

# CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

October 4, 2016

## H.R. 5122

A bill to prohibit further action on the proposed rule regarding testing of Medicare Part B prescription drug models

As introduced on April 29, 2016

#### **SUMMARY**

H.R. 5122 would prevent the Secretary of Health and Human Services (HHS) from implementing a proposed demonstration to modify payment for prescription drugs covered under Part B of the Medicare program. The Center for Medicare and Medicaid Innovation (CMMI) will manage the demonstration, and, under current law, CMMI has broad authority and funding to test various projects.

CBO estimates that enacting H.R. 5122 would increase direct spending by \$395 million over the 2017-2026 period. That estimate includes the savings that would be lost if the proposed demonstration was blocked, offset in part by additional savings that would result from CMMI's ability to mitigate that loss by replacing the blocked demonstration with other projects, some of which would reduce federal spending.

Pay-as-you-go procedures apply to the bill because enacting it would affect direct spending. The bill would not affect revenues.

CBO estimates that enacting the legislation would not increase net direct spending or on-budget deficits by more than \$5 billion in any of the four consecutive 10-year periods beginning in 2027.

H.R. 5122 contains no private-sector or intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

### ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary effect of H.R. 5122 is shown in the following table. The costs of this legislation fall within budget function 570 (Medicare).

	By Fiscal Year, in Millions of Dollars											
	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2017- 2021	2017
INCR	REASE (	OR DE	CREAS	SE (-) II	N DIRE	ECT SP	ENDIN	IG				
Direct Effect of Blocking Part B Drug Demonstration Estimated Outlays	60	85	90	100	110	120	130	140	150	160	445	1,14:
Effect of Replacement Demonstrations Estimated Outlays	0	0	-67	-75	-82	-90	-98	-105	-113	-120	-224	ŕ
Net Effect on Direct Spending Estimated Outlays	60	85	23	25	28	30	32	35	37	40	221	39.

#### BACKGROUND AND CURRENT LAW

Medicare Part B covers prescription drugs that must be infused or injected.<sup>1</sup> Payment for drugs covered under Part B is based on a drug's Average Sales Price (ASP), plus a six percent mark-up (about 4.3 percent after accounting for the effect of mandatory sequestration). CBO estimates that Medicare will spend about \$18 billion on drugs covered under Part B in 2017 and about \$240 billion over the 2017-2026 period.

CMMI, part of the Centers for Medicare and Medicaid Services (CMS), was established to test innovative approaches to delivering and paying for health care, primarily in the Medicare and Medicaid programs. CMMI was given significant funding and broad authority to expand approaches that reduce spending and to terminate approaches that do not. CBO's baseline reflects the expectation that CMMI will conduct demonstrations to test numerous ideas; that a small number of those tests will identify approaches that reduce spending without reducing quality; and that some of those approaches will be implemented more broadly. On that basis, CBO projects that under current law CMMI will reduce spending, on net, over the 2017-2026 period. That projection is subject to considerable uncertainty.<sup>2</sup>

Medicare Part B also covers a limited number of drugs that are administered orally. In general, those are oral
forms of anti-cancer drugs that are infused or injected, anti-emetic drugs administered in conjunction with
chemotherapy, and immunosuppressive drugs to prevent rejection of transplanted organs. It also covers some
drugs that are inhaled.

<sup>2.</sup> For additional information on CBO's approach to estimating legislation related to CMMI, see *Testimony on CBO's Estimates of the Budgetary Effects of the Center for Medicare & Medicaid Innovation*, September 7, 2016. <a href="https://www.cbo.gov/publication/51921">https://www.cbo.gov/publication/51921</a>

In March 2016, CMMI proposed a demonstration project related to Medicare's payments for drugs covered under Part B. As announced, the demonstration will have two phases:

- In phase one, the control group will receive payment at the current level—ASP plus 6 percent—and the demonstration group will receive payment equal to ASP plus 2.5 percent, plus a flat fee of \$16.80 per day of drug administration. The add-on percentage and flat fee were calculated so that overall aggregate spending on Part B drugs will be the same as it would be without the demonstration assuming no change in prescribing patterns.<sup>3</sup>
- In phase two, each of the groups from phase one will be further divided into two groups. Additional changes in payments based on the concepts of value-based purchasing will be layered on the policies applied in phase one. According to the proposal, the value-based purchasing in phase two could include reference pricing, in which payment for a group of therapeutically similar drugs is set at the level of the drug with the lowest cost; it could also include indication pricing, in which payment is linked to clinical efficacy or patient outcomes. However, the proposal does not specify which approaches will be applied in phase two.
- Once the demonstration is fully operational, providers will be in one of four groups:
  - Group 1: Payment at ASP plus 6 percent;
  - Group 2: Payment at ASP plus 2.5 percent plus flat fee
  - Group 3: Payment at ASP plus 6 percent, with value-based purchasing; and
  - Group 4: Payment at ASP plus 2.5 percent, plus flat fee, with value-based purchasing.
- CMMI indicated that almost all physicians and hospital outpatient departments that furnish drugs paid under Medicare Part B will be included. The demonstration will also include almost all drugs covered under Part B and the beneficiaries who use them.

#### **BASIS OF ESTIMATE**

As discussed further below, to estimate the effects of H.R. 5122, CBO first estimated how implementing the demonstration will affect Medicare spending. The effects of blocking the demonstration under H.R. 5122 would be the reverse of that estimate, offset in part by the effects of CMMI's authority to pursue alternative demonstrations that would have the potential to generate effects similar to those effects of the proposed demonstration. All told, CBO estimates that enacting H.R. 5122 would increase direct spending by about \$395 million over the 2017-2026 period.

<sup>3.</sup> Based on the parameters of a 2.5 percent markup and a \$16.80 fee, Medicare's payment under the demonstration will rise for drugs that cost less than \$480 per day and fall for those drugs that cost more than \$480 per day.

#### **Estimated Effects of the Demonstration**

CBO expects that both phases of the demonstration will reduce spending on drugs covered by Medicare Part B. For phase one of the demonstration, CBO's estimate of those savings is based on analysis of how the change in the formula for paying for drugs in Part B will affect the incentives providers face when prescribing those drugs. The change in the payment formula will reduce the difference in payments across drugs with different prices. CBO expects that, as a result, some providers will choose lower-cost therapeutic alternatives for some of their patients, which will reduce spending. With respect to phase two, CBO's estimate of savings is informed by prior analysis of similar value-based purchasing proposals, which will affect both the price of a given drug and the choice between competing therapies.<sup>4</sup>

Because the details of the demonstration have not yet been finalized, CBO's estimate of its effects reflects considerable uncertainty about the parameters of the final demonstration. The final demonstration could differ significantly from what is proposed—for example, in its scope or duration. Past experience with the relationship between proposed and final rules suggests that final rules often make smaller changes than originally proposed, so for purposes of this estimate, CBO estimates that half of the expected savings—or about \$1.1 billion— would be realized under current law.

## **Estimated Effects of Prohibiting the Demonstration**

CBO estimates that prohibiting the demonstration would result in lost savings of \$1.1 billion over the 2017-2026 period. Further, CBO estimates that some of those savings would be offset, because we expect that if CMMI were to be prevented from implementing the proposed demonstration for Part B drugs, it would pursue one or more alternative projects that also have the potential for savings, although developing and implementing those replacements would take time. In total, CBO estimates that CMMI would eventually "backfill" about \$750 million of the lost savings by carrying out other demonstration projects. Because H.R. 5122 would prevent CMMI only from implementing the specific demonstration it proposed in March 2016, those backfill projects could involve coverage and payment for Part B drugs or they could focus on other providers and services.

CBO estimates that the cost of blocking the demonstration would be highest in 2017 and 2018—about \$145 million over that two-year period—which is the same as CBO's estimate of savings from the demonstration in those years with the sign reversed. In subsequent years, as CMMI has the opportunity to develop and deploy alternative projects, the net cost of blocking the demonstration would be lower, averaging about \$30 million per

<sup>4.</sup> For example, CBO has previously estimated that a least-costly alternative policy for a certain class of therapies would reduce spending by about \$500 million over the 2010-2019 period. See Option 43 in *Budget Options Volume 1: Health Care*,

https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/12-18-healthoptions.pdf

year over the 2019-2026 period. The lower costs over that period reflect CBO's expectation that, by implementing other demonstrations and pilots, CMMI would recapture about 75 percent of the savings it would have achieved from the Part B drug demonstration.

#### **PAY-AS-YOU-GO CONSIDERATIONS**

The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. The net changes in outlays that are subject to those pay-as-you-go procedures are shown in the following table.

CBO Estimate of Pay-As-You-Go	Effects	for H.	R. 512	2, as in	troduce	ed on A	pril 29	, 2016					
	By Fiscal Year, in Millions of Dollars												
													2016-
	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2021	2026
NET INCREASE IN THE [ON-BUDGET] DEFICIT													
Statutory Pay-As-You-Go Impact	0	60	85	23	25	28	30	32	35	37	40	221	395

## INCREASE IN LONG-TERM DIRECT SPENDING AND DEFICITS

CBO estimates that enacting the legislation would not increase net direct spending or on-budget deficits by more than \$5 billion in any of the four consecutive 10-year periods beginning in 2027.

## INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT

H.R. 5122 contains no private sector or intergovernmental mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

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