

YOUTH POISONING PROTECTION ACT

MAY 10, 2024.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mrs. RODGERS of Washington, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 4310]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 4310) to ban the sale of products with a high concentration of sodium nitrite to individuals, and for other purposes, having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

CONTENTS

	Page
Purpose and Summary	1
Background and Need for Legislation	2
Committee Action	3
Committee Votes	3
Oversight Findings and Recommendations	5
New Budget Authority, Entitlement Authority, and Tax Expenditures	5
Congressional Budget Office Estimate	5
Federal Mandates Statement	14
Statement of General Performance Goals and Objectives	14
Duplication of Federal Programs	15
Related Committee and Subcommittee Hearings	15
Committee Cost Estimate	15
Earmark, Limited Tax Benefits, and Limited Tariff Benefits	15
Advisory Committee Statement	15
Applicability to Legislative Branch	15
Section-by-Section Analysis of the Legislation	15
Changes in Existing Law Made by the Bill, as Reported	16

PURPOSE AND SUMMARY

H.R. 4310, the “Youth Poisoning Protection Act” was introduced by Representative Trahan on June 22, 2023, and referred to the Committee on Energy and Commerce. H.R. 4310 bans the sale of

high-concentrate sodium nitrite to individuals by adding such products to the list of banned hazardous products in the Consumer Product Safety Act (15 U.S.C. 2057). H.R. 4310 does not ban the sale of sodium nitrite for business-to-business sales or sales to universities and schools for the purpose of education and research.

BACKGROUND AND NEED FOR LEGISLATION

Sodium nitrite is a substance that is generally used to cure meat and can be used medically to reverse cyanide poisoning. Swallowing a spoonful of sodium nitrite dissolved in a cup of water is likely to lead to a rapid death, and it is approximately 100 times more lethal than other poisoning methods used with suicidal intent.¹ Sodium nitrite causes hypotension, or low blood pressure, and methemoglobinemia, which inhibits the ability of blood to carry oxygen.

Amazon stated that it stopped selling the chemical to home consumers and offers it only on its Amazon business marketplace.² Still, online suicide assistance forums provide detailed instructions and real-time guidance on how to die by suicide using sodium nitrite. These sites are responsible for a sharp increase of deaths by sodium nitrite ingestion in the past few years, a trend expected to continue.³ Data from the National Poison Data System shows a rise in self-poisonings using sodium nitrite in the United States since 2017.⁴ Experts emphasize that high-concentration sodium nitrite is only appropriate for commercial purposes—not individual or household use.⁵

Sodium nitrite has a wide variety of valuable and important commercial and industrial uses. Large amounts of sodium nitrite are used by the chemical and pharmaceutical industries. Sodium nitrite has uses in the industrial production of organonitrogen compounds. Sodium nitrite enables manufacturing of certain dyes and rubber products, and it is also used in metallurgy applications, such as phosphatizing and detinning. Sodium nitrite is also used as a corrosion inhibitor, an industrial grease additive, and in cooling and heat transfer systems. It is also used as an emergency medication in certain poisoning cases. This legislation does not affect access to or use of sodium nitrite in any of these commercial and industrial uses, including small business uses.

The Act seeks to address this consumer harm with a narrowly tailored prohibition on sale of consumer products that contain sodium nitrite at concentrations greater than 10 percent, which precludes consumer access to Consumer Product Safety Act-regulated products. The 10 percent threshold allows consumer products with small or de minimis residuals of sodium nitrite, which do not otherwise present a safety concern, to be sold.

The prohibition applies only to a “consumer product,” which is defined in the Consumer Product Safety Act (15 U.S.C. 2052(a)(5)),

¹ Sean D. McCann, *et al.*, *Rising Incidence and High Mortality in Intentional Sodium Nitrite Exposures Reported to U.S. Poison Centers*, *Clinical Toxicology* (Mar. 31, 2021).

² Kaustuv Basu, *Chemical Used in Suicides Faces Sales Ban Under Proposed Law*, *Bloomberg Law* (June 22, 2023).

³ Yub Raj Sedhai, *et al.*, *The use of sodium nitrite for deliberate self-harm, and the online suicide market: Should we care?*, *The Medico-Legal Journal* (June 2022).

⁴ See Note 1.

⁵ Commonwealth of Australia, *Delegate’s final decision and reasons for decision—sodium nitrite* (Joint ACMS-ACCS #28, June 2021).

and thus expressly does not apply to products exempted from the definition, including but not limited to Federal Food, Drug, and Cosmetic Act-regulated foods and food additives, and drugs, devices, or cosmetics.

H.R. 4310 is needed to ensure that sodium nitrite is no longer accessible to consumers at a percentage greater than 10 percent. There are no known consumer products that need to contain sodium nitrite above this level. At the same time, H.R. 4310 will preserve access to sodium nitrite for businesses and educational institutions.

COMMITTEE ACTION

On September 27, 2023, the Subcommittee on Innovation, Data, and Commerce held a hearing on H.R. 4310. The Subcommittee received testimony from:

- Kathleen Callahan, Owner, Xpertech Auto Repair;
- Scott Benavidez, Chairman, Automotive Service Association;
- Steven Michael Gentine, Counsel, Arnold & Porter, LLP;
- John Breyault, Vice President of Public Policy, Telecommunications and Fraud, National Consumers League; and
- David Touhey, Principal, Connett Consulting, appearing on behalf of International Association of Venue Managers.

On November 2, 2023, the Subcommittee on Innovation, Data, and Commerce met in open markup session and forwarded H.R. 4310, without amendment, to the full Committee by a voice vote.

On December 6, 2023, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 4310, without amendment, favorably reported to the House by a record vote of 42 yeas and 0 nays.

COMMITTEE VOTES

Clause 3(b) of rule XIII requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following reflects the record votes taken during the Committee consideration:

**COMMITTEE ON ENERGY AND COMMERCE
118TH CONGRESS
ROLL CALL VOTE #25**

BILL: H.R. 4310, Youth Poisoning Protection Act

AMENDMENT: A motion by Chair Rodgers to order H.R. 4310 favorably reported to the House, without amendment (Final Passage).

DISPOSITION: **AGREED TO**, by a roll call vote of 42 yeas to 0 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Rep. Rodgers	X			Rep. Pallone	X		
Rep. Burgess	X			Rep. Eshoo	X		
Rep. Latta	X			Rep. DeGette	X		
Rep. Guthrie	X			Rep. Schakowsky	X		
Rep. Griffith	X			Rep. Matsui			
Rep. Bilirakis	X			Rep. Castor	X		
Rep. Johnson	X			Rep. Sarbanes	X		
Rep. Bucshon	X			Rep. Tonko			
Rep. Hudson	X			Rep. Clarke			
Rep. Walberg	X			Rep. Cárdenas	X		
Rep. Carter	X			Rep. Ruiz	X		
Rep. Duncan	X			Rep. Peters	X		
Rep. Palmer	X			Rep. Dingell	X		
Rep. Dunn				Rep. Veasey	X		
Rep. Curtis	X			Rep. Kuster			
Rep. Lesko	X			Rep. Kelly	X		
Rep. Pence	X			Rep. Barragán			
Rep. Crenshaw				Rep. Blunt Rochester	X		
Rep. Joyce	X			Rep. Soto	X		
Rep. Armstrong	X			Rep. Craig			
Rep. Weber	X			Rep. Schrier			
Rep. Allen	X			Rep. Trahan	X		
Rep. Balderson	X			Rep. Fletcher			
Rep. Fulcher	X						
Rep. Pfluger	X						
Rep. Harshbarger	X						
Rep. Miller-Meeks	X						
Rep. Cammack	X						
Rep. Obernolte	X						

12/06/2023

OVERSIGHT FINDINGS AND RECOMMENDATIONS

Pursuant to clause 2(b)(1) of rule X and clause 3(c)(1) of rule XIII, the Committee held a hearing and made findings that are reflected in this report.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY,
AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R. 4310 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

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.

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

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—Continued

	By fiscal year, millions of dollars—													
	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2024–2029	2024–2034	
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 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.

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 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 prod-

²See 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>.

ucts. 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 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 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.

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/29djdvrz>.

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;
- 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—						2024–2029
	2024	2025	2026	2027	2028	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 requir-

ing 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.

Estimate prepared by: Federal Costs: Austin Barselau (Medicare), Ezra Cohn (public health), Cornelia Hall (Medicare), Hudson Osgood (Medicare), Lara Robillard (Medicare), Sarah Sajewski (Medicare), Katie Zhang (public health), Noah Zwiefel (Medicare); Mandates: Andrew Laughlin.

Estimate reviewed by: Sean Dunbar, Chief, Low-Income Health Programs and Prescription Drugs Cost Estimates Unit; Kathleen FitzGerald, Chief, Public and Private Mandates Unit; Sarah Masi, Senior Adviser, Budget Analysis Division; Asha Saavoss, Chief, Medicare and Health Systems Cost Estimates Unit; Chad Chirico, Director of Budget Analysis.

Estimate approved by: Phillip L. Swagel, Director, Congressional Budget Office.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to ban high-concentrate sodium nitrite to individuals by adding such products to the list of

banned hazardous products in the Consumer Product Safety Act (15 U.S.C. 2057).

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 4310 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

RELATED COMMITTEE AND SUBCOMMITTEE HEARINGS

Pursuant to clause 3(c)(6) of rule XIII, the following related hearing was used to develop or consider H.R. 4310:

- On September 27, 2023, the Subcommittee on Innovation, Data, and Commerce held a hearing on H.R. 4310. The Subcommittee received testimony from:
 - Kathleen Callahan, Owner, Xpertech Auto Repair;
 - Scott Benavidez, Chairman, Automotive Service Association;
 - Steven Michael Gentine, Counsel, Arnold & Porter, LLP;
 - John Breyault, Vice President of Public Policy, Telecommunications and Fraud, National Consumers League; and,
 - David Touhey, Principal, Connett Consulting, appearing on behalf of International Association of Venue Managers.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 4310 contains no earmarks, limited tax benefits, or limited tariff benefits.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 provides that the Act may be cited as the “Youth Poisoning Protection Act.”

Section 2. Banning of products containing a high concentration of sodium nitrite

Section 2 requires any consumer product containing a high concentration of sodium nitrite be considered a banned hazardous product under section 8 of the Consumer Product Safety Act. This section also defines key terms and sets an effective date of 90 days after enactment.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

This legislation does not amend any existing Federal statute.

