarily based on judgments about the effectiveness of the process, not on judgments about the expected results of particular demonstrations."

[9] Hadley, Mark. "Answers to Questions for the Record Following a Hearing by the House Committee on the Budget on CBO's Estimates of the Budgetary Effects of the Center for Medicare & Medicaid Innovation." CBO, October 28, 2016. Retrieved from: https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/reports/52137-cmmiqfrs.pdf#page=2 (Accessed February 16, 2022.)



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# Key Facts:

**The Center for Medicare and Medicaid Innovation (CMMI) was created by the Affordable Care Act (ACA), with a broad mandate to model changes to Medicare and Medicaid payments.**

**The ACA offered CMMI unique insulation from oversight and scrutiny by the legislative and judicial branches, and models could be sweeping in scope.**

**Unfortunately, more than a decade of CMMI models in action has proven that the agency's promise to reduce costs and improve quality of care were overly optimistic at best.**

**Reining in CMMI still presents a challenge to Congress, though, because of unique quirks in how the Congressional Budget Office (CBO) scores CMMI reform efforts.**

**Notwithstanding CBO scoring challenges, there are still strong and bipartisan proposals in the current Congress to limit the scale and scope of CMMI going forward.**

Hadley was correct on one point: more than five years after his testimony, CMMI has not achieved any observable Medicare savings. Indeed, as discussed later in the paper, it has marginally increased Medicare spending.

CBO conjured its savings estimates through what NTU Foundation termed a "magic asterisk" – a term attributed to then-Tennessee Senator Howard Baker to describe an illusory, unspecified placeholder for a reduction in federal spending:

> CBO estimates that the total effect of a set of demonstrations started in a given year will be an eventual reduction of about 0.1 percent each year, on average....For example, the set of demonstrations begun [during fiscal year 2016] are expected to reduce spending by a total of about $1 billion in 2026.[10]

Those savings are cumulative. Every year, new projects undertaken are expected to yield eventual savings equal to 0.1 percent of Medicare spending.

In September 2016, CBO projected that CMMI savings in fiscal year 2017 would equal $1 billion. In 2026, cumulative savings will amount to $8 billion (since new successful projects, in CBO's judgment, will be launched every year).

Because CBO pegged CMMI's savings to a fixed percentage of Medicare outlays, the more Medicare spends, the more CMMI is presumed to save. Medicare spending rises annually, and CBO believes that CMMI's savings will automatically rise along with it and at precisely the same rate.

CBO's faith in the CMMI process impaired its core function of providing legislators with an estimate of the effect of proposed legislation. In a 2015 blog post, CBO officials Paul Masi and Tom Bradley wrote (emphasis added):

> CBO examines any legislative proposals that seek to enact approaches similar to ones that CMMI is testing to determine whether HHS **would do something different** under the proposal from what it would do under current law.... To the extent that legislative proposals overlap with initiatives that CMMI is undertaking (**or is expected to undertake**), the potential additional savings would be reduced [**emphasis added**].[11]

This bias in CBO's methodology meant that it would score any proposal from the legislative branch that touched on a real or imagined CMMI project as costing the government money.

The NTU Foundation paper criticized CBO's methodology and urged CBO to rethink assumptions about CMMI. It also called on Congress to revisit CMMI's structure and authority and encouraged HHS to undertake a rigorous review of whether it had the authority to require patients and providers to participate in demonstration projects. The paper concluded:

> Given the fiscal challenges faced by federal entitlement programs in general – and those affected by CMMI demonstrations in particular – it is vital that policymakers have realistic, analytically-grounded estimates, assumptions, and projections on which to base future

[10] Hadley, Mark. "CBO's Estimates of the Budgetary Effects of the Center for Medicare and Medicaid Innovation," CBO, September 7, 2016. Retrieved from: https://www.cbo.gov/publication/51921#page=6 (Accessed February 16, 2022.) To obtain savings for a CMMI demonstration product begun in a particular year, multiply 0.1 percent by the sum of Medicare spending under Parts A and B (but not Part D). According to the CBO baseline at the time Hadley testified, Medicare Parts A and B spending in 2026 were estimated to be $1.094 trillion. Multiplying that figure by 0.1 percent yields $1.09 billion. Since then, CBO has upwardly revised its estimate of 2026 Medicare spending. Using the CBO math, demonstration projects begun in FY 2016 will now yield $1.1 billion in savings in 2026, an increase of around $100 million. Because of the CBO methodology, the higher Medicare spending is expected to rise, the greater the savings CMMI will be estimated to achieve.

[11] Masi, Paul, and Bradley, Tom. "Estimating the Budgetary Effects of Legislation Involving the Center for Medicare and Medicaid Innovation," CBO, July 30, 2015. Retrieved from: https://www.cbo.gov/publication/50692 (Accessed February 16, 2022.)

decisions. It is time to evaluate how CBO has constructed the "scoreboard" for CMMI, so as to ensure that meaningful statistics are informing the true state of play.[12]

Unfortunately for taxpayers, four years after this recommendation was written CMMI's promises and premises remain fiscally underwhelming.

## Present-Day Review of CMMI

Halfway into CBO's 2017-26 forecast period – which projected $34 billion in net Medicare savings – the agency is not producing the savings hoped for by advocates and predicted by CBO.

The major promise of CMMI was to cut costs while maintaining or improving quality of care. A quick look at the existing evidence shows that CMMI has at best a mixed history on cost and quality of care.

The most recent and comprehensive evidence of CMMI's reach and success (or lack thereof) is in its 2020 report to Congress.[13]

That report found that, from fiscal year (FY) 2019 through FY 2020 – a two-year period beginning on October 1, 2018 and ending on September 30, 2020 – over 27.8 million Medicare, Medicaid, and privately covered individuals were affected by CMMI models, receiving care from 528,000 providers or plans.

Although CMMI is supposed to address spending in Medicare and Medicaid, the two largest federal health programs, almost one in five of the individuals affected by CMMI in this two-year period (more than 4.8 million in total) were individuals with *private* coverage, the uninsured, or people not covered by Medicare, Medicaid, or CHIP. An earlier 2018 report on CMMI's performance – covering FYs 2017 through 2018 – found that more than one third of individuals affected by CMMI models were privately covered.[14] NTU has been concerned about mission creep at the agency, and the high proportion of affected individuals who have *private* coverage (rather than Medicare or Medicaid coverage) provides evidence of this mission creep.

But what should be more concerning for CMMI proponents and skeptics alike is the performance of major models, *as reported by CMMI itself*.

CMMI announced or tested 44 models in the two-year period covered by their 2020 report.[15] Of five major models totaling nearly $2.9 billion in costs and 19 million individuals impacted:

- Three had not yet reported out major results on net cost savings or increases;
- One (the Medicare Advantage Value-Based Insurance Design, or VBID, Model) was "not yet generating savings," but also "not costing CMS additional money"[16]; and

[12] Badger, Doug. "Resetting the Scoreboard: Why CBO Should Abandon Its Flawed Analysis of the Center for Medicare and Medicaid Innovation." NTU Foundation, February 8, 2018. Retrieved from: https://www.ntu.org/foundation/detail/resetting-the-scoreboard (Accessed February 16, 2022.)

[13] Center for Medicare and Medicaid Innovation (CMMI). "2020 Report to Congress." August 11, 2021. Retrieved from: https://innovation.cms.gov/data-and-reports/2021/rtc-2020 (Accessed February 16, 2022.)

[14] CMMI. "2018 Report to Congress." 2019. Retrieved from: https://innovation.cms.gov/files/reports/rtc-2018.pdf (Accessed February 16, 2022.)

[15] CMMI. "2020 Report to Congress." August 11, 2021. Retrieved from: https://innovation.cms.gov/data-and-reports/2021/rtc-2020 (Accessed February 16, 2022.)

[16] The earlier NTU paper noted that Congress considered two separate pieces of legislation dealing with the VBID demonstration. The first, which was reported favorably in 2015 by House and Senate committees of jurisdiction, would have directed the HHS Secretary to launch a VBID demonstration program. CBO reasoned that the bill would increase federal Medicare spending by $210 million, since CBO believed that CMMI would at some future date propose a more "flexible" VBID than that envisioned in the legislation and one that would save more money. CMMI launched a VBID demonstration program in seven states in January 2017. Congress considered legislation allowing Medicare Advantage plans in all 50 states to participate in the VBID program. Once again, CBO concluded that this legislation would cost the federal government money, since Congress and not the agency would determine the project's scope. Neither piece of legislation gained enactment and the demonstration went forward according to CMMI's specifications, without the involvement of Congress. The program has not

- One (the Next Generation Accountable Care Organization, or NGACO Model) "reduced total Medicare Part A and B spending, but was associated with an *increase* ... in net Medicare spending" by $118 million (emphasis ours);[17] over the first four years of the NGACO model, total net losses for Medicare were $243 million.[18]

This is hardly the resounding, routinely replicable success story that CMMI advocates hoped for upon passage of the ACA.

Additional, prominent models promulgated by CMMI have had anywhere from mixed to no evidence of Medicare savings at best:

- The first two years of the Bundled Payments for Care Improvement (BPCI) Advanced Model, which included 334 participants and promised to "accelerate the value-based transformation of America's healthcare system" and "provide an off-ramp to the inefficient fee-for-service system," resulted in $66 million in net losses for Medicare;[19] through the third performance year, BPCI Advanced had 694 participants and $158.6 million in net losses;[20]

- The first six years of the Independence at Home (IAH) demonstration for "home-based primary care" found "no compelling evidence that the payment incentive affected the delivery of care in a way that measurably reduced total Medicare expenditures or hospital use";[21] and

- The first four years of Comprehensive Care for Joint Replacement (CJR) Model – which mandated participation for hundreds of hospitals – resulted in only $21.4 million in estimated net savings after CMS estimated the Model would save $343 million in its first five years, leaving CMMI to state that it "[c]annot conclude that Medicare realized savings across the entire CJR model."[22]

A 2020 study conducted by the healthcare consulting firm Avalere provides an even starker picture of CMMI's potentially bleak future.[23]

Avalere casts significant doubt on CBO estimates for CMMI's future success.[24] While CBO projected $34 billion in net savings from CMMI for the FYs 2017-2026 period (which incorporates the budgetary cost of CMMI over the same period), Avalere projects only $18 billion in net savings over the same period.[25] This is barely more than half of CBO's projected savings.

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generated savings, despite CBO's faith in the agency. See Badger, "Resetting the Scoreboard."

[17] Though the model reduced gross spending in Medicare Parts A and B, taxpayers experienced a net loss after accounting for "shared savings" and "Coordinated Care Reward payments" to participating ACOs. For more, see: CMMI. "2020 Report to Congress." August 11, 2021. Retrieved from: https://innovation.cms.gov/data-and-reports/2021/rtc-2020 (Accessed February 16, 2022.)

[18] CMMI. "Next Generation Accountable Care Organization (NGACO) Model." 2021. Retrieved from: https://innovation.cms.gov/data-and-reports/2021/nextgenaco-fg-fourthevalrpt (Accessed February 16, 2022.)

[19] CMMI. "Bundled Payments for Care Improvement Advanced (BPCI Advanced) Model Years 1 & 2." 2022. Retrieved from: https://innovation.cms.gov/data-and-reports/2022/bpci-adv-ar3-findings-aag (Accessed February 16, 2022.)

[20] CMMI. "Bundled Payments for Care Improvement Advanced (BPCI Advanced) Model Years 1, 2 & 3." 2021. Retrieved from: https://innovation.cms.gov/data-and-reports/2021/bpci-yr2-annual-report-findings-aag (Accessed February 16, 2022.)

[21] CMMI. "Independence at Home Evaluation of Performance Years 1 to 6 (2012 to 2019)." 2021. Retrieved from: https://innovation.cms.gov/data-and-reports/2021/iah-year6-eval-report-fg (Accessed February 16, 2022.)

[22] CMMI. "Comprehensive Care for Joint Replacement (CJR) Model Evaluation of Performance Years 1 to 4 (2016 - 2019)." 2021. Retrieved from: https://innovation.cms.gov/data-and-reports/2021/cjr-py4-ar-findings-aag (Accessed February 16, 2022.)

[23] Avalere. "CMMI's Financial Impact on Medicare Spending Challenging to Project (Updated)." January 14, 2020. Retrieved from: https://avalere.com/insights/cmmis-financial-impact-updated (Accessed February 16, 2022.)

[24] *Ibid*. The firm notes that their "approach for projecting future CMMI activity is generally consistent with CBO, with the notable exception that Avalere's projected savings for CMMI rely on demonstration-specific savings estimates, based on program evaluation reports for existing demonstrations and CMS regulatory impact analyses for proposed demonstrations."

[25] *Ibid*.

CMMI proponents might argue that $18 billion in savings would still be significant for Medicare and Medicaid and could point the way to larger savings in future decades. They could be correct, but a closer look at Avalere's analysis reveals that almost all the firm's projected CMMI savings derive from a single demonstration project (the International Pricing Index, or IPI) that the Trump administration never launched.

That demonstration project, discussed at greater length in the next section, would have pegged the prices Medicare pays for Part B drugs and biologics to prices in a basket of other countries. NTU expressed strong concerns with the IPI proposal, warning it was "seriously misguided" and would have harmed patients and reduced innovation in America's pharmaceutical sector, potentially leading to downstream cost increases for taxpayers who would be on the hook for more expensive medical treatments like surgeries and hospital stays.[26] As discussed in further detail in the next section, neither this demonstration project nor a successor announced in November 2020 (which NTU expressed strong concerns over) ever took effect.[27]

Without major potential savings from the Medicare drug pricing demonstrations, both of which have been scuttled, Avalere projected that CMMI would actually impose a *net cost* on the federal government, of $2.8 billion, rather than net savings, over the FYs 2017-2026 window.[28]

Therefore, it's quite possible, even probable, that in a given 10-year window the agency is actually costing taxpayers rather than providing the significant savings promised by some CMMI proponents and projected by CBO. Combined with the unique insulation the agency enjoys against congressional oversight and judicial review, it's clear CMMI requires some short- and long-term reform.

Thus, as suggested in our 2018 paper, CBO was incorrect in forecasting that CMMI demonstration projects would produce tens of billions of dollars in savings to the federal government. CMMI may now be on track to lose $2.8 billion over that ten-year window, according to the Avalere Health analysis.[29]

CBO should revise its scoring methodology and not assume that CMMI would save money simply because CBO is enamored of the process. This assumption not only has proven false, but it also serves as an impediment to congressional reform of CMMI. Such an assumption means that any legislative intervention will cost the government money, since the CBO bakes phantom assumptions about CMMI-induced Medicare "savings" into its baseline.

CBO has generally avoided incorporating partisan assumptions into its baseline, preferring data-based metrics. It has, for example, acknowledged that adding staff to the Internal Revenue Service would increase tax collections, but its estimates are far below those floated by advocates.[30] It also has taken a measured approach to the drug pricing issue, putting it at variance with the assumptions of partisans who argue that government should use price controls to combat rising drug prices. In a January 2022 report, CBO observed that the average net price per prescription fell between 2009 and 2018, and that per capita spending on medicines grew more slowly than other health care spending over that period.[31]

CBO should align the methodology it uses to estimate the budgetary effects of CMMI to its customary approach.

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[26] Lautz, Andrew. "International Pricing Index Proposals Would Harm Patients and Reduce Innovation." NTU, July 20, 2020. Retrieved from: https://www.ntu.org/publications/detail/international-pricing-index-proposals-would-harm-patients-and-reduce-innovation.

[27] Lautz, Andrew. "CMS Should Withdraw Most Favored Nation Rule." December 18, 2020. Retrieved from: https://www.ntu.org/publications/detail/cms-should-withdraw-most-favored-nation-rule

[28] Avalere. "CMMI's Financial Impact on Medicare Spending Challenging to Project (Updated)." January 14, 2020. Retrieved from: https://avalere.com/insights/cmmis-financial-impact-updated (Accessed February 16, 2022.)

[29] *Ibid*.

[30] Swagel, Phill. "The Effects of Increased Funding for the IRS." Congressional Budget Office. September 2, 2021. Retrieved from: https://www.cbo.gov/publication/57444 (Accessed March 8, 2022.)

[31] "Prescription Drugs: Spending, Use, and Prices." Congressional Budget Office. January 2022. Retrieved from: https://www.cbo.gov/system/files/2022-01/57050-Rx-Spending.pdf (Accessed March 8, 2022.)

## How CMMI has Abused Authority and Possible Future Abuses

Congress established CMMI and vested it with unprecedented powers on the theory that federal bureaucrats and political appointees, unencumbered by the need to answer to voters, would use those powers and superior acumen to achieve budgetary savings. Faith in the CMMI process induced CBO to forecast savings that have, as we have seen, proven illusory.

Nevertheless, CMMI retains enormous power, including making demonstration programs unlimited in duration and unbounded in scope.

Two successive administrations have proposed sweeping demonstration projects designed to reduce Medicare spending on physician-administered drugs. Both were subsequently scuttled, and both show CMMI's willingness to rewrite Medicare reimbursement rules in ways that render nugatory congressionally-enacted statutes.

## Background on CMMI Medicare Drug Pricing Demonstrations

Medicare Part D covers prescription medicines that seniors typically pick up at pharmacy counters or through mail-order distributors. Drugs that patients don't ordinarily self-administer are covered under Medicare Part B. These are typically injected or infused biologics like chemotherapy and products that treat autoimmune diseases. Unlike Part D drugs, the medical practice or hospital – not the patient – obtains medications that Part B covers. Medicare reimburses the provider for the drug and for the costs of administering it to patients.

| Medicare Part B Reimbursement CMMI Demonstration Projects | | | |
|---|---|---|---|
| **Description** | **Proposed** | **Withdrawn** | **Comments** |
| Notice of proposed rulemaking to change the add-on payment for physician-administered drugs from 6% to a lesser amount. | March 11, 2016 (notice of proposed rulemaking) | August 1, 2017 | The proposed demonstration project was the subject of bipartisan criticism. The Obama administration delayed its launch, scheduled for fall 2016. The Trump Administration formally withdrew the proposal. |
| Advance notice of proposed rulemaking that would have based Medicare reimbursement on an international price index, established by looking at prices in a select list of developed countries. | October 25, 2018 (advance notice of proposed rulemaking) | | Although never formally withdrawn, the administration took no action after issuing the ANPRM. |
| Interim final rule that would have based Medicare reimbursement on a "most-favored nation" approach. The Secretary would establish Medicare reimbursement based on the lowest price for a drug among a list of nations chosen on certain economic criteria. | November 27, 2020 (interim final rule) | December 27, 2021 (effective February 28, 2022) | Several federal courts issued injunctions against launching the demonstration, based on violation of the Administrative Procedures Act. The Biden Administration did not contest the rulings and later formally scuttled the demo. |

Medicare bases reimbursement on the medicine's "average sales price" (ASP) – the average price manufacturers are paid for a product, net of discounts, rebates, and other price concessions – plus six percentage points.[32] This "ASP+6" formula attempts to capture market prices for the therapeutic along with an additional sum to compensate for other costs, such as storage, wastage and spillage. The provider bills

[32] 42 U.S.C. §1395w-3a. Retrieved from: https://uscode.house.gov/view.xhtml?req=(title:42 section:1395w-3a edition:prelim) (Accessed February 16, 2022.)

Medicare for the drug itself – and is reimbursed at ASP+6 – and separately for the expense of administering the product to patients, for example, by infusion.

The Trump Administration demonstration project would have scuttled the ASP portion of the Part B formula. The Obama Administration project proposed to change the "+6" component. Neither project launched.

## Obama Administration CMMI Medicare Drug Pricing Demonstration

Our previous paper discussed the Obama Administration's demonstration project on physician-administered drugs at greater length. As noted above, it proposed to address the "+6" portion of the statutory ASP+6 formula. Under the demonstration project, the government would immediately depart from the statutory formula in half the country, paying ASP+2.5+$16.80 – the drug's average sales price, plus 2.5 percent of that price, plus $16.80.[33] That methodology was to take effect in the fall of 2016.

Beginning in January 2017, the second phase of the demonstration was to launch, introducing "value-based purchasing tools" (e.g., reference pricing, risk-sharing arrangements with manufacturers) into the mix.

CMMI never initiated the demonstration, which was the target of bipartisan criticism, and the Trump Administration formally retired the proposal on August 1, 2017. The demonstration raised concerns among Democrats and Republicans alike over its mandatory, nationwide nature, and its impact on access to innovator specialty medications such as cancer treatments. Even House Speaker Pelosi welcomed the withdrawal noting the members of her caucus had "raised a number of concerns."[34]

## Trump Administration CMMI Medicare Drug Pricing Demonstration

The Trump administration advanced two proposals that would have replaced the statutory reimbursement formula for physician-administered drugs from one based on a product's average sales price to one pegged to prices paid by certain foreign governments. While both incorporated foreign reference pricing, each had its particularly problematic characteristics.

The first, proposed as a five-year demonstration project in October 2018, would have established an international pricing index (IPI) to set reimbursement for certain Part B physician-administered drugs. As CMS explained in its Advance Notice of Proposed Rulemaking:

> Specifically, CMS intends to test whether phasing down the Medicare payment amount for selected Part B drugs to more closely align with international prices; allowing private-sector vendors to negotiate prices for drugs, take title to drugs, and compete for physician and hospital business; and changing the 4.3 percent (post-sequester) drug add-on payment in the model to reflect 6 percent of historical drug costs translated into a set payment amount, would lead to higher quality of care for beneficiaries and reduced expenditures for the Medicare program.
>
> The IPI Model would test whether increasing competition for private-sector vendors to negotiate drug prices and aligning Medicare payments for drugs with prices that are paid in foreign countries, improves beneficiary access and quality of care while reducing expenditures.[35]

[33] Centers for Medicare and Medicaid Services (CMS). "Medicare Program; Part B Drug Payment Model." March 11, 2016. Retrieved from: https://www.govinfo.gov/content/pkg/FR-2016-03-11/pdf/FR-2016-03-11.pdf#page=441 (Accessed February 16, 2022.)
[34] Office of Information and Regulatory Affairs. "Part B Drug Payment Model." 2022. Retrieved from: https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0938-AS85 (Accessed February 16, 2022.) Also, Pear, Robert. "Plan to Reduce Medicare Drug Costs Is Withdrawn After Bipartisan Criticism," The New York Times, December 16, 2016. Retrieved from: https://www.nytimes.com/2016/12/16/us/politics/plan-to-reduce-medicare-drug-costs-is-withdrawn-after-bipartisan-criticism.html.
[35] CMS. "International Pricing Index Model." 2018. Retrieved from: https://innovation.cms.gov/innovation-models/ipi-model (Accessed February 16, 2022.)

The linchpin of this scheme was to establish an IPI based on prices of comparable drugs in 14 developed countries. The rule was roundly criticized by taxpayer advocates. It also ran counter to the President's own Council of Economic Advisers, who noted that "[r]educing foreign price controls [on prescription drugs] would increase profits and innovation, thereby leading to greater competition and lower prices for U.S. patients."[36]

Although the plan was for the demonstration to take effect in the spring of 2020, the administration never formally proposed nor finalized the project. Instead, the administration issued an interim final rule in late 2020 that would have launched an even more damaging proposal: The Most Favored Nation (MFN) Model. Unlike IPI, which imposed price controls predicated on a 14-country *average*, MFN would have imposed the *lowest* price for a drug from among a select list of countries. Furthermore, the administration proposed to levy penalties on producers whose prices rose faster than the rate of inflation, a penalty without statutory authorization. That penalty would have applied both during and after the MFN price phase-in; a feature not present in IPI.[37]

The mandatory, nationwide MFN program would at first target 50 single-source drugs and biologicals that accounted for a large percentage of Medicare Part B spending in 2019. Physicians, hospitals, group practices, supplier groups, and other entities that acquire and administer these drugs to patients would be required to participate in the project.

Once CMMI selected the 50 drugs, it would examine the GDP-adjusted country-level price in OECD countries with a per capita GDP of at least 60 percent of the U.S. per capita GDP. The agency would then identify the lowest price among those countries based on purchasing power parity. That would become the reference price that Part B would reimburse for that product.

CMS would phase in that new reimbursement rate over four years. Medicare reimbursement would be based 25 percent on the reference price and 75 percent on ASP in the first year. By the fourth year, Medicare reimbursement would be entirely based on the reference price.[38]

The Trump administration published the interim final rule in November 2020 and set an effective date of January 1, 2021. The proposal met with immediate judicial challenges. In three separate cases, federal judges held that the action violated the Administrative Procedure Act because CMMI did not solicit public comments before putting the rule into effect.[39] A nationwide injunction was entered on December 28, 2020.[40] On December 27, 2021, the Biden administration formally withdrew the proposal, effective February 28, 2022.[41]

The critical point is that two administrations of different parties with divergent ideologies and governing styles sought to use CMMI to replace statutory Medicare drug reimbursement provisions with methodologies of their own devising on a national basis. While a successor administration withdrew both and multiple federal judges held that the Trump Administration proposal ran afoul of the Administrative Procedure

[36] The Council of Economic Advisers. "Funding the Global Benefits to Biopharmaceutical Innovation." February 2020. Retrieved from: https://trumpwhitehouse.archives.gov/wp-content/uploads/2020/02/Funding-the-Global-Benefits-to-Biopharmaceutical-Innovation.pdf#page=3 (Accessed February 16, 2022.)

[37] CMS. "Most Favored Nation Model." 2022. Retrieved from: https://innovation.cms.gov/innovation-models/most-favored-nation-model (Accessed February 16, 2022.)

[38] The rule also sets the add-on payment at 6.1224 percent of the product's average sales price in 2019. 42 CFR 513.220(b), withdrawn effective February 28, 2022. https://www.law.cornell.edu/cfr/text/42/513.220 (Accessed February 19, 2022).

[39] California Life Sciences Association v. CMS, United States District Court for the Northern District of California, Case No. 20-cv-08603-VC, December 28, 2020. https://innovation.cms.gov/media/document/mfn-ca-50-order-prelim-injunct (Accessed February 19, 2022). Association of Community Cancer Centers v. Azar, United States District Court for the District of Maryland, Case No. GJH-20-3531, January 6, 2021 https://innovation.cms.gov/media/document/mfn-d-md-tro-extend-memo (Accessed February 19, 2022). Regeneron Pharmaceuticals v. HHS, United States District Court for the Southern District of New York, Case No. 20-CV-10488 (KMK), December 30, 2020. https://innovation.cms.gov/media/document/mfn-ny-order-prelim-injunct (accessed February 19, 2022).

[40] California Life Sciences Association v. CMS, December 28, 2020.

[41] CMS. "Most Favored Nation (MFN) Model." December 29, 2021. Retrieved from: https://www.govinfo.gov/content/pkg/FR-2021-12-29/pdf/2021-28225.pdf (Accessed February 16, 2022.)

Act, CMMI can be expected to use its unprecedented authorities to pursue the practice of supplanting statutory reimbursement methodologies on a national basis. Indeed, it would appear that the only way CMMI's proposals can save significant money for taxpayers is for the agency to exercise unlawful authority to impose price controls and other schemes that Congress has not enacted, for fear of incurring voters' wrath. Some would call this a feature of CMMI; we believe it to be a fatal flaw.

## Potential Future CMMI Demos

President Biden, like his predecessor, has harshly criticized prescription drug prices and urged Congress to enact legislation to curb those prices. Once it became clear that Congress would not act, President Trump directed HHS to implement reductions on Medicare drug prices through regulatory action.

The Biden administration is following a similar path. The House-passed version of the Build Back Better Act authorized the HHS Secretary to "negotiate" prices for prescription drugs.[42] As of April 2022, action on the overall measure remains stalled, and the prospects for sweeping prescription drugs price controls remain uncertain.

If congressional efforts falter, the Biden administration may follow the Trump administration template and seek to accomplish through a CMMI demonstration at least part of what it failed to achieve through legislation. The probability of such action would increase if the president's party lost its House or Senate majority in November 2022.

In those circumstances, the administration could use CMMI to accomplish some of the drug pricing policies that the president has supported. These include:

- *Part D prescription drug price negotiation*. Manufacturers and prescription drug plan sponsors negotiate prices for drugs under Part D. The statute prohibits the Secretary from interfering in these negotiations.[43] This so-called "noninterference" provision has drawn criticism since Congress enacted legislation creating the Part D benefit in 2003.[44] While past demonstration projects have sought to replace the statutory Part B reimbursement methodology, CMMI could propose to create an alternative Part D scheme that circumvents the noninterference clause.

- *Incorporation of foreign drug prices into Medicare*. Biden has said that he supports "empower[ing] the HHS Secretary to negotiate prices that are capped to a level associated with average OECD median prices."[45] His administration could follow a notice-and-comment rulemaking process in proposing a revised version of the scuttled Trump Administration demonstration project.

- *Limiting increases in Medicare reimbursement for drugs to the CPI*. The Build Back Better Act contained a provision that would limit increases in Medicare reimbursement for products whose price growth exceeded the overall rate of inflation.[46] If this provision fails enactment, CMMI could incorporate it into a demonstration.

[42] Rules Committee Print 117-18, Text of H.R. 5376, Build Back Better Act, November 3, 2021, section 139001. https://www.congress.gov/117/cprt/HPRT46234/CPRT-117HPRT46234.pdf (Accessed February 19, 2022).
[43] 42 USC §1395w-111(i). Retrieved from: https://uscode.house.gov/view.xhtml?req=(title:42%20section:1395w-111%20edition:prelim)%20OR%20(granuleid:USC-prelim-title42-section1395w-111)&f=treesort&edition=prelim&num=0&jumpTo=true (Accessed February 16, 2022.)
[44] Cubanski, Juliette; Neuman, Tricia; and Freed, Meredith. "What's the Latest on Medicare Drug Price Negotiations?" Kaiser Family Foundation, July 23, 2021. Retrieved from: https://www.kff.org/medicare/issue-brief/whats-the-latest-on-medicare-drug-price-negotiations/ (Accessed February 16, 2022.)
[45] Cubanski, Juliette; Neuman, Tricia; and Freed, Meredith. "Moving the Needle on Prescription Drug Costs: Using the Innovation Center and Other Demonstration Authority." Kaiser Family Foundation, March 25, 2021. Retrieved from: https://www.kff.org/medicare/issue-brief/moving-the-needle-on-prescription-drug-costs-using-the-innovation-center-and-other-demonstration-authority/ (Accessed February 16, 2022.)
[46] Congress.gov. (Introduced September 27, 2021.) "H.R.5376 - Build Back Better Act." Retrieved from: https://www.congress.gov/bill/117th-congress/house-bill/5376/text (Accessed February 16, 2022; Sections 139101 and 139102.)

Nor would CMMI necessarily limit itself to revising Medicare reimbursement for drugs. The agency could seek out opportunities to alter reimbursement structures for other medical goods and services. Once again, CMMI's prospects for achieving significant savings for taxpayers would appear tied to its ability to overstep legal and constitutional boundaries.

CMMI has repeatedly drifted from its core function of innovation and into the realm of policymaking. The agency is charged with testing innovative approaches that will save Medicare money, enhance medical care quality, or both. Such tests should be limited in scope and duration and subject to rigorous evaluation. If the Secretary determines a project to be successful, he or she should ask Congress to extend it nationally. Making changes of unlimited duration and scope is a legislative prerogative, not an administrative one.

So long as CMMI retains the power and the appetite to launch national "demonstration" projects that circumvent federal statutes, then – in the absence of congressional reform legislation — only the courts can restrain it. Federal judges so far have not thought themselves bound by the statutory limitations on judicial review.[47] Their rulings thus far, however, have only extended to procedural issues. The courts seem likely to continue to require notice and comment rulemaking to be part of any significant CMMI project.

If the agency adhered to this procedural constraint, it remains an open question as to whether the courts would regard themselves as barred from hearing cases that deal with issues such as the scope and duration of a demonstration program.

Lawmakers erred in 2010 in conferring on CMMI a license to legislate. Congress should amend the CMMI authorizing statute to curtail the agency's power, rather than consigning protection of its legislative prerogatives to the whims of political appointees and the wisdom of judges.

## NTU Proposals for CMMI Reform

CMMI's flaws are so significant – and its promise of savings so dubious – that lawmakers would be well within their rights to shutter the agency and cut off its funding, while potentially providing for certain demonstration projects to continue under the Centers for Medicare and Medicaid Services' (CMS) pre-ACA demonstration project authority.

Absent widespread and bipartisan support for CMMI repeal, though, lawmakers should pursue reforms that limit the agency's powers and make it more accountable to Congress, the courts, and the public.

Fortunately, there is bipartisan support for CMMI reform. During the 116th Congress, Reps. Terri Sewell (D-AL) and Adrian Smith (R-NE) introduced H.R. 5741, the Strengthening Innovation in Medicare and Medicaid Act.[48] The legislation earned the support of nine additional Democrats and seven additional Republicans, making it broadly bipartisan.

The bill would require the Secretary, before the testing, expansion, or modification of a demonstration project, to notify committees of jurisdiction in the House and Senate. That notification would trigger a 45-calendar-day period during which Congress could enact a resolution disapproving the project. Such resolution would be considered under "fast-track" rules and would be subject to presidential veto. The

[47] 42 USC 1395a(d)(2). Retrieved from: https://uscode.house.gov/view.xhtml?req=(title:42%20section:1395a%20edition:prelim)%20OR%20(granuleid:USC-prelim-title42-section1395a)&f=treesort&edition=prelim&num=0&jumpTo=true (Accessed February 16, 2022.) The provision lays out the following limitations: There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise of (A) the selection of models for testing or expansion under this section; (B) the selection of organizations, sites, or participants to test those models selected; (C) the elements, parameters, scope, and duration of such models for testing or dissemination; (D) determinations regarding budget neutrality under subsection (b)(3); (E) the termination or modification of the design and implementation of a model under subsection (b)(3)(B); and (F) determinations about expansion of the duration and scope of a model under subsection (c), including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection.

[48] Congress.gov. (Introduced February 3, 2020.) "H.R.5741 - Strengthening Innovation in Medicare and Medicaid Act." Retrieved from: https://www.congress.gov/bill/116th-congress/house-bill/5741 (Accessed February 16, 2022.)

testing, expansion or modification of the demonstration project could not take effect until the expiration of the 45-day period.

While this is an important limitation on secretarial authority, it could be improved. As a practical matter, even if Congress disapproved a proposal to extend a demonstration project nationwide, a president could be expected to veto it. Presidents are unlikely to sign into law resolutions that kill projects that their subordinates have devised.

Instead of allowing the Secretary to expand projects nationally, Congress should require the Secretary to seek legislation to codify models he or she deems successful. The Secretary can test ideas on a geographically limited basis for a defined period, but only Congress has the constitutional authority to extend them nationally by amending the Medicare statute.

The bill would place several additional important guardrails on CMMI and its current, sweeping authority:

- It limits CMMI models to five years and to no more individuals than necessary "to obtain a statistically valid sample";
- It requires HHS to allow providers and suppliers to request a waiver from model requirements for "undue economic hardship … or loss of access to such provider or supplier for vulnerable populations";
- It requires HHS to develop a plan to continuously monitor the effects of models and to "mitigate any adverse impact";
- It requires HHS to provide at least 45 days for public comment on proposed models, during model development, prior to testing, prior to modification, and prior to rulemaking on expansion;
- Importantly, the legislation restores judicial review for "[e]lements, parameters, scope, and duration of models" and "[d]eterminations about expansion of duration/scope of a model"; and finally
- It requires annual reports instead of biennial reports, ensuring Congress hears from CMMI regularly about its models' performance and its future plans.[49]

Legislation from this current session of Congress, H.R. 5125, the Strengthening Innovation in Medicare and Medicaid Act, would make many of the same reforms.[50] It currently lacks the bipartisan support of H.R. 5741 from the previous Congress, but the reforms therein have a track record of bipartisan support.

There are several additional steps Congress could take to rein in CMMI that go even further than the Strengthening Innovation in Medicare and Medicaid Act. For example, even though the bill limits CMMI models to five years, NTU actually asked former CMS Administrator Verma in 2017 to limit demonstrations to *no more than 24 months* rather than five years.[51]

Here are a few other levers Congress could pull to exercise more effective oversight of CMMI and to limit the agency's power:

- Require models to limit testing to certain geographic areas;

[49] *Ibid*.
[50] Congress.gov. (Introduced August 27, 2021.) "H.R.5125 - Strengthening Innovation in Medicare and Medicaid Act." Retrieved from: https://www.congress.gov/bill/117th-congress/house-bill/5125/text (Accessed February 16, 2022.)
[51] Sepp, Pete. "NTU's Comments on Centers for Medicare & Medicaid Services." November 22, 2017. Retrieved from: https://www.ntu.org/publications/detail/ntus-comments-on-centers-for-medicare-medicaid-services.

- Narrowly define, in the general criteria for CMMI phase 1 testing, "deficits of care," "poor clinical outcomes," and "potentially avoidable expenditures";
- Require HHS to project that a model will, at minimum, be budget neutral before proceeding with phase 1 testing;
- Require HHS to terminate a model if it's not expected to 1) improve quality of care without increasing spending or 2) reduce spending without reducing quality of care (under current law HHS must terminate *or modify*);[52]
- Require public reporting on CMMI models within a specified period, rather than just in a "timely fashion"; and
- Require the CMS Actuary to certify net spending reductions, rather than mere budget neutrality, in order to approve phase 2 expansion.

Additional recommendations from NTU and its partners outside government can be found in 2017 comments to CMS[53] and in a 2016 letter to Congress.[54] While repeal of the agency and its expansive authorities may be the best path forward, there is no shortage of reform ideas noted above that either *currently* have bipartisan support or that may garner bipartisan support in the future.

## Conclusion

Congress created CMMI with visions of transforming health care delivery and achieving significant budgetary savings. More than a decade later, these hopes have not materialized. For the most part, CMMI-initiated demonstrations have neither saved the government money nor improved medical care quality.

Given CMMI's track record, Congress should revisit the starry-eyed assumptions that accompanied its creation. CBO should take a clear-eyed look at CMMI's track record and not base cost estimates on misguided faith in the agency's process. HHS has long-standing authority to test ideas for cutting costs and enhancing quality. Congress has often directed the agency to conduct demonstrations. Agency-initiated projects should be limited in duration and scope and rigorously evaluated. If HHS conducts a demonstration that it believes merits nationwide expansion, then it should propose that Congress amend the Medicare statute.

This approach to the proper use of demonstration authority is plodding, prosaic, and solidly constitutional. For more than a decade, CMMI's exotic flights of bureaucratic fancy have crashed into experiential, judicial, and political reality. It has neither restructured health care delivery, improved its quality, nor reduced its cost.

Controlling Medicare spending is a matter of highest urgency for Congress. Federal actuaries have forecast that Medicare's health insurance (HI) fund will be insolvent within four years.[55] More broadly, health care entitlement spending – including Medicare, Medicaid, and the Affordable Care Act – is the largest and fastest-growing component of the federal budget and the leading cause of long-term fiscal instability.[56] Congress has not seriously engaged in curbing Medicare and other health care entitlement spending in

[52] Lawmakers should also define "quality of care" more precisely – such a term could be manipulated by stakeholders in order to defeat any proposals that may present modest savings to taxpayers and/or streamline access to care for Medicare and Medicaid patients.
[53] *Ibid*.
[54] NTU. "Congress Must Repeal or Restrain Obamacare's CMMI." November 16, 2016. Retrieved from: https://www.ntu.org/publications/detail/congress-must-repeal-or-restrain-obamacares-cmmi (Accessed February 16, 2022.)
[55] *2021 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplemental Medical Insurance Trust Funds.* August 2021. Page 6. Retrieved from: https://www.cms.gov/files/document/2021-medicare-trustees-report.pdf (Accessed March 8, 2022.)
[56] Badger, Doug. "A Major threat to our Economy – Health Care Spending." Fox Business. October 29, 2019. Retrieved from: https://www.foxbusiness.com/money/doug-badger-major-threat-economy-health-care-spending (Accessed March 8, 2022.)

a generation and neither the administration nor the current congressional leadership has expressed any interest in doing so.

Congress can't outsource to the executive branch the critical tasks of stabilizing the Medicare program and ensuring its solvency. CMMI's track record proves what should always have been obvious: the agency can't be expected to devise projects that will meaningfully improve Medicare's dismal financial outlook. CMMI is little more than a distraction from daunting fiscal issues that demand the attention of lawmakers.

Congress should retool the agency into one that minds the constitutional rules of the road and provides a better sense of direction toward more fiscally sustainable federal health care programs.

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