118TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPT. 118–764
Part 1

MANDATING EXCLUSIVE REVIEW OF INDIVIDUAL TREATMENTS ACT

NOVEMBER 22, 2024.—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. 133]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 133) to amend title XVIII of the Social Security Act to clarify the use of the national coverage determination process under the Medicare program, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

CONTENTS

	Page
Purpose and Summary	2
Background and Need for Legislation	2
Committee Action	2
Committee Votes	2
Oversight Findings and Recommendations	4
New Budget Authority, Entitlement Authority, and Tax Expenditures	4
Congressional Budget Office Estimate	4
Federal Mandates Statement	14
Statement of General Performance Goals and Objectives	14
Duplication of Federal Programs	14
Related Committee and Subcommittee Hearings	14
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	15

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Mandating Exclusive Review of Individual Treatments Act" or the "MERIT Act".

SEC. 2. CLARIFICATION ON MEDICARE NATIONAL COVERAGE DETERMINATION PROCESS.

Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)) is amended by adding at the end the following new sentence: "For purposes of paragraph (1)(E), with respect to a determination made on or after the date of the enactment of this sentence of whether a drug or biological is reasonable and necessary to carry out the purposes of such section, such determination shall be made with respect to each drug or biological involved and not with respect to a class of drugs or biologicals.".

PURPOSE AND SUMMARY

H.R. 133 clarifies that national coverage determinations for drugs and biologics under the Medicare program must be made with respect to each drug or biologic, not with respect to a class of drugs or of biologics.

BACKGROUND AND NEED FOR LEGISLATION

H.R. 133 would ensure that prospectively, any national coverage decision that the Centers for Medicare and Medicaid (CMS) makes will only apply to that specific therapy and not an entire class of drugs. Medicare includes several pathways to coverage for items and services, including for drugs and breakthrough medical devices. The national coverage determination (NCD) process provides coverage of an item or service nationally. Currently, CMS makes NCDs on an entire class of drugs. This legislation would ensure that CMS must make NCDs on individual drugs.

COMMITTEE ACTION

On September 19, 2023, the Subcommittee on Health held a hearing on H.R. 133. The title of the hearing was "Examining Policies to Improve Seniors' Access to Innovative Drugs, Medical Devices, and Technology." The Subcommittee received testimony from:

- Dora Hughes, MD, MPH, Acting Director, Center for Clinical Standards and Quality, Acting Chief Medical Officer, U.S. Centers for Medicare and Medicaid Services; and
- John Dicken, Director, Health Care—Public Health and Private Markets, U.S. Government Accountability Office.

On November 15, 2023, the Subcommittee on Health met in open markup session and forwarded H.R. 133, as amended, to the full Committee by voice vote.

On December 6, 2023, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 133, as amended, 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 #

BILL: H.R. 133, Mandating Exclusive Review of Individual Treatments (MERIT) Act, as amended

AMENDMENT: A motion by Chair Rodgers to order H.R. 133 favorably reported to the House, as amended (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			
Rep. Johnson				Rep. Sarbanes	X		
Rep. Bucshon	X			Rep. Tonko	X		
Rep. Hudson				Rep. Clarke	X		
Rep. Walberg	X			Rep. Cárdenas	X		
Rep. Carter	X			Rep. Ruiz	X		
Rep. Duncan				Rep. Peters	X		
Rep. Palmer				Rep. Dingell	X		
Rep. Dunn				Rep. Veasey	X		
Rep. Curtis				Rep. Kuster	X		
Rep. Lesko	X			Rep. Kelly	X		
Rep. Pence	X			Rep. Barragán	X		
Rep. Crenshaw	X			Rep. Blunt Rochester	X		
Rep. Joyce	X			Rep. Soto	X		
Rep. Armstrong	X			Rep. Craig			
Rep. Weber	X			Rep. Schrier	X		
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						

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. 133 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	40	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 ex-

[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.

ceeds 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 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 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.

---

[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.

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.

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.

[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.

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.

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 clarify that Medicare must reach coverage determination outcomes by evaluating each individual drug or biologic, rather than making coverage determinations with respect to a class of drugs or biologics.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 133 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 hearing was used to develop or consider H.R. 133:

- September 19, 2023, the Subcommittee on Health held a hearing on H.R. 133. The title of the hearing was "Examining Policies to Improve Seniors' Access to Innovative Drugs, Med-

ical Devices, and Technology." The Subcommittee received testimony from:

- Dora Hughes, MD, MPH, Acting Director, Center for Clinical Standards and Quality, Acting Chief Medical Officer, U.S. Centers for Medicare and Medicaid Services; and
- John Dicken, Director, Health Care—Public Health and Private Markets, U.S. Government Accountability Office.

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. 133 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 "Mandating Exclusive Review of Individual Treatments Act" or the "MERIT Act."

Section 2. Clarification on Medicare national coverage determination process

Section 2 amends Title XVIII of the Social Security Act to clarify the use of the national coverage determination process under the Medicare program and specifies that the coverage determinations under Medicare must be made with respect to each drug or biologic, rather than with respect to a class of drugs or biologics.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italics and existing law in which no change is proposed is shown in roman):

SOCIAL SECURITY ACT

* * * * * * *

TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

* * * * * * *

PART E—MISCELLANEOUS PROVISIONS

* * * * * * *

EXCLUSIONS FROM COVERAGE AND MEDICARE AS SECONDARY PAYER

SEC. 1862. (a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(1)(A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1861(ddd)(1)), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

(B) in the case of items and services described in section 1861(s)(10), which are not reasonable and necessary for the prevention of illness,

(C) in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal illness,

(D) in the case of clinical care items and services provided with the concurrence of the Secretary and with respect to research and experimentation conducted by, or under contract with, the Medicare Payment Advisory Commission or the Secretary, which are not reasonable and necessary to carry out the purposes of section 1886(e)(6),

(E) in the case of research conducted pursuant to section 1142, which is not reasonable and necessary to carry out the purposes of that section,

(F) in the case of screening mammography, which is performed more frequently than is covered under section 1834(c)(2) or which is not conducted by a facility described in section 1834(c)(1)(B), in the case of screening pap smear and screening pelvic exam, which is performed more frequently than is provided under section 1861(nn), and, in the case of screening for glaucoma, which is performed more frequently than is provided under section 1861(uu),

(G) in the case of prostate cancer screening tests (as defined in section 1861(oo)), which are performed more frequently than is covered under such section,

(H) in the case of colorectal cancer screening tests, which are performed more frequently than is covered under section 1834(d),

(I) the frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation,

(J) in the case of a drug or biological specified in section 1847A(c)(6)(C) for which payment is made under part B that is furnished in a competitive area under section 1847B, that is not furnished by an entity under a contract under such section,

(K) in the case of an initial preventive physical examination, which is performed more than 1 year after the date the individual's first coverage period begins under part B,

(L) in the case of cardiovascular screening blood tests (as defined in section 1861(xx)(1)), which are performed more frequently than is covered under section 1861(xx)(2),

(M) in the case of a diabetes screening test (as defined in section 1861(yy)(1)), which is performed more frequently than is covered under section 1861(yy)(3),

(N) in the case of ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under section 1861(s)(2)(AA),

(O) in the case of kidney disease education services (as defined in paragraph (1) of section 1861(ggg)), which are furnished in excess of the number of sessions covered under paragraph (4) of such section, and

(P) in the case of personalized prevention plan services (as defined in section 1861(hhh)(1)), which are performed more frequently than is covered under such section;

(2) for which the individual furnished such items or services has no legal obligation to pay, and which no other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for, except in the case of Federally qualified health center services;

(3) which are paid for directly or indirectly by a governmental entity (other than under this Act and other than under a health benefits or insurance plan established for employees of such an entity), except in the case of rural health clinic services, as defined in section 1861(aa)(1), in the case of Federally qualified health center services, as defined in section 1861(aa)(3), in the case of services for which payment may be made under section 1880(e), and in such other cases as the Secretary may specify;

(4) which are not provided within the United States (except for inpatient hospital services furnished outside the United States under the conditions described in section 1814(f) and, subject to such conditions, limitations, and requirements as are provided under or pursuant to this title, physicians' services and ambulance services furnished an individual in conjunction with such inpatient hospital services but only for the period during which such inpatient hospital services were furnished);

(5) which are required as a result of war, or of an act of war, occurring after the effective date of such individual's current coverage under such part;

(6) which constitute personal comfort items (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(7) where such expenses are for routine physical checkups, eyeglasses (other than eyewear described in section 1861(s)(8)) or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes, hearing aids or examinations therefor, or immunizations (except as otherwise allowed under section 1861(s)(10) and subparagraph (B), (F), (G), (H), (K), or (P) of paragraph (1));

(8) where such expenses are for orthopedic shoes or other supportive devices for the feet, other than shoes furnished pursuant to section 1861(s)(12);

(9) where such expenses are for custodial care (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(10) where such expenses are for cosmetic surgery or are incurred in connection therewith, except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member;

(11) where such expenses constitute charges imposed by immediate relatives of such individual or members of his household;

(12) where such expenses are for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, except that payment may be made under part A in the case of inpatient hospital services in connection with the provision of such dental services if the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services;

(13) where such expenses are for—

(A) the treatment of flat foot conditions and the prescription of supportive devices therefor,

(B) the treatment of subluxations of the foot, or

(C) routine foot care (including the cutting or removal of corns or calluses, the trimming of nails, and other routine hygienic care);

(14) which are other than physicians' services (as defined in regulations promulgated specifically for purposes of this paragraph), services described by section 1861(s)(2)(K), certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist, and which are furnished to an individual who is a patient of a hospital or critical access hospital by an entity other than the hospital or critical access hospital, unless the services are furnished under arrangements (as defined in section 1861(w)(1)) with the entity made by the hospital or critical access hospital;

(15)(A) which are for services of an assistant at surgery in a cataract operation (including subsequent insertion of an intraocular lens) unless, before the surgery is performed, the appropriate quality improvement organization (under part B of title XI) or a carrier under section 1842 has approved of the use of such an assistant in the surgical procedure based on the existence of a complicating medical condition, or

(B) which are for services of an assistant at surgery to which section 1848(i)(2)(B) applies;

(16) in the case in which funds may not be used for such items and services under the Assisted Suicide Funding Restriction Act of 1997;

(17) where the expenses are for an item or service furnished in a competitive acquisition area (as established by the Secretary under section 1847(a)) by an entity other than an entity with which the Secretary has entered into a contract under

section 1847(b) for the furnishing of such an item or service in that area, unless the Secretary finds that the expenses were incurred in a case of urgent need, or in other circumstances specified by the Secretary;

(18) which are covered skilled nursing facility services described in section 1888(e)(2)(A)(i) and which are furnished to an individual who is a resident of a skilled nursing facility during a period in which the resident is provided covered post-hospital extended care services (or, for services described in section 1861(s)(2)(D), which are furnished to such an individual without regard to such period), by an entity other than the skilled nursing facility, unless the services are furnished under arrangements (as defined in section 1861(w)(1)) with the entity made by the skilled nursing facility;

(19) which are for items or services which are furnished pursuant to a private contract described in section 1802(b);

(20) in the case of outpatient physical therapy services, outpatient speech-language pathology services, or outpatient occupational therapy services furnished as an incident to a physician's professional services (as described in section 1861(s)(2)(A)), that do not meet the standards and conditions (other than any licensing requirement specified by the Secretary) under the second sentence of section 1861(p) (or under such sentence through the operation of subsection (g) or (ll)(2) of section 1861) as such standards and conditions would apply to such therapy services if furnished by a therapist;

(21) where such expenses are for home health services (including medical supplies described in section 1861(m)(5), but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who is under a plan of care of the home health agency if the claim for payment for such services is not submitted by the agency;

(22) subject to subsection (h), for which a claim is submitted other than in an electronic form specified by the Secretary;

(23) which are the technical component of advanced diagnostic imaging services described in section 1834(e)(1)(B) for which payment is made under the fee schedule established under section 1848(b) and that are furnished by a supplier (as defined in section 1861(d)), if such supplier is not accredited by an accreditation organization designated by the Secretary under section 1834(e)(2)(B);

(24) where such expenses are for renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14)) for which payment is made under such section unless such payment is made under such section to a provider of services or a renal dialysis facility for such services; or

(25) not later than January 1, 2014, for which the payment is other than by electronic funds transfer (EFT) or an electronic remittance in a form as specified in ASC X12 835 Health Care Payment and Remittance Advice or subsequent standard.

Paragraph (7) shall not apply to Federally qualified health center services described in section 1861(aa)(3)(B). In making a national coverage determination (as defined in paragraph (1)(B) of section 1869(f)) the Secretary shall ensure consistent with subsection (l) that the public is afforded notice and opportunity to comment prior

to implementation by the Secretary of the determination; meetings of advisory committees with respect to the determination are made on the record; in making the determination, the Secretary has considered applicable information (including clinical experience and medical, technical, and scientific evidence) with respect to the subject matter of the determination; and in the determination, provide a clear statement of the basis for the determination (including responses to comments received from the public), the assumptions underlying that basis, and make available to the public the data (other than proprietary data) considered in making the determination. *For purposes of paragraph (1)(E), with respect to a determination made on or after the date of the enactment of this sentence of whether a drug or biological is reasonable and necessary to carry out the purposes of such section, such determination shall be made with respect to each drug or biological involved and not with respect to a class of drugs or biologicals.*

(b) MEDICARE AS SECONDARY PAYER.—

(1) REQUIREMENTS OF GROUP HEALTH PLANS.—

(A) WORKING AGED UNDER GROUP HEALTH PLANS.—

(i) IN GENERAL.—A group health plan—

(I) may not take into account that an individual (or the individual's spouse) who is covered under the plan by virtue of the individual's current employment status with an employer is entitled to benefits under this title under section 226(a), and

(II) shall provide that any individual age 65 or older (and the spouse age 65 or older of any individual) who has current employment status with an employer shall be entitled to the same benefits under the plan under the same conditions as any such individual (or spouse) under age 65.

(ii) EXCLUSION OF GROUP HEALTH PLAN OF A SMALL EMPLOYER.—Clause (i) shall not apply to a group health plan unless the plan is a plan of, or contributed to by, an employer that has 20 or more employees for each working day in each of 20 or more calendar weeks in the current calendar year or the preceding calendar year.

(iii) EXCEPTION FOR SMALL EMPLOYERS IN MULTIEMPLOYER OR MULTIPLE EMPLOYER GROUP HEALTH PLANS.—Clause (i) also shall not apply with respect to individuals enrolled in a multiemployer or multiple employer group health plan if the coverage of the individuals under the plan is by virtue of current employment status with an employer that does not have 20 or more individuals in current employment status for each working day in each of 20 or more calendar weeks in the current calendar year and the preceding calendar year; except that the exception provided in this clause shall only apply if the plan elects treatment under this clause.

(iv) EXCEPTION FOR INDIVIDUALS WITH END STAGE RENAL DISEASE.—Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or

(without regard to entitlement under section 226) would upon application be, entitled to benefits under section 226A.

(v) GROUP HEALTH PLAN DEFINED.—In this subparagraph, and subparagraph (C), the term "group health plan" has the meaning given such term in section 5000(b)(1) of the Internal Revenue Code of 1986, without regard to section 5000(d) of such Code

(B) DISABLED INDIVIDUALS IN LARGE GROUP HEALTH PLANS.—

(i) IN GENERAL.—A large group health plan (as defined in clause (iii)) may not take into account that an individual (or a member of the individual's family) who is covered under the plan by virtue of the individual's current employment status with an employer is entitled to benefits under this title under section 226(b).

(ii) EXCEPTION FOR INDIVIDUALS WITH END STAGE RENAL DISEASE.—Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or (without regard to entitlement under section 226) would upon application be, entitled to benefits under section 226A.

(iii) LARGE GROUP HEALTH PLAN DEFINED.—In this subparagraph, the term "large group health plan" has the meaning given such term in section 5000(b)(2) of the Internal Revenue Code of 1986, without regard to section 5000(d) of such Code.

(C) INDIVIDUALS WITH END STAGE RENAL DISEASE.—A group health plan (as defined in subparagraph (A)(v))—

(i) may not take into account that an individual is entitled to or eligible for benefits under this title under section 226A during the 12-month period which begins with the first month in which the individual becomes entitled to benefits under part A under the provisions of section 226A, or, if earlier, the first month in which the individual would have been entitled to benefits under such part under the provisions of section 226A if the individual had filed an application for such benefits; and

(ii) may not differentiate in the benefits it provides between individuals having end stage renal disease and other individuals covered by such plan on the basis of the existence of end stage renal disease, the need for renal dialysis, or in any other manner;

except that clause (ii) shall not prohibit a plan from paying benefits secondary to this title when an individual is entitled to or eligible for benefits under this title under section 226A after the end of the 12-month period described in clause (i). Effective for items and services furnished on or after February 1, 1991, and before the date of enactment of the Balanced Budget Act of 1997 (with respect to periods beginning on or after February 1, 1990), this subparagraph shall be applied by substituting "18- month" for "12-

month" each place it appears. Effective for items and services furnished on or after the date of enactment of the Balanced Budget Act of 1997, (with respect to periods beginning on or after the date that is 18 months prior to such date), clauses (i) and (ii) shall be applied by substituting "30-month" for "12-month" each place it appears.

(D) TREATMENT OF CERTAIN MEMBERS OF RELIGIOUS ORDERS.—In this subsection, an individual shall not be considered to be employed, or an employee, with respect to the performance of services as a member of a religious order which are considered employment only by virtue of an election made by the religious order under section 3121(r) of the Internal Revenue Code of 1986.

(E) GENERAL PROVISIONS.—For purposes of this subsection:

(i) AGGREGATION RULES.—

(I) All employers treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as a single employer.

(II) All employees of the members of an affiliated service group (as defined in section 414(m) of such Code) shall be treated as employed by a single employer.

(III) Leased employees (as defined in section 414(n)(2) of such Code) shall be treated as employees of the person for whom they perform services to the extent they are so treated under section 414(n) of such Code.

In applying sections of the Internal Revenue Code of 1986 under this clause, the Secretary shall rely upon regulations and decisions of the Secretary of the Treasury respecting such sections.

(ii) CURRENT EMPLOYMENT STATUS DEFINED.—An individual has "current employment status" with an employer if the individual is an employee, is the employer, or is associated with the employer in a business relationship.

(iii) TREATMENT OF SELF-EMPLOYED PERSONS AS EMPLOYERS.—The term "employer" includes a self-employed person.

(iv) APPLICATION TO CERTAIN POSTAL SERVICE ANNUITANTS OR FAMILY MEMBERS.—Nothing in this paragraph shall prohibit a group health plan from determining an individual's eligibility to enroll in a health benefits plan offered under the Postal Service Health Benefits Program under section 8903c of title 5, United States Code, in accordance with subsection (e) of such section.

(F) LIMITATION ON BENEFICIARY LIABILITY.—An individual who is entitled to benefits under this title and is furnished an item or service for which such benefits are incorrectly paid is not liable for repayment of such benefits under this paragraph unless payment of such benefits was made to the individual.

(2) MEDICARE SECONDARY PAYER.—

(A) IN GENERAL.—Payment under this title may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that—

(i) payment has been made, or can reasonably be expected to be made, with respect to the item or service as required under paragraph (1), or

(ii) payment has been made or can reasonably be expected to be made under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance.

In the subsection, the term "primary plan" means a group health plan or large group health plan, to the extent that clause (i) applies, and a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance, to the extent that clause (ii) applies. An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.

(B) CONDITIONAL PAYMENT.—

(i) AUTHORITY TO MAKE CONDITIONAL PAYMENT.—The Secretary may make payment under this title with respect to an item or service if a primary plan described in subparagraph (A)(ii) has not made or cannot reasonably be expected to make payment with respect to such item or service promptly (as determined in accordance with regulations). Any such payment by the Secretary shall be conditioned on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.

(ii) REPAYMENT REQUIRED.—Subject to paragraph (9), a primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this title with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means. If reimbursement is not made to the appropriate Trust Fund before the expiration of the 60-day period that begins on the date notice of, or information related to, a primary plan's responsibility for such payment or other information is received, the Secretary may charge interest (beginning with the date on which the notice or other information is received)

on the amount of the reimbursement until reimbursement is made (at a rate determined by the Secretary in accordance with regulations of the Secretary of the Treasury applicable to charges for late payments).

(iii) ACTION BY UNITED STATES.—In order to recover payment made under this title for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity. The United States may not recover from a third-party administrator under this clause in cases where the third-party administrator would not be able to recover the amount at issue from the employer or group health plan and is not employed by or under contract with the employer or group health plan at the time the action for recovery is initiated by the United States or for whom it provides administrative services due to the insolvency or bankruptcy of the employer or plan. An action may not be brought by the United States under this clause with respect to payment owed unless the complaint is filed not later than 3 years after the date of the receipt of notice of a settlement, judgment, award, or other payment made pursuant to paragraph (8) relating to such payment owed.

(iv) SUBROGATION RIGHTS.—The United States shall be subrogated (to the extent of payment made under this title for such an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan.

(v) WAIVER OF RIGHTS.—The Secretary may waive (in whole or in part) the provisions of this subparagraph in the case of an individual claim if the Secretary determines that the waiver is in the best interests of the program established under this title.

(vi) CLAIMS-FILING PERIOD.—Notwithstanding any other time limits that may exist for filing a claim under an employer group health plan, the United States may seek to recover conditional payments in accordance with this subparagraph where the request for payment is submitted to the entity required or responsible under this subsection to pay with respect to the item or service (or any portion thereof) under a primary plan within the 3-year period beginning on the date on which the item or service was furnished.

(vii) USE OF WEBSITE TO DETERMINE FINAL CONDITIONAL REIMBURSEMENT AMOUNT.—

(I) NOTICE TO SECRETARY OF EXPECTED DATE OF A SETTLEMENT, JUDGMENT, ETC.—In the case of a payment made by the Secretary pursuant to clause (i) for items and services provided to the claimant, the claimant or applicable plan (as defined in paragraph (8)(F)) may at any time beginning 120 days before the reasonably expected date of a settlement, judgment, award, or other payment, notify the Secretary that a payment is reasonably expected and the expected date of such payment.

(II) SECRETARIAL PROVIDING ACCESS TO CLAIMS INFORMATION THROUGH A WEBSITE.—The Secretary shall maintain and make available to individuals to whom items and services are furnished under this title (and to authorized family or other representatives recognized under regulations and to an applicable plan which has obtained the consent of the individual) access to information on the claims for such items and services (including payment amounts for such claims), including those claims that relate to a potential settlement, judgment, award, or other payment. Such access shall be provided to an individual, representative, or plan through a website that requires a password to gain access to the information. The Secretary shall update the information on claims and payments on such website in as timely a manner as possible but not later than 15 days after the date that payment is made. Information related to claims and payments subject to the notice under subclause (I) shall be maintained and made available consistent with the following:

(aa) The information shall be as complete as possible and shall include provider or supplier name, diagnosis codes (if any), dates of service, and conditional payment amounts.

(bb) The information accurately identifies those claims and payments that are related to a potential settlement, judgment, award, or other payment to which the provisions of this subsection apply.

(cc) The website provides a method for the receipt of secure electronic communications with the individual, representative, or plan involved.

(dd) The website provides that information is transmitted from the website in a form that includes an official time and date that the information is transmitted.

(ee) The website shall permit the individual, representative, or plan to download a statement of reimbursement amounts (in this

clause referred to as a "statement of reimbursement amount") on payments for claims under this title relating to a potential settlement, judgment, award, or other payment.

(III) USE OF TIMELY WEB DOWNLOAD AS BASIS FOR FINAL CONDITIONAL AMOUNT.—If an individual (or other claimant or applicable plan with the consent of the individual) obtains a statement of reimbursement amount from the website during the protected period as defined in subclause (V) and the related settlement, judgment, award or other payment is made during such period, then the last statement of reimbursement amount that is downloaded during such period and within 3 business days before the date of the settlement, judgment, award, or other payment shall constitute the final conditional amount subject to recovery under clause (ii) related to such settlement, judgment, award, or other payment.

(IV) RESOLUTION OF DISCREPANCIES.—If the individual (or authorized representative) believes there is a discrepancy with the statement of reimbursement amount, the Secretary shall provide a timely process to resolve the discrepancy. Under such process the individual (or representative) must provide documentation explaining the discrepancy and a proposal to resolve such discrepancy. Within 11 business days after the date of receipt of such documentation, the Secretary shall determine whether there is a reasonable basis to include or remove claims on the statement of reimbursement. If the Secretary does not make such determination within the 11 business-day period, then the proposal to resolve the discrepancy shall be accepted. If the Secretary determines within such period that there is not a reasonable basis to include or remove claims on the statement of reimbursement, the proposal shall be rejected. If the Secretary determines within such period that there is a reasonable basis to conclude there is a discrepancy, the Secretary must respond in a timely manner by agreeing to the proposal to resolve the discrepancy or by providing documentation showing with good cause why the Secretary is not agreeing to such proposal and establishing an alternate discrepancy resolution. In no case shall the process under this subclause be treated as an appeals process or as establishing a right of appeal for a statement of reimbursement amount and there shall be no administrative or judicial review of the Secretary's determinations under this subclause.

(V) PROTECTED PERIOD.—In subclause (III), the term "protected period" means, with respect to a settlement, judgment, award or other payment re-

lating to an injury or incident, the portion (if any) of the period beginning on the date of notice under subclause (I) with respect to such settlement, judgment, award, or other payment that is after the end of a Secretarial response period beginning on the date of such notice to the Secretary. Such Secretarial response period shall be a period of 65 days, except that such period may be extended by the Secretary for a period of an additional 30 days if the Secretary determines that additional time is required to address claims for which payment has been made. Such Secretarial response period shall be extended and shall not include any days for any part of which the Secretary determines (in accordance with regulations) that there was a failure in the claims and payment posting system and the failure was justified due to exceptional circumstances (as defined in such regulations). Such regulations shall define exceptional circumstances in a manner so that not more than 1 percent of the repayment obligations under this subclause would qualify as exceptional circumstances.

(VI) EFFECTIVE DATE.—The Secretary shall promulgate final regulations to carry out this clause not later than 9 months after the date of the enactment of this clause.

(VII) WEBSITE INCLUDING SUCCESSOR TECHNOLOGY.—In this clause, the term "website" includes any successor technology.

(viii) RIGHT OF APPEAL FOR SECONDARY PAYER DETERMINATIONS RELATING TO LIABILITY INSURANCE (INCLUDING SELF-INSURANCE), NO FAULT INSURANCE, AND WORKERS' COMPENSATION LAWS AND PLANS.—The Secretary shall promulgate regulations establishing a right of appeal and appeals process, with respect to any determination under this subsection for a payment made under this title for an item or service for which the Secretary is seeking to recover conditional payments from an applicable plan (as defined in paragraph (8)(F)) that is a primary plan under subsection (A)(ii), under which the applicable plan involved, or an attorney, agent, or third party administrator on behalf of such plan, may appeal such determination. The individual furnished such an item or service shall be notified of the plan's intent to appeal such determination

(C) TREATMENT OF QUESTIONNAIRES.—The Secretary may not fail to make payment under subparagraph (A) solely on the ground that an individual failed to complete a questionnaire concerning the existence of a primary plan.

(3) ENFORCEMENT.—

(A) PRIVATE CAUSE OF ACTION.—There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary pay-

ment (or appropriate reimbursement) in accordance with paragraphs (1) and (2)(A).

(B) REFERENCE TO EXCISE TAX WITH RESPECT TO NONCONFORMING GROUP HEALTH PLANS.—For provision imposing an excise tax with respect to nonconforming group health plans, see section 5000 of the Internal Revenue Code of 1986.

(C) PROHIBITION OF FINANCIAL INCENTIVES NOT TO ENROLL IN A GROUP HEALTH PLAN OR A LARGE GROUP HEALTH PLAN.—It is unlawful for an employer or other entity to offer any financial or other incentive for an individual entitled to benefits under this title not to enroll (or to terminate enrollment) under a group health plan or a large group health plan which would (in the case of such enrollment) be a primary plan (as defined in paragraph (2)(A)). Any entity that violates the previous sentence is subject to a civil money penalty of not to exceed $5,000 for each such violation. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(4) COORDINATION OF BENEFITS.—Where payment for an item or service by a primary plan is less than the amount of the charge for such item or service and is not payment in full, payment may be made under this title (without regard to deductibles and coinsurance under this title) for the remainder of such charge, but—

(A) payment under this title may not exceed an amount which would be payable under this title for such item or service if paragraph (2)(A) did not apply; and

(B) payment under this title, when combined with the amount payable under the primary plan, may not exceed—

(i) in the case of an item or service payment for which is determined under this title on the basis of reasonable cost (or other cost-related basis) or under section 1886, the amount which would be payable under this title on such basis, and

(ii) in the case of an item or service for which payment is authorized under this title on another basis—

(I) the amount which would be payable under the primary plan (without regard to deductibles and coinsurance under such plan), or

(II) the reasonable charge or other amount which would be payable under this title (without regard to deductibles and coinsurance under this title),

whichever is greater.

(5) IDENTIFICATION OF SECONDARY PAYER SITUATIONS.—

(A) REQUESTING MATCHING INFORMATION.—

(i) COMMISSIONER OF SOCIAL SECURITY.—The Commissioner of Social Security shall, not less often that annually, transmit to the Secretary of the Treasury a list of the names and TINs of medicare beneficiaries (as defined in section 6103(l)(12) of the Internal Rev-

enue Code of 1986) and request that the Secretary disclose to the Commissioner the information described in subparagraph (A) of such section.

(ii) ADMINISTRATOR.—The Administrator of the Centers for Medicare & Medicaid Services shall request, not less often than annually, the Commissioner of the Social Security Administration to disclose to the Administrator the information described in subparagraph (B) of section 6103(l)(12) of the Internal Revenue Code of 1986.

(B) DISCLOSURE TO FISCAL INTERMEDIARIES AND CARRIERS.—In addition to any other information provided under this title to fiscal intermediaries and carriers, the Administrator shall disclose to such intermediaries and carriers (or to such a single intermediary or carrier as the Secretary may designate) the information received under subparagraph (A) for purposes of carrying out this subsection.

(C) CONTACTING EMPLOYERS.—

(i) IN GENERAL.—With respect to each individual (in this subparagraph referred to as an "employee") who was furnished a written statement under section 6051 of the Internal Revenue Code of 1986 by a qualified employer (as defined in section 6103(l)(12)(E)(iii) of such Code), as disclosed under subparagraph (B), the appropriate fiscal intermediary or carrier shall contact the employer in order to determine during what period the employee or employee's spouse may be (or have been) covered under a group health plan of the employer and the nature of the coverage that is or was provided under the plan (including the name, address, and identifying number of the plan).

(ii) EMPLOYER RESPONSE.—Within 30 days of the date of receipt of the inquiry, the employer shall notify the intermediary or carrier making the inquiry as to the determinations described in clause (i). An employer (other than a Federal or other governmental entity) who willfully or repeatedly fails to provide timely and accurate notice in accordance with the previous sentence shall be subject to a civil money penalty of not to exceed $1,000 for each individual with respect to which such an inquiry is made. The provision of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(D) OBTAINING INFORMATION FROM BENEFICIARIES.—Before an individual applies for benefits under part A or enrolls under part B, the Administrator shall mail the individual a questionnaire to obtain information on whether the individual is covered under a primary plan and the nature of the coverage provided under the plan, including the name, address, and identifying number of the plan.

(E) END DATE.—The provisions of this paragraph shall not apply to information required to be provided on or after July 1, 2016.

(6) SCREENING REQUIREMENTS FOR PROVIDERS AND SUPPLIERS.—

(A) IN GENERAL.—Notwithstanding any other provision of this title, no payment may be made for any item or service furnished under part B unless the entity furnishing such item or service completes (to the best of its knowledge and on the basis of information obtained from the individual to whom the item or service is furnished) the portion of the claim form relating to the availability of other health benefit plans.

(B) PENALTIES.—An entity that knowingly, willfully, and repeatedly fails to complete a claim form in accordance with subparagraph (A) or provides inaccurate information relating to the availability of other health benefit plans on a claim form under such subparagraph shall be subject to a civil money penalty of not to exceed $2,000 for each such incident. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(7) REQUIRED SUBMISSION OF INFORMATION BY GROUP HEALTH PLANS.—

(A) REQUIREMENT.—On and after the first day of the first calendar quarter beginning after the date that is 1 year after the date of the enactment of this paragraph, an entity serving as an insurer or third party administrator for a group health plan, as defined in paragraph (1)(A)(v), and, in the case of a group health plan that is self-insured and self-administered, a plan administrator or fiduciary, shall—

(i) secure from the plan sponsor and plan participants such information as the Secretary shall specify for the purpose of identifying situations where the group health plan is or has been—

(I) a primary plan to the program under this title; or

(II) for calendar quarters beginning on or after January 1, 2020, a primary payer with respect to benefits relating to prescription drug coverage under part D; and

(ii) submit such information to the Secretary in a form and manner (including frequency) specified by the Secretary.

(B) ENFORCEMENT.—

(i) IN GENERAL.—An entity, a plan administrator, or a fiduciary described in subparagraph (A) that fails to comply with the requirements under such subparagraph shall be subject to a civil money penalty of $1,000 for each day of noncompliance for each individual for which the information under such subparagraph should have been submitted. The provisions of

subsections (e) and (k) of section 1128A shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). A civil money penalty under this clause shall be in addition to any other penalties prescribed by law and in addition to any Medicare secondary payer claim under this title with respect to an individual.

(ii) DEPOSIT OF AMOUNTS COLLECTED.—Any amounts collected pursuant to clause (i) shall be deposited in the Federal Hospital Insurance Trust Fund under section 1817.

(C) SHARING OF INFORMATION.—Notwithstanding any other provision of law, under terms and conditions established by the Secretary, the Secretary—

(i) shall share information on entitlement under Part A and enrollment under Part B under this title with entities, plan administrators, and fiduciaries described in subparagraph (A);

(ii) may share the entitlement and enrollment information described in clause (i) with entities and persons not described in such clause; and

(iii) may share information collected under this paragraph as necessary for purposes of the proper coordination of benefits.

(D) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

(8) REQUIRED SUBMISSION OF INFORMATION BY OR ON BEHALF OF LIABILITY INSURANCE (INCLUDING SELF-INSURANCE), NO FAULT INSURANCE, AND WORKERS' COMPENSATION LAWS AND PLANS.—

(A) REQUIREMENT.—On and after the first day of the first calendar quarter beginning after the date that is 18 months after the date of the enactment of this paragraph, an applicable plan shall—

(i) determine whether a claimant (including an individual whose claim is unresolved) is entitled to benefits under the program under this title on any basis; and

(ii) if the claimant is determined to be so entitled, submit the information described in subparagraph (B) with respect to the claimant to the Secretary in a form and manner (including frequency) specified by the Secretary.

(B) REQUIRED INFORMATION.—The information described in this subparagraph is—

(i) the identity of the claimant for which the determination under subparagraph (A) was made; and

(ii) such other information as the Secretary shall specify in order to enable the Secretary to make an appropriate determination concerning coordination of benefits, including any applicable recovery claim.

Not later than 18 months after the date of enactment of this sentence, the Secretary shall modify the reporting re-

quirements under this paragraph so that an applicable plan in complying with such requirements is permitted but not required to access or report to the Secretary beneficiary social security account numbers or health identification claim numbers, except that the deadline for such modification shall be extended by one or more periods (specified by the Secretary) of up to 1 year each if the Secretary notifies the committees of jurisdiction of the House of Representatives and of the Senate that the prior deadline for such modification, without such extension, threatens patient privacy or the integrity of the secondary payer program under this subsection. Any such deadline extension notice shall include information on the progress being made in implementing such modification and the anticipated implementation date for such modification.

(C) TIMING.—Information shall be submitted under subparagraph (A)(ii) within a time specified by the Secretary after the claim is resolved through a settlement, judgment, award, or other payment (regardless of whether or not there is a determination or admission of liability).

(D) CLAIMANT.—For purposes of subparagraph (A), the term "claimant" includes—

(i) an individual filing a claim directly against the applicable plan; and

(ii) an individual filing a claim against an individual or entity insured or covered by the applicable plan.

(E) ENFORCEMENT.—

(i) IN GENERAL.—An applicable plan that fails to comply with the requirements under subparagraph (A) with respect to any claimant may be subject to a civil money penalty of up to $1,000 for each day of noncompliance with respect to each claimant. The provisions of subsections (e) and (k) of section 1128A shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). A civil money penalty under this clause shall be in addition to any other penalties prescribed by law and in addition to any Medicare secondary payer claim under this title with respect to an individual.

(ii) DEPOSIT OF AMOUNTS COLLECTED.—Any amounts collected pursuant to clause (i) shall be deposited in the Federal Hospital Insurance Trust Fund.

(F) APPLICABLE PLAN.—In this paragraph, the term "applicable plan" means the following laws, plans, or other arrangements, including the fiduciary or administrator for such law, plan, or arrangement:

(i) Liability insurance (including self-insurance).

(ii) No fault insurance.

(iii) Workers' compensation laws or plans.

(G) SHARING OF INFORMATION.—

(i) IN GENERAL.—The Secretary may share information collected under this paragraph as necessary for purposes of the proper coordination of benefits.

(ii) SPECIFIED INFORMATION.—In responding to any query made on or after the date that is 1 year after the date of the enactment of this clause from an applicable plan related to a determination described in subparagraph (A)(i), the Secretary, notwithstanding any other provision of law, shall provide to such applicable plan—

(I) whether a claimant subject to the query is, or during the preceding 3-year period has been, entitled to benefits under the program under this title on any basis; and

(II) to the extent applicable, the plan name and address of any Medicare Advantage plan under part C and any prescription drug plan under part D in which the claimant is enrolled or has been enrolled during such period.

(H) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

(I) REGULATIONS.—Not later than 60 days after the date of the enactment of this subparagraph, the Secretary shall publish a notice in the Federal Register soliciting proposals, which will be accepted during a 60-day period, for the specification of practices for which sanctions will and will not be imposed under subparagraph (E), including not imposing sanctions for good faith efforts to identify a beneficiary pursuant to this paragraph under an applicable entity responsible for reporting information. After considering the proposals so submitted, the Secretary, in consultation with the Attorney General, shall publish in the Federal Register, including a 60-day period for comment, proposed specified practices for which such sanctions will and will not be imposed. After considering any public comments received during such period, the Secretary shall issue final rules specifying such practices.

(9) EXCEPTION.—

(A) IN GENERAL.—Clause (ii) of paragraph (2)(B) and any reporting required by paragraph (8) shall not apply with respect to any settlement, judgment, award, or other payment by an applicable plan arising from liability insurance (including self-insurance) and from alleged physical trauma-based incidents (excluding alleged ingestion, implantation, or exposure cases) constituting a total payment obligation to a claimant of not more than the single threshold amount calculated by the Secretary under subparagraph (B) for the year involved.

(B) ANNUAL COMPUTATION OF THRESHOLD.—

(i) IN GENERAL.—Not later than November 15 before each year, the Secretary shall calculate and publish a single threshold amount for settlements, judgments, awards, or other payments for obligations arising from liability insurance (including self-insurance) and for alleged physical trauma-based incidents (excluding alleged ingestion, implantation, or exposure cases) subject to this section for that year. The annual single

threshold amount for a year shall be set such that the estimated average amount to be credited to the Medicare trust funds of collections of conditional payments from such settlements, judgments, awards, or other payments arising from liability insurance (including self-insurance) and for such alleged incidents subject to this section shall equal the estimated cost of collection incurred by the United States (including payments made to contractors) for a conditional payment arising from liability insurance (including self-insurance) and for such alleged incidents subject to this section for the year. At the time of calculating, but before publishing, the single threshold amount for 2014, the Secretary shall inform, and seek review of, the Comptroller General of the United States with regard to such amount.

(ii) PUBLICATION.—The Secretary shall include, as part of such publication for a year—

(I) the estimated cost of collection incurred by the United States (including payments made to contractors) for a conditional payment arising from liability insurance (including self-insurance) and for such alleged incidents; and

(II) a summary of the methodology and data used by the Secretary in computing such threshold amount and such cost of collection.

(C) EXCLUSION OF ONGOING EXPENSES.—For purposes of this paragraph and with respect to a settlement, judgment, award, or other payment not otherwise addressed in clause (ii) of paragraph (2)(B) that includes ongoing responsibility for medical payments (excluding settlements, judgments, awards, or other payments made by a workers' compensation law or plan or no fault insurance), the amount utilized for calculation of the threshold described in subparagraph (A) shall include only the cumulative value of the medical payments made under this title.

(D) REPORT TO CONGRESS.—Not later than November 15 before each year, the Secretary shall submit to the Congress a report on the single threshold amount for settlements, judgments, awards, or other payments for conditional payment obligations arising from liability insurance (including self-insurance) and alleged incidents described in subparagraph (A) for that year and on the establishment and application of similar thresholds for such payments for conditional payment obligations arising from worker compensation cases and from no fault insurance cases subject to this section for the year. For each such report, the Secretary shall—

(i) calculate the threshold amount by using the methodology applicable to certain liability claims described in subparagraph (B); and

(ii) include a summary of the methodology and data used in calculating each threshold amount and the amount of estimated savings under this title achieved by the Secretary implementing each such threshold.

(c) No payment may be made under part B for any expenses incurred for—

(1) a drug product—

(A) which is described in section 107(c)(3) of the Drug Amendments of 1962,

(B) which may be dispensed only upon prescription,

(C) for which the Secretary has issued a notice of an opportunity for a hearing under subsection (e) of section 505 of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug product under such section because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling, and

(D) for which the Secretary has not determined there is a compelling justification for its medical need; and

(2) any other drug product—

(A) which is identical, related, or similar (as determined in accordance with section 310.6 of title 21 of the Code of Federal Regulations) to a drug product described in paragraph (1), and

(B) for which the Secretary has not determined there is a compelling justification for its medical need,

until such time as the Secretary withdraws such proposed order.

(d) For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1867 to an individual who is entitled to benefits under this title, determinations as to whether the item or service is reasonable and necessary shall be made on the basis of the information available to the treating physician or practitioner (including the patient's presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not on the patient's principal diagnosis). When making such determinations with respect to such an item or service, the Secretary shall not consider the frequency with which the item or service was provided to the patient before or after the time of the admission or visit.

(e)(1) No payment may be made under this title with respect to any item or service (other than an emergency item or service, not including items or services furnished in an emergency room of a hospital) furnished—

(A) by an individual or entity during the period when such individual or entity is excluded pursuant to section 1128, 1128A, 1156 or 1842(j)(2) from participation in the program under this title; or

(B) at the medical direction or on the prescription of a physician during the period when he is excluded pursuant to section 1128, 1128A, 1156 or 1842(j)(2) from participation in the program under this title and when the person furnishing such item or service knew or had reason to know of the exclusion (after a reasonable time period after reasonable notice has been furnished to the person).

(2) Where an individual eligible for benefits under this title submits a claim for payment for items or services furnished by an individual or entity excluded from participation in the programs under

this title, pursuant to section 1128, 1128A, 1156, 1160 (as in effect on September 2, 1982), 1842(j)(2), 1862(d) (as in effect on the date of the enactment of the Medicare and Medicaid Patient and Program Protection Act of 1987), or l866, and such beneficiary did not know or have reason to know that such individual or entity was so excluded, then, to the extent permitted by this title, and notwithstanding such exclusion, payment shall be made for such items or services. In each such case the Secretary shall notify the beneficiary of the exclusion of the individual or entity furnishing the items or services. Payment shall not be made for items or services furnished by an excluded individual or entity to a beneficiary after a reasonable time (as determined by the Secretary in regulations) after the Secretary has notified the beneficiary of the exclusion of that individual or entity.

(f) The Secretary shall establish utilization guidelines for the determination of whether or not payment may be made, consistent with paragraph (1)(A) of subsection (a), under part A or part B for expenses incurred with respect to the provision of home health services, and shall provide for the implementation of such guidelines through a process of selective postpayment coverage review by intermediaries or otherwise.

(g)(1) The Secretary shall, in making the determinations under paragraphs (1) and (9) of subsection (a), and for the purposes of promoting the effective, efficient, and economical delivery of health care services, and of promoting the quality of services of the type for which payment may be made under this title, enter into contracts with quality improvement organizations pursuant to part B of title XI of this Act.

(2) In addition to any funds otherwise available, there are appropriated to the Secretary, out of any monies in the Treasury not otherwise obligated, $200,000,000, to remain available until expended, for purposes of requiring multiple organizations described in paragraph (1) to provide to skilled nursing facilities (as defined in section 1819(a)), infection control and vaccination uptake support relating to the prevention or mitigation of COVID–19, as determined appropriate by the Secretary.

(h)(1) The Secretary—

(A) shall waive the application of subsection (a)(22) in cases in which—

(i) there is no method available for the submission of claims in an electronic form; or

(ii) the entity submitting the claim is a small provider of services or supplier; and

(B) may waive the application of such subsection in such unusual cases as the Secretary finds appropriate.

(2) For purposes of this subsection, the term "small provider of services or supplier" means—

(A) a provider of services with fewer than 25 full-time equivalent employees; or

(B) a physician, practitioner, facility, or supplier (other than provider of services) with fewer than 10 full-time equivalent employees.

(i) In order to supplement the activities of the Medicare Payment Advisory Commission under section 1886(e) in assessing the safety, efficacy, and cost-effectiveness of new and existing medical proce-

dures, the Secretary may carry out, or award grants or contracts for, original research and experimentation of the type described in clause (ii) of section 1886(e)(6)(E) with respect to such a procedure if the Secretary finds that—

(1) such procedure is not of sufficient commercial value to justify research and experimentation by a commercial organization;

(2) research and experimentation with respect to such procedure is not of a type that may appropriately be carried out by an institute, division, or bureau of the National Institutes of Health; and

(3) such procedure has the potential to be more cost-effective in the treatment of a condition than procedures currently in use with respect to such condition.

(j)(1) Any advisory committee appointed to advise the Secretary on matters relating to the interpretation, application, or implementation of subsection (a)(1) shall assure the full participation of a nonvoting member in the deliberations of the advisory committee, and shall provide such nonvoting member access to all information and data made available to voting members of the advisory committee, other than information that—

(A) is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section (relating to trade secrets); or

(B) the Secretary determines would present a conflict of interest relating to such nonvoting member.

(2) If an advisory committee described in paragraph (1) organizes into panels of experts according to types of items or services considered by the advisory committee, any such panel of experts may report any recommendation with respect to such items or services directly to the Secretary without the prior approval of the advisory committee or an executive committee thereof.

(k)(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)) providing supplemental or secondary coverage to individuals also entitled to services under this title shall not require a medicare claims determination under this title for dental benefits specifically excluded under subsection (a)(12) as a condition of making a claims determination for such benefits under the group health plan.

(2) A group health plan may require a claims determination under this title in cases involving or appearing to involve inpatient dental hospital services or dental services expressly covered under this title pursuant to actions taken by the Secretary.

(l) NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS.—

(1) FACTORS AND EVIDENCE USED IN MAKING NATIONAL COVERAGE DETERMINATIONS.—The Secretary shall make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary shall develop guidance documents to carry out this paragraph in a manner similar to the development of guidance documents under section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)).

(2) TIMEFRAME FOR DECISIONS ON REQUESTS FOR NATIONAL COVERAGE DETERMINATIONS.—In the case of a request for a national coverage determination that—

(A) does not require a technology assessment from an outside entity or deliberation from the Medicare Coverage Advisory Committee, the decision on the request shall be made not later than 6 months after the date of the request; or

(B) requires such an assessment or deliberation and in which a clinical trial is not requested, the decision on the request shall be made not later than 9 months after the date of the request.

(3) PROCESS FOR PUBLIC COMMENT IN NATIONAL COVERAGE DETERMINATIONS.—

(A) PERIOD FOR PROPOSED DECISION.—Not later than the end of the 6-month period (or 9-month period for requests described in paragraph (2)(B)) that begins on the date a request for a national coverage determination is made, the Secretary shall make a draft of proposed decision on the request available to the public through the Internet website of the Centers for Medicare & Medicaid Services or other appropriate means.

(B) 30-DAY PERIOD FOR PUBLIC COMMENT.—Beginning on the date the Secretary makes a draft of the proposed decision available under subparagraph (A), the Secretary shall provide a 30-day period for public comment on such draft.

(C) 60-DAY PERIOD FOR FINAL DECISION.—Not later than 60 days after the conclusion of the 30-day period referred to under subparagraph (B), the Secretary shall—

(i) make a final decision on the request;

(ii) include in such final decision summaries of the public comments received and responses to such comments;

(iii) make available to the public the clinical evidence and other data used in making such a decision when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and

(iv) in the case of a final decision under clause (i) to grant the request for the national coverage determination, the Secretary shall assign a temporary or permanent code (whether existing or unclassified) and implement the coding change.

(4) CONSULTATION WITH OUTSIDE EXPERTS IN CERTAIN NATIONAL COVERAGE DETERMINATIONS.—With respect to a request for a national coverage determination for which there is not a review by the Medicare Coverage Advisory Committee, the Secretary shall consult with appropriate outside clinical experts.

(5) LOCAL COVERAGE DETERMINATION PROCESS.—

(A) PLAN TO PROMOTE CONSISTENCY OF COVERAGE DETERMINATIONS.—The Secretary shall develop a plan to evaluate new local coverage determinations to determine which determinations should be adopted nationally and to what extent greater consistency can be achieved among local coverage determinations.

(B) CONSULTATION.—The Secretary shall require the fiscal intermediaries or carriers providing services within the same area to consult on all new local coverage determinations within the area.

(C) DISSEMINATION OF INFORMATION.—The Secretary should serve as a center to disseminate information on local coverage determinations among fiscal intermediaries and carriers to reduce duplication of effort.

(D) LOCAL COVERAGE DETERMINATIONS.—The Secretary shall require each Medicare administrative contractor that develops a local coverage determination to make available on the Internet website of such contractor and on the Medicare Internet website, at least 45 days before the effective date of such determination, the following information:

(i) Such determination in its entirety.

(ii) Where and when the proposed determination was first made public.

(iii) Hyperlinks to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.

(iv) A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence.

(v) An explanation of the rationale that supports such determination.

(6) NATIONAL AND LOCAL COVERAGE DETERMINATION DEFINED.—For purposes of this subsection—

(A) NATIONAL COVERAGE DETERMINATION.—The term "national coverage determination" means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title.

(B) LOCAL COVERAGE DETERMINATION.—The term "local coverage determination" has the meaning given that in section 1869(f)(2)(B).

(m) COVERAGE OF ROUTINE COSTS ASSOCIATED WITH CERTAIN CLINICAL TRIALS OF CATEGORY A DEVICES.—

(1) IN GENERAL.—In the case of an individual entitled to benefits under part A, or enrolled under part B, or both who participates in a category A clinical trial, the Secretary shall not exclude under subsection (a)(1) payment for coverage of routine costs of care (as defined by the Secretary) furnished to such individual in the trial.

(2) CATEGORY A CLINICAL TRIAL.—For purposes of paragraph (1), a "category A clinical trial" means a trial of a medical device if—

(A) the trial is of an experimental/investigational (category A) medical device (as defined in regulations under section 405.201(b) of title 42, Code of Federal Regulations (as in effect as of September 1, 2003));

(B) the trial meets criteria established by the Secretary to ensure that the trial conforms to appropriate scientific and ethical standards; and

(C) in the case of a trial initiated before January 1, 2010, the device involved in the trial has been determined by the Secretary to be intended for use in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition.

(n) REQUIREMENT OF A SURETY BOND FOR CERTAIN PROVIDERS OF SERVICES AND SUPPLIERS.—

(1) IN GENERAL.—The Secretary may require a provider of services or supplier described in paragraph (2) to provide the Secretary on a continuing basis with a surety bond in a form specified by the Secretary in an amount (not less than $50,000) that the Secretary determines is commensurate with the volume of the billing of the provider of services or supplier. The Secretary may waive the requirement of a bond under the preceding sentence in the case of a provider of services or supplier that provides a comparable surety bond under State law.

(2) PROVIDER OF SERVICES OR SUPPLIER DESCRIBED.—A provider of services or supplier described in this paragraph is a provider of services or supplier the Secretary determines appropriate based on the level of risk involved with respect to the provider of services or supplier, and consistent with the surety bond requirements under sections 1834(a)(16)(B) and 1861(o)(7)(C).

(o) SUSPENSION OF PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD.—

(1) IN GENERAL.—The Secretary may suspend payments to a provider of services or supplier under this title pending an investigation of a credible allegation of fraud against the provider of services or supplier, unless the Secretary determines there is good cause not to suspend such payments.

(2) CONSULTATION.—The Secretary shall consult with the Inspector General of the Department of Health and Human Services in determining whether there is a credible allegation of fraud against a provider of services or supplier.

(3) PROMULGATION OF REGULATIONS.—The Secretary shall promulgate regulations to carry out this subsection, section 1860D–12(b)(7) (including as applied pursuant to section 1857(f)(3)(D)), and section 1903(i)(2)(C).

(4) CREDIBLE ALLEGATION OF FRAUD.—In carrying out this subsection, section 1860D–12(b)(7) (including as applied pursuant to section 1857(f)(3)(D)), and section 1903(i)(2)(C), a fraud hotline tip (as defined by the Secretary) without further evidence shall not be treated as sufficient evidence for a credible allegation of fraud.

* * * * * * *

○