Congressional Budget Office
Cost Estimate

March 13, 2024

At a Glance

Health Care Legislation

As ordered reported by the House Committee on Energy and Commerce on December 6, 2023

On December 6, 2023, the House Committee on Energy and Commerce ordered reported 41 bills related to health care and energy. This single, comprehensive document provides estimates for 21 bills related to health care and consumer protection.

Five bills would affect spending subject to appropriation. Ten would affect direct spending; thus, pay-as-you-go procedures apply. One bill would significantly increase net direct spending or on-budget deficits in at least one of the four consecutive 10-year periods beginning in 2035. Three bills would impose private-sector mandates. Details of the estimated costs of each bill are discussed in the text below.

Bill	Net Increase or Decrease (-) in the Deficit Over the 2024-2034 Period (Millions of Dollars)	Changes in Spending Subject to Appropriation Over the 2024-2029 Period (Outlays, Millions of Dollars)	Mandate Effects?
H.R. 133	0	0	No
H.R. 1797	0	6	Yes
H.R. 2365	0	3	No
H.R. 2880	-226	0	No
H.R. 3842	*	0	No
H.R. 4310	0	2	Yes
H.R. 4881[a]	754	0	No
H.R. 5202	0	22	No
H.R. 5371	0	0	No
H.R. 5372	-145	0	No
H.R. 5380	15	0	No
H.R. 5385	-381	0	No
H.R. 5386	*	0	No
H.R. 5388	0	0	No
H.R. 5389	0	0	No
H.R. 5393	6	0	No
H.R. 5396	0	0	No
H.R. 5397	-139	0	No
H.R. 5555	145	0	No
H.R. 6132	0	3	Yes
H.R. 6364	0	0	No

* = between -$500,000 and $500,000.

a. H.R. 4881 would increase on-budget deficits by more than $5 billion in at least one of the four consecutive 10-year periods beginning in 2035.

Detailed estimate begins on the next page.

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

Summary

On December 6, 2023, the House Committee on Energy and Commerce ordered 41 pieces of legislation to be reported. This document provides estimates for 21 bills in that package that are related to health care and consumer protection.

Generally, the bills in this group that would affect direct spending would:

- Limit beneficiary cost sharing for certain prescription drugs and add certain drugs to the group of products covered by the Medicare home infusion benefit;
- Prohibit pharmacy benefit managers (PBMs) from collecting certain fees from prescription drug manufacturers and require PBMs to provide additional information to Medicare Part D plans (which provide prescription drug coverage);
- Allow Part D plans more flexibility to add biosimilar biological products to their formularies and to change the cost-sharing status of reference biological products;
- Temporarily increase Medicare payment rates for durable medical equipment (DME); and
- Provide mandatory funding for implementation of certain provisions in several bills.

Estimated Federal Cost

The costs of the legislation fall within budget functions 550 (health) and 570 (Medicare).

Basis of Estimate

For this estimate, CBO assumes that the bills will be enacted near the middle of fiscal year 2024 and that the estimated amounts will be appropriated each year. This cost estimate does not include any effects of interactions among the bills. If all 21 bills were combined and enacted as a single piece of legislation, the effects could be different from the sum of the separate estimates.

Direct Spending

Enacting 10 bills in the group would affect direct spending over the 2024-2034 period (see Table 1).

Table 1.
Estimated Effects on Direct Spending of Health Care Legislation, as Ordered Reported by the House Committee on Energy and Commerce on December 6, 2023

	By Fiscal Year, Millions of Dollars												
	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2024-2029	2024-2034
	Increases or Decreases (-) in Direct Spending												
H.R. 2880													
Budget Authority	0	0	0	-29	-39	-31	-31	-28	-26	-24	-18	-99	-226
Outlays	0	0	0	-29	-39	-31	-31	-28	-26	-24	-18	-99	-226
H.R. 3842													
Budget Authority	0	*	*	*	*	*	*	*	*	*	*	*	*
Outlays	0	*	*	*	*	*	*	*	*	*	*	*	*
H.R. 4881													
Budget Authority	0	0	0	0	77	88	100	106	113	134	136	165	754
Outlays	0	0	0	0	77	88	100	106	113	134	136	165	754
H.R. 5372													
Budget Authority	0	-9	-12	-12	-14	-12	-14	-16	-17	-20	-19	-59	-145
Outlays	0	-9	-12	-12	-14	-12	-14	-16	-17	-20	-19	-59	-145
H.R. 5380													
Budget Authority	15	0	0	0	0	0	0	0	0	0	0	15	15
Outlays	13	1	1	0	0	0	0	0	0	0	0	15	15
H.R. 5385													
Budget Authority	55	0	0	-55	-75	-60	-60	-55	-50	-46	-35	-135	-381
Outlays	49	4	2	-55	-75	-60	-60	-55	-50	-46	-35	-135	-381
H.R. 5386													
Budget Authority	0	0	*	*	*	*	*	*	*	*	*	*	*
Outlays	0	0	*	*	*	*	*	*	*	*	*	*	*
H.R. 5393													
Budget Authority	0	6	0	0	0	0	0	0	0	0	0	6	6
Outlays	0	6	0	0	0	0	0	0	0	0	0	6	6
H.R. 5397													
Budget Authority	0	0	-9	-13	-15	-14	-15	-17	-17	-20	-19	-37	-139
Outlays	0	0	-9	-13	-15	-14	-15	-17	-17	-20	-19	-37	-139
H.R. 5555													
Budget Authority	144	1	0	0	0	0	0	0	0	0	0	145	145
Outlays	144	1	0	0	0	0	0	0	0	0	0	145	145

All amounts for outlays are estimates; except for H.R. 5380 and H.R. 5393, all amounts for budget authority are estimated;
* = between -$500,000 and $500,000.

H.R. 2880, the Protecting Patients Against PBM Abuses Act, would modify the rules with respect to certain fees that PBMs collect from prescription drug manufacturers. In Medicare

Part D (which provides prescription drug coverage), sponsors of private insurance plans contract with the government to deliver benefits to Medicare beneficiaries. Those insurance plans usually contract with PBMs to negotiate with drug manufacturers, design formularies, and perform other administrative functions. A PBM can be owned by the plan sponsor or it can be an independent corporate entity.

H.R. 2880 would prohibit PBMs from collecting service fees from manufacturers that are based on drug prices, manufacturer discounts, or formulary placement decisions. Under the bill, those fees would be specific dollar amounts based on the fair market value of a PBM's services. Under current law, PBMs can be compensated for services they provide to manufacturers, but compensation that exceeds the fair market value of a service must be classified as direct and indirect remuneration and reported to the Centers for Medicare & Medicaid Services (CMS). According to the Government Accountability Office, however, CMS does not routinely monitor how PBMs classify those fees.[1] Under the bill, CMS and the Office of Inspector General would more closely monitor those classifications.

CBO estimates that manufacturers' service fees are roughly 1 percent of Part D retail spending under current law. CBO expects that under H.R. 2880, a portion of those fees would be reclassified as direct and indirect remuneration by PBMs and, because of stronger oversight, passed along to the sponsors of prescription drug plans. That action would reduce bid amounts for plans' expected benefit payments, which in turn would reduce spending in Part D. CBO estimates that the provision would decrease federal spending by $226 million over the 2024-2034 period, or by roughly 1 percent of the amount expected to be collected in service fees over that period.

H.R. 3842, the Expanding Access to Diabetes Self-Management Training Act of 2023, would allow more providers to refer eligible patients to diabetes self-management training covered by Medicare and would codify regulatory time limits on use of the training. CBO expects that enacting H.R. 3842 would result in more patients receiving such training, which would lead to increased Medicare spending. CBO expects that such training would reduce the use of acute-care services, at least partly offsetting that increase in costs. As a result, CBO estimates that enacting the bill would increase or decrease direct spending by less than $500,000 over the 2024-2034 period.

H.R. 4881, a bill to amend title XVIII of the Social Security Act to limit cost sharing for drugs under the Medicare program, would limit cost sharing above the deductible to no more than the average net price for a drug, which is the list price minus after-sale discounts from the drug's manufacturer. From 2028 to 2034, CBO projects, less than 1 percent of Part D spending above the deductible under current law will be for drugs with cost sharing that exceeds net drug costs. Under the bill, CBO expects that some out-of-pocket spending by beneficiaries and some federal subsidies for low-income beneficiaries would shift onto

1. See Government Accountability Office, *Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures,* GAO-19-498 (July 2019), Appendix III, www.gao.gov/products/gao-19-498.

Part D plans, which would increase the bids they submit to the federal government to cover expected benefits spending and therefore increase federal spending. CBO estimates that enacting H.R. 4881 would increase direct spending by $754 million over the 2024-2034 period.

H.R. 5372, the Expanding Seniors' Access to Lower Cost Medications Act of 2023, would allow Part D plans to add biosimilar biological products to their formularies and change the cost-sharing status of a reference biological product after the first 60 days of a plan year. (A reference biological product is the approved product against which a proposed biosimilar product is compared.) Under current law, Part D plans must exempt beneficiaries who currently use reference biological products from changes in coverage and cost sharing for the remainder of the year. That restriction limits a plan's ability to promote use of a biosimilar product immediately following that product's entry to the market. CMS has proposed rules that overlap with the bill's provisions concerning formulary substitutions for biosimilar products.[2] CBO's estimate of Medicare spending for those products under current law accounts for 50 percent of the effect of the proposed rules. As a result, CBO's estimate of the decrease in direct spending under H.R. 5372 is larger than it might be if CMS's rules had become final.

Under the bill, the addition of biosimilar products to formularies could lead to a shift away from the use of reference biological products. CBO estimates that the government will spend about $10 billion over the 2024-2034 period to cover reference biological products under current law. CBO anticipates that under H.R. 5372 approximately 20 percent of the current use of reference biological products would be replaced by biosimilar products. The prices for biosimilar products are estimated to be 15 percent lower, on average, than the prices for the reference products. Using information about spending on both types of products under current law and adjusting for current regulatory proposals by CMS that would streamline coverage for biosimilar products, CBO estimates that enacting H.R. 5372 would decrease direct spending by $145 million over the 2024-2034 period.

H.R. 5380, a bill to amend title XVIII of the Social Security Act to increase data transparency for supplemental benefits under Medicare Advantage, would provide $15 million in 2024 for the Department of Health and Human Services (HHS) to implement reporting requirements for supplemental benefits under Medicare Advantage plans. Based on

2. See Centers for Medicare & Medicaid Services, "Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications," Notice of Proposed Rulemaking, 88 *Fed. Reg.* 78476 (November 15, 2023), http://tinyurl.com/wv7yprfm; and
"Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications," Notice of Proposed Rulemaking, 87 *Fed. Reg.* 79452 (December 27, 2022), http://tinyurl.com/3754c49x

historical spending patterns for HHS programs, CBO estimates that enacting H.R. 5380 would increase direct spending by $15 million over the 2024-2034 period.

H.R. 5385, the Medicare PBM Accountability Act, would require pharmacy benefit managers to provide plan sponsors with information not furnished under current law. Part D plans have access to certain aggregate and drug-specific information from PBMs concerning prescriptions, prices, rebates, and out-of-pocket charges, but may lack information about PBM-affiliated entities and contractors, rationales for formulary decisions, and explanations for benefit designs that favor certain pharmacies. H.R. 5385 would require PBMs to report such information to Part D plans but also, subject to certain restrictions, would allow plans to audit PBMs' business practices and request other information. The bill would provide $55 million for HHS to implement those requirements.

H.R. 5385 also would require PBMs to make their business practices clearer to Part D plans, thus promoting competition among PBMs. CBO estimates that the increased competition would reduce net spending for Part D by less than 0.1 percent over the 2024-2034 period—reducing federal spending by $436 million over that period.

CBO estimates that the net effect of the bill would be a reduction in direct spending of $381 million over the 2024-2034 period.

H.R. 5386, the Cutting Copays Act, would prohibit cost sharing for generic drugs for beneficiaries who are eligible for the low-income subsidy, which pays most or all of their premium and cost-sharing requirements. Under current law, plans have an option but not an obligation to do so. CBO expects that enacting the bill would increase the use of generic drugs, which would increase plan bid submissions for expected benefits payments and, therefore, federal spending. CBO expects that some of the increase would be offset by reduced spending on brand-name drugs and certain medical services. CBO estimates that enacting the bill would increase direct spending by less than $500,000 over the 2024-2034 period.

H.R. 5393, a bill to amend title XVIII of the Social Security Act to ensure fair assessment of pharmacy performance and quality under Medicare Part D, and for other purposes, would provide $4 million in in 2025 for CMS program management to implement pharmacy performance and quality measures for Part D and $2 million in that year to implement pharmacy transparency requirements. Based on historical spending patterns for CMS administrative costs, CBO estimates that enacting H.R. 5393 would increase direct spending by $6 million over the 2024-2034 period.

H.R. 5397, the Joe Fiandra Access to Home Infusion Act of 2023, would add drugs to the current Medicare benefit that allows patients to receive some drugs by infusion under nursing care at home. H.R. 5397 would allow other drugs to meet the statutory criteria for coverage in the home setting by establishing those products as suitable for delivery through a pump and requiring patients receiving those drugs also to receive regular nursing services.

Based on its analysis of the beneficiary population and Medicare payment rates, CBO estimates that enacting the bill would reduce direct spending by $139 million over the 2024-2034 period, primarily because beneficiaries would bear a larger share of the cost of infusions that occur at home. Under current law, there is a cap on beneficiary cost sharing in outpatient hospital settings, which is where CBO expects that beneficiaries receive those drugs now. There is no equivalent cap for the home infusion benefit.

CBO's estimate for H.R. 5397 is subject to considerable uncertainty. First, it is not known how many drugs would qualify for coverage under the bill. CBO's estimate focused on three products that industry and clinical experts mentioned as likely candidates, but the actual number could be larger or smaller. In addition, given that cost sharing could increase significantly for patients, it is not known how many beneficiaries would choose to receive home infusions.[3]

H.R. 5555, the DMEPOS Relief Act of 2023, would temporarily increase Medicare rates in some areas of the country for DMEPOS (durable medical equipment, prosthetics, orthotics, and supplies). Under current law, Medicare's payments for some equipment are based on competitive bidding among suppliers. CMS uses those results to set rates (either directly or through a blend with the historic fee schedule) in areas of the country where formal bidding has not occurred. Prior legislation directed CMS to use a blend of fee schedule and competitively bid rates in some areas of the country; the use of those blended rates expired at the end of calendar year 2023. Enacting H.R. 5555 would extend the use of those blended rates through calendar year 2024. Based on an analysis of historic claim spending, CBO estimates that the DME provision of the bill would increase direct spending by $145 million over the 2024-2034 period. H.R. 5555 also would reduce amounts available to the Medicare Improvement Fund by $177 million, however the Consolidated Appropriations Act, 2024 rescinded all funding from the Medicare Improvement Fund. As a result, the provision would not affect direct spending. In total, CBO estimates that enacting H.R. 5555 would increase net direct spending by $145 million over the 2024-2034 period.

Legislation With No Effect on Direct Spending

CBO estimates that enacting 11 bills in this estimate would have no effect on direct spending over the 2024-2034 period:

- H.R. 133, the Mandating Exclusive Review of Individual Treatments (MERIT) Act;
- H.R. 1797, the Setting Consumer Standards for Lithium-Ion Batteries Act;

3. CMS proposed a similar but not identical policy in a proposed rulemaking. In the regulatory impact analysis, CMS estimated that, for one product, beneficiaries' cost sharing would be about triple the amount if the product was received in a home setting. For more information, see Centers for Medicare & Medicaid Services, "Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS)," Notice of Proposed Rulemaking, 85 *Fed. Reg.* 70358 (November 4, 2020), http://tinyurl.com/29djdrvz.

- H.R. 2365, the Dr. Emmanuel Bilirakis National Plan to End Parkinson's Act;
- H.R. 4310, the Youth Poisoning Protection Act;
- H.R. 5202, the Virginia Graeme Baker Pool and Spa Safety Reauthorization Act;
- H.R. 5371, the Choices for Increased Mobility Act of 2023;
- H.R. 5388, the Supporting Innovation for Seniors Act;
- H.R. 5389, the National Coverage Determination Transparency Act;
- H.R. 5396, the Coverage Determination Clarity Act of 2023;
- H.R. 6132, the Awning Safety Act of 2023; and
- H.R. 6364, the Medicare Telehealth Privacy Act of 2023.

Spending Subject to Appropriation

CBO estimates that five bills would increase spending subject to appropriation (see Table 2). Any spending would be subject to the availability of appropriated funds.

Table 2.
Estimated Increases in Spending Subject to Appropriation Under Health Care Legislation,as Ordered Reported by the House Committee on Energy and Commerce on December 6, 2023

	By Fiscal Year, Millions of Dollars						
	2024	2025	2026	2027	2028	2029	2024-2029
H.R. 1797							
Estimated Authorization	*	1	1	1	1	2	6
Estimated Outlays	*	1	1	1	1	2	6
H.R. 2365							
Estimated Authorization	*	1	*	1	*	1	3
Estimated Outlays	*	1	*	1	*	1	3
H.R. 4310							
Estimated Authorization	*	*	*	1	*	1	2
Estimated Outlays	*	*	*	1	*	1	2
H.R. 5202							
Authorization	5	5	5	5	5	0	25
Estimated Outlays	4	4	4	5	5	0	22
H.R. 6132							
Estimated Authorization	*	1	*	1	*	1	3
Estimated Outlays	*	1	*	1	*	1	3

* = between zero and $500,000.

H.R. 1797, the Setting Consumer Standards for Lithium-Ion Batteries Act, would require the Consumer Product Safety Commission (CPSC) to issue a final safety standard to reduce the risk of fire from rechargeable lithium-ion batteries that are used to power electric-assist bicycles and electric scooters, for example. Based on information provided by the commission, CBO expects that CPSC would need less than two employees for the first two years after enactment and six employees thereafter, at an average annual cost of $190,000

per employee, to issue and enforce the standard. In total, CBO estimates that it would cost $6 million over the 2024-2029 period for CPSC to implement H.R. 1797, assuming appropriation of the necessary amounts.

H.R. 2365, the Dr. Emmanuel Bilirakis National Plan to End Parkinson's Act, would require HHS to establish an advisory council and to create and update several plans and reports as part of a national project to prevent, diagnose, treat, and cure Parkinson's disease. Using information about similar activities, CBO expects that HHS would need two employees for the first year after enactment and three employees thereafter, at an average annual cost in 2024 of $160,000 per employee, to carry out activities required under the act. In total, CBO estimates that it would cost $3 million over the 2024-2029 period for HHS to implement H.R. 2365, assuming appropriation of the necessary amounts.

H.R. 4310, the Youth Poisoning Protection Act, would ban the sale of consumer products containing 10 percent or more of sodium nitrite by weight. Using information from CPSC, CBO expects the commission would need less than one employee for the first two years after enactment and around two employees thereafter, at an average annual cost of $190,000 per employee, to enforce the standard. In total, CBO estimates it would cost about $2 million over the 2024-2029 period for CPSC to implement H.R. 4310, assuming appropriation of the necessary amounts.

H.R. 5202, the Virginia Graeme Baker Pool and Spa Safety Reauthorization Act, would authorize the appropriation of $5 million annually over the 2024-2028 period for CPSC to continue a grant program and public outreach concerning the safety of children in pools and spas. The bill would require CPSC to extend grant eligibility to nonprofit organizations, appoint a Director of Drowning Prevention, and report to the Congress annually on the program's results. Using information from CPSC, CBO estimates that the cost of implementing the bill would be $22 million over the 2024-2029 period, assuming appropriation of the necessary amounts.

H.R. 6132, the Awning Safety Act of 2023, would require CPSC to issue a final safety standard for retractable awnings. Using information from that agency, CBO expects the commission would need an average of two employees per year, at an average annual cost of $190,000 per employee, to issue and enforce the standard. In total, CBO estimates it would cost about $3 million over the 2024-2029 period for CPSC to implement H.R. 6132, assuming appropriation of the necessary amounts.

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 for the 10 bills that are subject to those pay-as-you-go procedures are shown in Table 1.

Increase in Long-Term Net Direct Spending and Deficits

CBO estimates that enacting H.R. 4881 would increase long-term net direct spending and that such spending would increase by more than $5 billion in at least one of the four consecutive 10-year periods beginning in 2035.

CBO estimates that none of the other bills discussed in this estimate would increase net direct spending or deficits in any of the four consecutive 10-year periods beginning in 2035.

Mandates

H.R. 1797 would impose a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA) by requiring manufacturers of electric-assist bicycles and electric scooters, for example, to comply with a prospective CPSC safety standard concerning the risk of fire in lithium-ion batteries. Limited data are available about the extent of industry compliance with the current voluntary standards or about the cost of bringing products into compliance. Therefore, CBO cannot determine whether the cost of the mandate would exceed the private-sector threshold established in UMRA ($200 million in 2024, adjusted annually for inflation).

H.R. 1797 would not impose any intergovernmental mandates.

H.R. 4310 would impose a private-sector mandate as defined in UMRA by banning the sale of consumer products containing 10 percent or more of sodium nitrite by weight. The prohibition would not apply to industrial uses or to food preservation. Because there is only a small market for consumer products containing more than 10 percent by weight and some states already have curtailed the sale of products containing sodium nitrite, CBO estimates that the cost of the mandate would not exceed the private-sector threshold established in UMRA.

H.R. 4310 would not impose any intergovernmental mandates.

H.R. 6132 would impose a private-sector mandate as defined in UMRA by requiring awning manufacturers to comply with a prospective CPSC safety standard concerning fixed and freestanding retractable awnings. CBO expects that the standard could require awnings to be equipped with safety clips and to issue visual or audible alerts when in motion. Based on the cost of such additional equipment and the number of such awnings likely to be sold, CBO estimates that the cost of the mandate would not exceed the private-sector threshold established in UMRA.

H.R. 6132 would not impose any intergovernmental mandates.

CBO has determined that none of the other bills in this estimate would impose intergovernmental or private-sector mandates as defined in UMRA.

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