Congressional Budget Office
Cost Estimate

September 8, 2023

At a Glance

H.R. 485, Protecting Health Care for All Patients Act of 2023

As reported by the House Committee on Energy and Commerce on May 17, 2023

By Fiscal Year, Millions of Dollars	2023	2023-2028	2023-2033
Direct Spending (Outlays)	0	344	1,117
Revenues	0	0	0
Increase or Decrease (-) in the Deficit	0	344	1,117
Spending Subject to Appropriation (Outlays)	0	75	304

Increases *net direct spending* in any of the four consecutive 10-year periods beginning in 2034?	> $2.5 billion	Statutory pay-as-you-go procedures apply?	Yes
Increases *on-budget deficits* in any of the four consecutive 10-year periods beginning in 2034?	> $5 billion	**Mandate Effects**	
		Contains intergovernmental mandate?	No
		Contains private-sector mandate?	No

The bill would

- Prevent the use of the quality-adjusted life year (QALY) measure and similar measures in federal health care programs, including Medicare and Medicaid

Estimated budgetary effects would mainly stem from

- Increased spending for prescription drugs in Medicare, Medicaid, and other federal programs

Areas of significant uncertainty include

- Identifying how agencies might interpret the definitions and terms in the bill
- Anticipating the use of QALYs by federal and state programs in the absence of the bill's prohibition

Detailed estimate begins on the next page.

See also
CBO's Cost Estimates Explained, *CBO Describes Its Cost-Estimating Process*, *Glossary*.

Bill Summary

H.R. 485 would prohibit federal health programs, including Medicare and Medicaid, from using the quality-adjusted life year (QALY) and similar measures to assess the relative value of medical interventions.

Estimated Federal Cost

The estimated budgetary effects of H.R. 485 are shown in Table 1. The costs of the legislation fall within budget functions 050 (national defense), 550 (health), 570 (Medicare), and 700 (veterans benefits and services).

Table 1.
Estimated Budgetary Effects of H.R. 485

	By Fiscal Year, Millions of Dollars												
	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2023-2028	2023-2033
Increases in Direct Spending													
Estimated Budget Authority	0	0	46	82	99	120	128	137	151	167	192	347	1,122
Estimated Outlays	0	0	45	81	98	119	127	137	150	167	192	344	1,117
Increases in Spending Subject to Appropriation													
Estimated Authorization	0	0	7	15	24	33	42	44	46	48	50	79	309
Estimated Outlays	0	0	6	14	23	32	41	44	46	48	50	75	304

Components may not sum to totals because of rounding; * = between zero and $500,000.

Basis of Estimate

Enactment of H.R. 485 could limit the types of evidence that can be used in decisions about how certain medical technologies are covered and paid for under federal health programs. CBO expects that such changes would tend to increase federal spending. For this estimate, CBO assumes that H.R. 485 will be enacted by the end of fiscal year 2023.

Background

The quality-adjusted life year is used to assess the relative value of medical interventions. A QALY is calculated by assigning a number between 1 (indicating complete health) and 0 (death) and multiplying that number by the amount of time a person lives in that state of health, expressed in years. Thus, 1 QALY would be the value assigned to one year lived in complete health, and 0.5 QALY would indicate one year lived in relatively poorer health. That metric is used to compare outcomes from different medical interventions. The cost of an intervention that yields additional years of life and health adds another dimension for

measuring relative value; for example, for therapies with the same QALY value but with different costs.

Many payers and insurers use cost-effectiveness and comparative-effectiveness research, including QALYs, in negotiations over how to cover and pay for different interventions and products. For example, QALYs or similar measures may be used in negotiations with pharmaceutical manufacturers when several competing drugs may be used to treat the same condition. That research can affect decisionmaking about product coverage, patient cost sharing, and negotiations between payers and manufacturers over a product's cost.[1]

Under current law, the Social Security Act prohibits the use of QALYs by the Secretary of Health and Human Services (HHS) in Medicare; title XI cites their general use in the Medicare program:

> The Secretary shall not use evidence or findings from comparative clinical effectiveness research … in determining coverage, reimbursement, or incentive programs under title XVIII [Medicare] in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.[2]

Another provision in title XI (section 1182(e) of the Social Security Act) applies a similar prohibition to the Patient-Centered Outcomes Research Institute, barring it from using a "dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended."[3]

Public Law 117-169 (an act to provide reconciliation pursuant to title II of S. Con. Res. 14) prohibits the Secretary of HHS from using QALYs in negotiating the prices of prescription drugs for Medicare's Part B (Medical Insurance) and Part D (prescription drug coverage), as follows:

> The Secretary shall not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.[4]

H.R. 485 would change certain prohibitions on federal and state agency use of QALYs and similar measures. First, the bill would modify the prohibitions in section 1182(e) of the

1. CBO's estimates assess the federal budgetary effects of legislation. For this estimate, CBO's analysis did not include a normative assessment of how federal agencies or other payers might use QALYs.
2. Section 1182(a) of the Social Security Act (42 U.S.C. § 1320e–1(c)(1)).
3. P.L. 117-169, section 1182(e) (42 U.S.C. 1320 e-1(e)). The institute was created as part of the Affordable Care Act to sponsor comparative-effectiveness research. See Patient-Centered Outcomes Research Institute, www.pcori.org.
4. P.L. 117-169, codified at section 1194 of the Social Security Act (42 U.S.C. § 1320f-3(e)(2)).

Social Security Act by adding "or treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill" after "because of an individual's disability" in the existing text. Second, it would apply the language in section 1182(e) (as amended) to other federal health care programs: Medicare (including Medicare Advantage), Medicaid, the Children's Health Insurance Program (CHIP), the health programs of the Department of Defense (DoD) and the Department of Veterans Affairs (VA), and the Federal Employees Health Benefits (FEHB) program. Under current law, those programs and agencies are allowed to use cost-effectiveness and comparative-effectiveness research in decisions about formulary or preferred-drug list (PDL) placement and to secure price concessions from manufacturers. CBO expects that the bill would limit the information that federal and state agencies would use when making decisions about how to cover and pay for medical interventions in federal health programs.

In developing this estimate, CBO consulted stakeholders and experts in health economics and in the analysis of comparative effectiveness. CBO also reviewed research on economic and public health policy, including its own work on the subject.[5]

Direct Spending

CBO estimates that, if enacted, H.R. 485 would increase direct spending by $1.1 billion over the 2023-2033 period (see Table 2).

Medicaid and the Children's Health Insurance Program. As a condition of coverage under the Medicaid program, pharmaceutical manufacturers pay rebates based on a statutory formula that incorporates the price of a drug, the best price offered to other types of payers, and the amount by which the price has exceeded an inflation-based benchmark. Although state Medicaid programs generally must cover all drugs produced by a manufacturer for which a rebate agreement is in effect, states can retain some controls on drug use, for example by creating a PDL or by using prior authorization or a similar management tool. To have a product included on a PDL—and as a way to face fewer restrictions on use—drug manufacturers may agree to pay supplemental rebates that are shared with the federal government. Some states have created drug affordability boards to help manage costs for certain drugs by negotiating with manufacturers for additional supplemental rebates.

When states create PDLs or negotiate with manufacturers for supplemental rebates, panels of physicians, pharmacists, and other experts assess the merits of competing products. That process may use information from cost-effectiveness and comparative-effectiveness research.

5. Congressional Budget Office, *Research on the Comparative Effectiveness of Medical Treatments: Issues and Options for an Expanded Federal Role* (December 2007), www.cbo.gov/publication/41655.

Table 2.
Estimated Increases in Direct Spending Under H.R. 485

	By Fiscal Year, Millions of Dollars												
	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2023-2028	2023-2033
Increases in Direct Spending													
Medicaid													
Estimated Budget Authority	0	0	32	47	50	53	57	60	64	69	73	182	505
Estimated Outlays	0	0	32	47	50	53	57	60	64	69	73	182	505
CHIP													
Estimated Budget Authority	0	0	0	0	0	0	0	0	0	0	0	0	0
Estimated Outlays	0	0	*	*	*	*	*	*	*	0	0	*	*
Medicare													
Estimated Budget Authority	0	0	8	22	30	40	35	40	48	57	75	100	355
Estimated Outlays	0	0	8	22	30	40	35	40	48	57	75	100	355
DoD, VA													
Estimated Budget Authority	0	0	6	12	18	25	34	35	37	38	40	61	245
Estimated Outlays	0	0	5	11	17	24	33	35	37	38	40	57	240
FEHB													
On-Budget													
Estimated Budget Authority	0	0	*	1	1	2	2	2	2	2	3	4	15
Estimated Outlays	0	0	*	1	1	2	2	2	2	2	3	4	15
Off-Budget													
Estimated Budget Authority	0	0	0	0	0	0	0	0	0	1	1	0	2
Estimated Outlays	0	0	0	0	0	0	0	0	0	1	1	0	2
Total Changes													
Estimated Budget Authority	0	0	46	82	99	120	128	137	151	167	192	347	1,122
Estimated Outlays	0	0	45	81	98	119	127	137	150	167	192	344	1,117

Components may not sum to totals because of rounding; CHIP = Children's Health Insurance Program; DoD = Department of Defense; FEHB = Federal Employees Health Benefits Program; VA = Department of Veterans Affairs; * = between zero and $500,000.
Some spending in FEHB (for annuitants and Postal Service employees) is classified as off-budget.

The federal government currently does not prohibit states from using any specific methods or metrics in creating PDLs or from using drug affordability boards or similar initiatives to garner supplemental rebates. Many states report using comparative-effectiveness research; some rely on reports that incorporate data on QALYs and alternative measures.[6]

In CBO's judgment, the bill's prohibition on the use of QALYs by state Medicaid programs would not by itself have a budgetary effect because other metrics would be available for use in securing supplemental rebates or developing PDLs. However, given the reference to

6. See KFF, "Use of Comparative Effectiveness Reviews in Medicaid Drug Reviews, as of July 1, 2019," KFF State Health Facts, https://tinyurl.com/mtn7juuh (accessed September 7, 2023).

"similar measures" in the bill, states may anticipate federal interpretation of the language more broadly and thus refrain from using QALYs and similar measures. As a result, states would have less leverage when negotiating supplemental rebates, particularly for drugs that have no therapeutic competition. States also would face more difficulties in developing PDLs and using prior authorization—again, from reduced leverage in negotiations with manufacturers. CBO did not estimate any budgetary effects associated with other services provided by Medicaid and CHIP because QALYs and similar measures are not used to determine the availability of medical services in those programs.

CBO therefore estimates that enacting H.R. 485 would increase federal spending for Medicaid by $505 million over the 2023-2033 period. That cost is the result of a small percentage of lost supplemental rebates and less use of PDLs and prior authorization, in particular for brand-name drugs without competitors in the same therapeutic class. In developing this estimate, CBO analyzed administrative data about supplemental rebates and consulted experts in state management of Medicaid drug benefits.

In states where CHIP is operated separately from Medicaid, patient services, including access to prescription drugs, are largely provided by managed care companies. Those companies may use QALYs and similar measures to create drug formularies, and CBO expects that the bill's prohibition on QALYs and other metrics would hamper the states' ability to negotiate rebates, which would increase federal costs for CHIP and in turn result in higher premiums. CBO estimates that enacting H.R. 485 would increase federal spending for CHIP by less than $500,000 over the 2023-2033 period.

Medicare. H.R. 485 would extend the prohibition on the use of QALYs and similar measures to Medicare Advantage plans (which deliver Medicare benefits under Parts A and B through private plans) and Medicare prescription drug plans (PDPs, which deliver benefits under Part D). Based on an analysis of comparative-effectiveness research and Medicare spending on prescription drugs, CBO estimates that, over the 2023-2033 period, roughly 10 percent of federal spending under Part D would be for drugs for which rebate negotiations were affected by a published comparative-effectiveness analysis using QALYs or similar measures. Enactment would result in changes to those formulary decisions and negotiations, which would reduce the negotiated discounts for those products by roughly 1 percent, CBO estimates. That estimate reflects CBO's judgment of the effect, and it is informed by discussions with stakeholders and other experts. CBO estimates that those reduced discounts would increase spending under Medicare Part D by $355 million over the 2023-2033 period. CBO expects that the effect on negotiated discounts would be relatively small because those negotiations are private, and enforcing the limitations of the legislation could be challenging.

Under current law, the Secretary of HHS will negotiate with drug manufacturers for a maximum price that can be charged to PDPs for certain products in 2026 and subsequent

years.[7] As noted above, current law already prohibits the Secretary from using QALYs and similar measures. Thus, CBO does not expect that enacting H.R. 485 would affect the prices that result from negotiations between the Secretary and drug manufacturers.

Departments of Defense and Veterans Affairs. Like Medicaid, the health programs of DoD and VA have special pricing arrangements for prescription drugs that rely on up-front discounts and rebates.[8] Those agencies use comparative-effectiveness research to determine formulary placement and obtain additional discounts.[9] CBO expects that enacting H.R. 485 would increase spending for DoD and VA health programs for the same reason that it estimates a budgetary effect for Medicaid: The uncertainty about permissible metrics would reduce those agencies' flexibility in determining formulary placement and obtaining drug discounts.

Pharmaceutical expenditures by DoD and VA are split between mandatory funding and spending that is subject to appropriation. For DoD, those costs are split between the DoD Medicare-Eligible Retiree Health Care Fund (a mandatory account) and the Defense Health Program (which is discretionary). For VA, those costs are split between the Toxic Exposures Fund, which is derived from mandatory appropriations, and discretionary appropriations to the Veterans Health Administration.

CBO estimates that, if enacted, H.R. 485 would increase direct spending for DoD and VA by $240 million over the 2023-2033 period. Higher pharmacy costs for DoD and VA also would affect discretionary spending. Those effects are described under "Spending Subject to Appropriation."

Federal Employee Health Benefits Program. FEHB provides health insurance coverage to federal workers and annuitants and to their dependents and survivors. Policyholders, whether they are active employees or annuitants, generally pay 25 percent of the premium for lower-cost plans and a larger share for higher-cost plans; the federal government pays the rest of the premium. Federal spending for premiums for annuitants and Postal Service employees is classified as mandatory spending; outlays for premiums for other federal employees are classified as discretionary spending. Because FEHB plans may use QALYs and similar measures in creating formularies, CBO expects that the prohibition on those metrics would lessen the program's ability to negotiate rebates and would increase federal

7. That maximum fair price, in turn, affects what PDPs may charge beneficiaries for drugs subject to negotiation. In practice, beneficiary cost sharing will often be a percentage of that maximum price or a specific dollar amount, depending on how the PDP structures its benefits.
8. For more information on the prices available to DoD, see Congressional Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* (February 2021), www.cbo.gov/publication/56978.
9. For instance, DoD has authority under 10 U.S.C. § 1074g(a)(10) to exclude from its formulary drugs that provide limited clinical effectiveness. DoD also can give preferential formulary placement to drugs with similar effectiveness and lower cost relative to other drugs in the same therapeutic class.

costs, resulting in higher premiums. Higher premiums would increase federal spending under the program.

CBO expects that, over the 2023-2033 period, H.R. 485 would increase mandatory spending for FEHB by $17 million, with $2 million of that total categorized as off-budget. (The federal government's contributions to premiums for annuitants are classified as on-budget direct spending. Federal payments for Postal Service employees are classified as off-budget.) Some spending by FEHB for health insurance benefits is classified as discretionary; the bill's effects on discretionary spending for FEHB are described below.

Spending Subject to Appropriation

As discussed above, in addition to direct spending, implementing H.R. 485 would affect discretionary spending. CBO estimates that under the bill discretionary spending would need to increase by $304 million over the 2023-2033 period (see Table 3); $288 million of that amount would be for DoD and VA, and $16 million for FEHB. Such spending would be subject to appropriation of the estimated amounts.

Table 3.
Estimated Spending Subject to Appropriation Under H.R. 485

	By Fiscal Year, Millions of Dollars												
	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2023-2028	2023-2033
Increases in Spending Subject to Appropriation													
Estimated Authorization	0	0	7	15	24	33	42	44	46	48	50	79	309
Estimated Outlays	0	0	6	14	23	32	41	44	46	48	50	75	304

Uncertainty

CBO's estimate for H.R. 485 is subject to considerable uncertainty. First, although the definition of QALY is well understood, it is not clear how "similar measures" would be defined and what metrics could be prohibited if the bill was enacted. CBO expects that federal agencies would need to define allowable measures through the rulemaking process. Because the resulting definitions could be narrow or broad, CBO cannot predict what types of measures might be permissible. It also is not clear whether, in the absence of H.R. 485, entities that do not now use QALYs or similar measures would adopt them in the future.

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 Table 4.

Table 4.
CBO's Estimate of the Statutory Pay-As-You-Go Effects of H.R. 485, the Protecting Health Care for All Patients Act of 2023, as Ordered Reported by the House Committee on Energy and Commerce on March 24, 2023

	By Fiscal Year, Millions of Dollars												
	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2023-2028	2023-2033
	Net Increase in the On-Budget Deficit												
Pay-As-You-Go Effect	0	0	45	81	98	119	127	137	150	166	191	344	1,115

Components do not sum to totals because of rounding.

Increase in Long-Term Net Direct Spending and Deficits

CBO estimates that enacting H.R. 485 would increase net direct spending by more than $2.5 billion in any of the four consecutive 10-year periods beginning in 2034.

CBO estimates that enacting H.R. 485 would increase on-budget deficits by more than $5 billion in any of the four consecutive 10-year periods beginning in 2034.

Mandates: None.

Estimate Prepared By

Federal Costs:

Stuart Hammond (formerly of CBO, Federal Employees Health Benefits program)
Etaf Khan (veterans' benefits and services)
Lara Robillard (Medicare)
Matt Schmit (Department of Defense)
Robert Stewart (Children's Health Insurance Program)
Kate Young (Medicaid)

Mandates: Andrew Laughlin

Estimate Reviewed By

Sean Dunbar
Chief, Low-Income Health Programs and Prescription Drugs Cost Estimates Unit

David Newman
Chief, Defense, International Affairs, and Veterans' Affairs Cost Estimates Unit

Asha Saavoss
Chief, Health Systems and Medicare Cost Estimates Unit

Kathleen FitzGerald
Chief, Public and Private Mandates Unit

Chad Chirico
Director of Budget Analysis

Estimate Approved By

Phillip L. Swagel
Director, Congressional Budget Office