116TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPT. 116–696
Part 1

PROTECTING ACCESS TO INFORMATION FOR EFFECTIVE AND NECESSARY TREATMENT AND SERVICES ACT

DECEMBER 24, 2020.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. NEAL, from the Committee on Ways and Means, submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 3439]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 3439) to amend the Internal Revenue Code of 1986 and title XI of the Social Security Act to extend appropriations and transfers to the Patient-Centered Outcomes Research Trust Fund and to extend certain health insurance fees for such transfers, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

CONTENTS

19–006

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 "Protecting Access To Information for Effective & Necessary Treatment and Services Act" or the "PATIENTS Act".

SEC. 2. EXTENDING APPROPRIATIONS AND TRANSFERS TO THE PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND; EXTENSION OF CERTAIN HEALTH INSURANCE FEES.

(a) IN GENERAL.—

(1) INTERNAL REVENUE CODE.—Section 9511 of the Internal Revenue Code of 1986 is amended—

(A) in subsection (b)(1)(E), by striking "2014" and all that follows through "2019" and inserting "2014 through 2026";

(B) in subsection (d)(2)(A), by striking "2019" and inserting "2026"; and

(C) in subsection (f), by striking "2019" and inserting "2026".

(2) TITLE XI OF THE SOCIAL SECURITY ACT.—Section 1183(a)(2) of the Social Security Act (42 U.S.C. 1320e–2(a)(2)) is amended by striking "2014" and all that follows through "2019" and inserting "2014 through 2026".

(b) EXTENSION OF CERTAIN HEALTH INSURANCE FEES.—

(1) HEALTH INSURANCE POLICIES.—Section 4375(e) of the Internal Revenue Code of 1986 is amended by striking "2019" and inserting "2026".

(2) SELF-INSURED HEALTH PLANS.—Section 4376(e) of the Internal Revenue Code of 1986 is amended by striking "2019" and inserting "2026".

(c) PCORI RESEARCH PRIORITIES.—Section 1181(d)(1)(A) of the Social Security Act (42 U.S.C. 1320e(d)(1)(A)) is amended by adding at the end the following new sentence: "Such national priorities shall include research with respect to substance use (including opioid use disorders), mental health, and maternal morbidity and mortality.".

I. SUMMARY AND BACKGROUND

A. PURPOSE AND SUMMARY

The bill, H.R. 3439, the "Protecting Access to Information for Effective and Necessary Treatment (PATIENT) Act of 2019," as amended and ordered reported by the Committee on Ways and Means on June 26, 2019, amends IRC Section 9511(b) (26 U.S.C. § 9511(b)) to appropriate $150 million and an amount equal to the net revenues received from the fees on health insurance policies and self-insured plans for each of FY2014 through FY2026 to the Patient-Centered Outcomes Research Trust Fund (PCORTF).

In addition, H.R. 3439 amends the Internal Revenue Code of 1986 and title XI of the Social Security Act to extend appropriations and transfers to the Patient-Centered Outcomes Research Trust Fund (PCORTF) and to extend certain health insurance fees for such transfers, and for other purposes.

H.R. 3439, the "Protecting Access to Information for Effective and Necessary Treatment (PATIENT) Act of 2019," was introduced by Representative Donald Beyer (D–VA) on June 24, 2019.

B. Background and Need for Legislation

The Patient Protection and Affordable Care Act (ACA) established the Patient-Centered Outcomes Research Institute (PCORI) as a nonpartisan, independent research institute to conduct comparative clinical effectiveness research to improve patient outcomes.[1] PCORI has funded hundreds of research studies focused on improving health outcomes for patients through a range of research questions, including in the areas of: disparities, chronic diseases, rare diseases, veterans' health, pain management, and opioid use.

Three principles guide the work undertaken at PCORI: (1) to increase the quantity, quality, and timeliness of usable, trustworthy comparative research information; (2) to accelerate the implementation and use of research evidence; and (3) to exert influence on research funded by others to make it more patient-centered and useful. To ensure research results that are responsive to concerns across the industry, PCORI develops research questions by engaging individuals and organizations who represent a broad range of stakeholders, including patients, caregivers, clinicians, delivery systems, payers and purchasers, researchers, and policymakers, and industry.

PCORI is guided by a Board of Governors, with members of the Board, including the Chair and Vice Chair, appointed by the Comptroller General of the United States. The Board also includes the Directors of the National Institutes of Health and of the Agency for Healthcare Research and Quality, or their designees, and 19 other members representing a range of stakeholder audiences.

From FY 2010 through FY 2018, PCORI funded $1.9 billion in comparative clinical effectiveness research.[2] Currently, funding for PCORI comes from the Patient-Centered Outcomes Research Trust Fund (PCOR Trust Fund), which runs out at the end of FY 2019.

C. Legislative History

Background

H.R. 3439 was introduced by Representative Donald Beyer (D–VA) on June 24, 2019, and was referred to the Committee on Ways and Means and additionally the Committee on Energy and Commerce.

Committee hearings

On June 4, 2019, the Committee on Ways and Means held a Member Day hearing to discuss the range of issues, concerns, and proposals among on-committee and off-committee members. Members heard from several colleagues on- and off-Committee on a number of topics with great relevance to conversations about research within America's health care system.

Representative Ben McAdams (D–UT) who spoke in favor of increased transparency across the health care industry, and purposeful efforts to empower patients and payers to examine the practices of drug manufacturers and pharmaceutical benefit managers. Rep. McAdams also noted how the ability to research pricing and cov-

[1] *About Us & Our Funding*, PCORI (June 2012, updated 2020), https://www.pcori.org/about-us/financials-and-reports/our-funding.cite.

[2] 2018 *Annual Report* PCORI at 3 (2018), https://www.pcori.org/sites/default/files/PCORI-Annual-Report-2018.pdf.

erage would eliminate Americans being vulnerable to unknown costs for a visit to an emergency room or for in-network services received during a hospitalization.

Representative Elissa Slotkin (D–MI) testified to support increased transparency and efficiency across the health care industry as two essential components of any successful strategy to improve access to care and reduce costs.

Representative David Schweikert (R–AZ), Committee Member, testified about a number of issues that are critical in efforts to improve rural health access and outcomes. Rep. Schweikert noted the need for Congress to prepare for future policymaking in an era where artificial intelligence can conduct a routine medical office visit and life-saving cures are available but likely cost prohibitive for the average American. He also asked Members to consider the impact of promoting research, as Congress did through the 21st Century CURES Act, on the nation's health care costs in the years ahead.

Representative Tom Reed (R–NY) championed an all-hands approach to combating the scourge of diabetes across the United States. Rep. Reed's testimony also highlighted his prior collaboration with the Committee on Energy and Commerce Chair, Representative Diana DeGette (D–CO), to incorporate funding for Type 1 diabetes research.

Representative Rodney Davis (R–IL) also testified during the Member Day hearing on June 4, 2019. In his testimony, Rep. Davis explained efforts to champion legislation that would provide additional resources to dedicate to research on pediatric cancer and other childhood diseases. The proposal would designate unused amounts from the Presidential Election Campaign Fund for pediatric cancer research.

On May 16, 2019, the Committee on Ways and Means held a hearing, "Overcoming Racial Disparities and Social Determinants in the Maternal Mortality Crisis," focusing on maternal health.

On January 17, 2018, the Committee on Ways and Means held a hearing, "The Opioid Crisis: The Current Landscape and CMS Actions to Prevent Opioid Misuse" to discuss federal actions around substance abuse disorders and the opioid crisis.

Committee action

The Committee on Ways and Means marked up H.R. 3439, the "Protecting Access to Information for Effective and Necessary Treatment (PATIENT) Act of 2019," on June 26, 2019, and ordered the bill, as amended, favorably reported with a quorum being present by recorded vote of 26 to 15.

II. EXPLANATION OF THE BILL

A. The Protecting Access to Information for Effective and Necessary Treatment (PATIENT) Act of 2019

CURRENT LAW [3]

Section 1181 of the Social Security Act (SSA) establishes the Patient-Centered Outcomes Research Institute (PCORI) which is re-

[3] All discussions of Current Law in this report refer to current law as of the date of the mark-up (*i.e.,* June 20, 2019) and do not reflect subsequent law changes.

sponsible for coordinating and supporting comparative clinical effectiveness research. PCORI has entered into contracts with federal agencies as well as with academic and private sector research entities for both the management of funding and conduct of research. Section 937 of the Public Health Service Act (PHSA) requires the Agency for Healthcare Research and Quality (AHRQ) to broadly disseminate research findings that are published by PCORI and other government-funded comparative effectiveness research entities.

Internal Revenue Code of 1986 (IRC) Section 9511 establishes the "Patient-Centered Outcomes Research Trust Fund" (PCORTF) to support the activities of PCORI and to fund activities under PHSA Section 937. It provides annual funding to the PCORTF over the period FY2010–FY2019 from the following three sources: (1) annual appropriations; (2) fees on health insurance and self-insured plans (IRC Secs. 4375–4377); and (3) transfers from the Medicare Hospital Insurance (HI) and Supplementary Medical Insurance (SMI) Trust Funds. SSA Section 1183 provides for the transfer of the required funds from the Medicare HI and SMI Trust Funds; transfers to PCORTF from the Medicare Trust Funds are calculated based on the number of individuals entitled to benefits under Medicare Part A or enrolled in Medicare Part B.

For each of FY2011 through FY2019, IRC Section 9511 requires 80% of the PCORTF funds to be made available to PCORI, and the remaining 20% of funds to be transferred to the Secretary of Health and Human Services (HHS Secretary) for carrying out PHSA Section 937. Of the total amount transferred to HHS, 80% is to be distributed to AHRQ, with the remainder going to the HHS Office of the Secretary.

REASONS FOR CHANGE

Effective upon enactment, the PCORI Trust Fund will be extended through FY 2026. The Fund will be sustained by extending certain health insurance fees enacted in the Affordable Care Act through FY 2026. PCORI's national research priorities will be extended to include substance use (including opioid use disorders), mental health, and maternal morbidity and mortality. The Committee believes PCORI continues the mission of the ACA by assisting patients in making informed health care decisions that improve health care delivery and patient outcomes. PCORI does this by producing evidence-based information from credible research, incorporating both patients and provider perspectives. Extending PCORI funding though FY 2026 will continue the effective creation of research to improve health care outcomes used by patients and other health care decision makers.

EXPLANATION OF PROVISIONS

Section 1: Short title

This Act may be cited as the "Protecting Access To Information for Effective and Necessary Treatment Act" or the "PATIENT Act."

Section 2: Extending Appropriations and transfers to the Patient-Centered Outcomes Research Trust Fund; Extension of certain health insurance fees

Effective upon enactment, the PATIENT Act extends funding for the Patient Centered Outcomes Research Institute (PCORI) by extending the PCORI Trust Fund through Fiscal Year (FY) 2026. The Fund will be sustained by extending certain health insurance fees enacted in the ACA, and PCORI's national research priorities will be extended to include substance use (including opioid use disorders), mental health, and maternal morbidity and mortality.

EFFECTIVE DATE

Section 2: Effective beginning on or after enactment.

III. VOTES OF THE COMMITTEE

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the vote of the Committee on Ways and Means in its consideration of H.R. 3439, the "Protecting Access to Information for Effective and Necessary Treatment (PATIENT) Act of 2019," on June 26, 2019.

VOTES ON AMENDMENTS

An amendment, which would make PCORI fully discretionary offered by Dr. Wenstrup was defeated by a roll call vote of 16 yeas to 24 nays. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal		X		Mr. Brady	X		
Mr. Lewis		X		Mr. Nunes	X		
Mr. Doggett		X		Mr. Buchanan	X		
Mr. Thompson		X		Mr. Smith	X		
Mr. Larson		X		Mr. Marchant	X		
Mr. Blumenauer		X		Mr. Reed	X		
Mr. Kind		X		Mr. Kelly	X		
Mr. Pascrell		X		Mr. Holding	X		
Mr. Davis		X		Mr. Smith	X		
Ms. Sanchez		X		Mr. Rice	X		
Mr. Higgins		X		Mr. Schweikert	X		
Ms. Sewell		X		Ms. Walorski			
Ms. DelBene		X		Mr. LaHood (IL)	X		
Ms. Chu (CA)				Mr. Wenstrup	X		
Ms. Moore		X		Mr. Arrington	X		
Mr. Kildee		X		Mr. Ferguson	X		
Mr. Boyle		X		Mr. Estes	X		
Mr. Beyer		X					
Mr. Evans		X					
Mr. Schneider		X					
Mr. Suozzi		X					
Mr. Panetta		X					
Ms. Murphy		X					
Mr. Gomez		X					
Mr. Horsford		X					

An amendment, which would eliminate fees assessed on health insurance issuers, including the fees collected to fund PCORI and the health insurer fee was offered by Mr. Holding was defeated by a roll call vote of 16 yeas to 24 nays. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal		X		Mr. Brady	X		
Mr. Lewis		X		Mr. Nunes	X		
Mr. Doggett		X		Mr. Buchanan	X		
Mr. Thompson		X		Mr. Smith	X		
Mr. Larson		X		Mr. Marchant	X		
Mr. Blumenauer		X		Mr. Reed	X		
Mr. Kind		X		Mr. Kelly	X		
Mr. Pascrell		X		Mr. Holding	X		
Mr. Davis		X		Mr. Smith	X		
Ms. Sanchez		X		Mr. Rice	X		
Mr. Higgins		X		Mr. Schweikert	X		
Ms. Sewell		X		Ms. Walorski			
Ms. DelBene		X		Mr. LaHood (IL)	X		
Ms. Chu (CA)		X		Mr. Wenstrup	X		
Ms. Moore		X		Mr. Arrington	X		
Mr. Kildee		X		Mr. Ferguson	X		
Mr. Boyle		X		Mr. Estes	X		
Mr. Beyer		X					
Mr. Evans		X					
Mr. Schneider		X					
Mr. Suozzi		X					
Mr. Panetta		X					
Ms. Murphy		X					
Mr. Gomez		X					
Mr. Horsford							

The Chairman's amendment in the nature of a substitute was agreed to by voice vote (with a quorum being present).

H.R. 3439 was ordered favorably reported to the House of Representatives as amended by an amendment in the nature of a substitute offered by Chairman Neal by a roll call vote of 26 yeas to 15 nays. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal	X			Mr. Brady		X	
Mr. Lewis	X			Mr. Nunes		X	
Mr. Doggett	X			Mr. Buchanan		X	
Mr. Thompson	X			Mr. Smith (NE)		X	
Mr. Larson	X			Mr. Marchant		X	
Mr. Blumenauer	X			Mr. Reed	X		
Mr. Kind	X			Mr. Kelly		X	
Mr. Pascrell	X			Mr. Holding		X	
Mr. Davis	X			Mr. Smith (MO)		X	
Ms. Sanchez	X			Mr. Rice		X	
Mr. Higgins	X			Mr. Schweikert		X	
Ms. Sewell	X			Ms. Walorski			
Ms. DelBene	X			Mr. LaHood		X	
Ms. Chu (CA)	X			Mr. Wenstrup		X	
Ms. Moore	X			Mr. Arrington		X	
Mr. Kildee	X			Mr. Ferguson		X	
Mr. Boyle	X			Mr. Estes		X	
Mr. Beyer	X						
Mr. Evans	X						
Mr. Schneider	X						
Mr. Suozzi	X						
Mr. Panetta	X						
Ms. Murphy	X						
Mr. Gomez	X						
Mr. Horsford	X						

IV. BUDGET EFFECTS OF THE BILL

A. COMMITTEE ESTIMATE OF BUDGETARY EFFECTS

In compliance with clause 3(d) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the effects on the budget of the bill, H.R. 3439, as reported. The Committee agrees with the estimate prepared by the Congressional Budget Office (CBO), which is included below.

B. STATEMENT REGARDING NEW BUDGET AUTHORITY AND TAX EXPENDITURES BUDGET AUTHORITY

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee states that the bill involves no new or increased budget authority. The Committee states further that the bill involves no new or increased tax expenditures.

C. COST ESTIMATE PREPARED BY THE CONGRESSIONAL BUDGET OFFICE

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, requiring a cost estimate prepared by the CBO, the following statement by CBO is provided.

U.S. CONGRESS,
CONGRESSONAL BUDGET OFFICE,
Washington, DC, September 12, 2019.

Hon. RICHARD NEAL,
Chairman, Committee on Ways and Means,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 3439, the PATIENTS Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Sarah Sajewski.

Sincerely,

PHILLIP L. SWAGEL,
Director.

Enclosure.

At a Glance

H.R. 3439, PATIENTS Act

As ordered reported by the House Committee on Ways and Means on June 26, 2019

By Fiscal Year, Millions of Dollars	2019	2019-2024	2019-2029
Direct Spending (Outlays)	0	3,680	5,410
Revenues	0	0	0
Deficit Effect	0	3,680	5,410
Spending Subject to Appropriation (Outlays)	0	0	0

		Mandate Effects	
Statutory pay-as-you-go procedures apply?	Yes	Contains intergovernmental mandate?	No
Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2030?	No	Contains private-sector mandate?	Yes, Over Threshold

The bill would

- Extend funding for the Patient-Centered Outcomes Research Trust Fund through 2026
- Impose a private-sector mandate by authorizing fees on health insurance policies

Estimated budgetary effects would primarily stem from

- Increased direct spending for the Patient-Centered Outcomes Research Trust Fund

Bill summary: H.R. 3439 would reauthorize transfers to the Patient Center Outcomes Research (PCOR) Trust Fund and collection of certain excise taxes charged to health insurance plans.

Estimated Federal cost: The estimated budgetary effect of H.R. 3439 is shown in Table 1. The costs of the legislation fall within budget functions 550 (health) and 570 (Medicare).

TABLE 1.—ESTIMATED BUDGETARY EFFECTS OF H.R. 3439

	By fiscal year, millions of dollars—												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2019–2024	2019–2029
Increases or Decreases (−) in Direct Spending [a]													
Estimated Budget Authority	0	670	700	740	770	800	840	890	0	0	0	3,680	5,410
Estimated Outlays	0	670	700	740	770	800	840	890	0	0	0	3,680	5,410

[a] H.R. 3439 also would extend authority to collect certain revenues that are already assumed to be collected in CBO's baseline.

Basis of estimate: CBO's estimate of the budgetary impact of H.R. 3439 is based on the amounts historically received by the PCOR Trust Fund and disbursed to the Patient-Centered Outcomes Research Institute (PCORI, a private entity) and the Secretary of Health and Human Services (HHS). For this estimate, CBO assumes H.R. 3439 will be enacted near the end of fiscal year 2019.

Background

Under current law, the PCOR Trust Fund is authorized to spend amounts transferred to the account each year; however, that transfer authority will, along with the authority to collect one of the sources of funding, expire on September 30, 2019. H.R. 3439 would extend through 2026 the authority to transfer funds from the Medicare trust funds and other specified mandatory appropriations. The bill also would extend authority to collect excise taxes on certain health insurance policies and to transfer those collections to the fund. The trust fund disburses those funds to PCORI and to the Secretary of HHS; those entities disseminate the funds to support related healthcare research including comparative clinical effectiveness research.

Direct Spending

CBO estimates that enacting H.R. 3439 would increase amounts transferred to the PCOR trust fund and subsequently spent by PCORI and HHS by $5.4 billion dollars over the 2019–2029 period.

Transfers from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medicare Insurance Trust Fund are calculated by taking a per-enrollee amount (set at $2.00 in FY 2014), indexing it by the percentage increase in the projected-per-capita amount of the National Health Expenditures ($2.57 in FY 2020), and then multiplying it by the average number of individ-

uals entitled to benefits under Medicare Part A or enrolled under Medicare Part B during a given fiscal year (about 62 million in FY 2020).

CBO estimates that the amount transferred to the fund and subsequently spent would total $160 million in fiscal year 2020 and $1.4 billion over the 2020–2029 period. That spending would be partially offset by an increase totaling about $0.2 billion in Part B premiums paid by Medicare enrollees. Part B premiums are set to maintain a contingency reserve of the trust funds, so changes in Part B spending trigger a partially offsetting adjustment in premiums.

The fund also would receive transfers of other mandatory appropriations totaling $150 million annually. CBO estimates the amount disbursed from those appropriated funds would total about $1.1 billion over the 2020–2029 period.

Finally, the fund would spend revenues from an excise tax imposed on health insurance policies. (See discussion below on collections of those revenues) CBO estimates that spending would total $3.2 billion over the 2020–2029 period.

Revenues

H.R. 3439 would extend, through 2026, the authority to collect certain excise taxes on health insurance policies that are currently scheduled to expire in 2019. CBO projects that those collections would total $4 billion over the 2020–2029 period. Only a portion of those amounts ($3.2 billion) would be available for spending, however, because the Secretary of the Treasury is required to transfer to the PCOR trust fund only those amounts estimated to exceed reductions in income taxes that would result from the excise tax's collection. (When certain types of taxes and fees are imposed on goods and services, taxable income for workers and business owners decline.[1])

Furthermore, because the excise taxes collected under H.R. 3439 would be dedicated to a trust fund, they are already included in CBO's baseline and are thus not credited to this bill. (The Balanced Budget and Emergency Deficit Control Act of 1985 requires CBO to assume in its baseline projections that excise taxes dedicated to trust funds, if expiring, are extended.)

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 subject to those pay-as-you-go procedures are shown in Table 1.

Increase in long-term deficits: CBO estimates that enacting H.R. 3439 would not increase on-budget deficits in any of the four consecutive 10-year periods beginning in 2030.

Mandates: JCT has determined that the tax provisions of H.R. 3439 would impose a private-sector mandate by extending fees on health insurance policies to fund transfers to the PCOR trust fund. The revenue from those fees are part of the CBO baseline because current law requires CBO to assume that excise taxes dedicated to a trust fund, if expiring, are extended. For private entities, how-

[1] For further information on how indirect taxes and fees may reduce collections for other taxes, See Congressional Budget Office, The Role of the 25 Percent Revenue Offset in Estimating the Budgetary Effects of Legislation (January 2009), www.cbo.gov/publication/20110.

ever, paying the fees would extend an expiring duty, which is a mandate as defined in the Unfunded Mandates Reform Act (UMRA). Based on information from JCT, CBO estimates that the cost of the mandate would average $530 million annually and would exceed the private sector threshold established in UMRA ($164 million in 2019, adjusted annually for inflation) in each of the first five years that the mandate is in effect.

CBO has determined that the non-tax provisions of H.R. 3439 would not impose a private-sector mandate as defined in UMRA. Neither the tax nor the non-tax provisions of the bill would impose intergovernmental mandates as defined in UMRA.

Estimate prepared by: Federal Costs: Sarah Sajewski; Revenues: Bayard Meiser, and the staff of the Joint Committee on Taxation; Mandates: Andrew Laughlin, and the staff of the Joint Committee on Taxation.

Estimate reviewed by: Tom Bradley, Chief, Health Systems and Medicare Cost Estimates Unit; Susan Willie, Chief, Mandates Unit; Leo Lex, Deputy Assistant Director for Budget Analysis; Theresa Gullo, Assistant Director for Budget Analysis; John McClelland, Assistant Director for Budget Analysis.

V. OTHER MATTERS TO BE DISCUSSED UNDER THE RULES OF THE HOUSE

A. Committee Oversight Findings and Recommendations

With respect to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the Committee made findings and recommendations that are reflected in this report.

B. Statement of General Performance Goals and Objectives

With respect to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee advises that the bill contains no measure that authorizes funding, so no statement of general performance goals and objectives for which any measure authorizes funding is required.

C. Information Relating to Unfunded Mandates

This information is provided in accordance with section 423 of the Unfunded Mandates Reform Act of 1995 (Pub. L. No. 104–4).

The Committee has determined that the bill does contain Federal mandates on the private sector through the collection of excise taxes on health insurance plans. The Committee has determined that the bill does not impose a Federal intergovernmental mandate on State, local, or tribal governments.

D. Congressional Earmarks, Limited Tax Benefits, and Limited Tariff Benefits

With respect to clause 9 of rule XXI of the Rules of the House of Representatives, the Committee has carefully reviewed the provisions of the bill, and states that the provisions of the bill do not contain any congressional earmarks, limited tax benefits, or limited tariff benefits within the meaning of the rule.

E. TAX COMPLEXITY ANALYSIS

Section 4022(b) of Public Law 105–206, the Internal Revenue Service Restructuring and Reform Act of 1998 (the "RRA"), requires the staff of the Joint Committee on Taxation (in consultation with the Internal Revenue Service and the Treasury Department) to provide a tax complexity analysis. The complexity analysis is required for all legislation reported by the Senate Committee on Finance, the House Committee on Ways and Means, or any committee of conference if the legislation includes a provision that directly or indirectly amends the Internal Revenue Code of 1986 and has widespread applicability to individuals or small businesses.

Pursuant to clause 3(h)(1) of rule XIII of the Rules of the House of Representatives, the staff of the Joint Committee on Taxation has determined that a complexity analysis is not required under section 4022(b) of the RRA because the bill contains no provision that amends the Internal Revenue Code of 1986 and has "widespread applicability" to individuals or small businesses within the meaning of the rule.

F. DUPLICATION OF FEDERAL PROGRAMS

In compliance with clause 3(c)(5) of rule XIII of the Rules of the House of Representatives, the Committee states that no provision of the bill establishes or reauthorizes: (1) a program of the Federal Government known to be duplicative of another Federal program; (2) a program included in any report to Congress pursuant to section 21 of Public Law 111–139; or (3) a program related to a program identified in the most recent Catalog of Federal Domestic Assistance, published pursuant section 6104 of title 31, United States Code.

G. HEARINGS

In compliance with Sec. 103(i) of H. Res. 6 (116th Congress) (1) the following hearing was used to develop or consider H.R. 3439:

On June 4, 2019, the Committee on Ways and Means held a full committee Member Day hearing to discuss the range of issues, concerns, and proposals among on-committee and off-committee members. Members heard from several colleagues on- and off-Committee about the importance of research in establishing policies that assist patients in making informed health care decisions that improves health care delivery and patient outcomes.

On May 16, 2019, the Committee on Ways and Means held a hearing, "Overcoming Racial Disparities and Social Determinants in the Maternal Mortality Crisis," focusing on maternal morbidity and mortality, as well as social determinants of health.

VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e)(1)(B) of rule XIII of the Rules of the House of Representatives, changes in existing law proposed by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

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 (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

INTERNAL REVENUE CODE OF 1986

* * * * * * *

Subtitle D—Miscellaneous Excise Taxes

* * * * * * *

CHAPTER 34—TAXES ON CERTAIN INSURANCE POLICIES

* * * * * * *

Subchapter B—INSURED AND SELF-INSURED HEALTH PLANS

* * * * * * *

SEC. 4375. HEALTH INSURANCE.

(a) IMPOSITION OF FEE.—There is hereby imposed on each specified health insurance policy for each policy year ending after September 30, 2012, a fee equal to the product of $2 ($1 in the case of policy years ending during fiscal year 2013) multiplied by the average number of lives covered under the policy.

(b) LIABILITY FOR FEE.—The fee imposed by subsection (a) shall be paid by the issuer of the policy.

(c) SPECIFIED HEALTH INSURANCE POLICY.—For purposes of this section:

(1) IN GENERAL.—Except as otherwise provided in this section, the term "specified health insurance policy" means any accident or health insurance policy (including a policy under a group health plan) issued with respect to individuals residing in the United States.

(2) EXEMPTION FOR CERTAIN POLICIES.—The term "specified health insurance policy" does not include any insurance if substantially all of its coverage is of excepted benefits described in section 9832(c).

(3) TREATMENT OF PREPAID HEALTH COVERAGE ARRANGEMENTS.—

(A) IN GENERAL.—In the case of any arrangement described in subparagraph (B), such arrangement shall be treated as a specified health insurance policy, and the person referred to in such subparagraph shall be treated as the issuer.

(B) DESCRIPTION OF ARRANGEMENTS.—An arrangement is described in this subparagraph if under such arrange-

ment fixed payments or premiums are received as consideration for any person's agreement to provide or arrange for the provision of accident or health coverage to residents of the United States, regardless of how such coverage is provided or arranged to be provided.

(d) ADJUSTMENTS FOR INCREASES IN HEALTH CARE SPENDING.—In the case of any policy year ending in any fiscal year beginning after September 30, 2014, the dollar amount in effect under subsection (a) for such policy year shall be equal to the sum of such dollar amount for policy years ending in the previous fiscal year (determined after the application of this subsection), plus an amount equal to the product of—

(1) such dollar amount for policy years ending in the previous fiscal year, multiplied by

(2) the percentage increase in the projected per capita amount of National Health Expenditures, as most recently published by the Secretary before the beginning of the fiscal year.

(e) TERMINATION.—This section shall not apply to policy years ending after September 30, [2019] *2026*.

SEC. 4376. SELF-INSURED HEALTH PLANS.

(a) IMPOSITION OF FEE.—In the case of any applicable self-insured health plan for each plan year ending after September 30, 2012, there is hereby imposed a fee equal to $2 ($1 in the case of plan years ending during fiscal year 2013) multiplied by the average number of lives covered under the plan.

(b) LIABILITY FOR FEE.—

(1) IN GENERAL.—The fee imposed by subsection (a) shall be paid by the plan sponsor.

(2) PLAN SPONSOR.—For purposes of paragraph (1) the term "plan sponsor" means—

(A) the employer in the case of a plan established or maintained by a single employer,

(B) the employee organization in the case of a plan established or maintained by an employee organization,

(C) in the case of—

(i) a plan established or maintained by 2 or more employers or jointly by 1 or more employers and 1 or more employee organizations,

(ii) a multiple employer welfare arrangement, or

(iii) a voluntary employees' beneficiary association described in section 501(c)(9), the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan, or

(D) the cooperative or association described in subsection (c)(2)(F) in the case of a plan established or maintained by such a cooperative or association.

(c) APPLICABLE SELF-INSURED HEALTH PLAN.—For purposes of this section, the term "applicable self-insured health plan" means any plan for providing accident or health coverage if—

(1) any portion of such coverage is provided other than through an insurance policy, and

(2) such plan is established or maintained—

(A) by 1 or more employers for the benefit of their employees or former employees,

(B) by 1 or more employee organizations for the benefit of their members or former members,

(C) jointly by 1 or more employers and 1 or more employee organizations for the benefit of employees or former employees,

(D) by a voluntary employees' beneficiary association described in section 501(c)(9),

(E) by any organization described in section 501(c)(6), or

(F) in the case of a plan not described in the preceding subparagraphs, by a multiple employer welfare arrangement (as defined in section 3(40) of Employee Retirement Income Security Act of 1974), a rural electric cooperative (as defined in section 3(40)(B)(iv) of such Act), or a rural telephone cooperative association (as defined in section 3(40)(B)(v) of such Act).

(d) ADJUSTMENTS FOR INCREASES IN HEALTH CARE SPENDING.—In the case of any plan year ending in any fiscal year beginning after September 30, 2014, the dollar amount in effect under subsection (a) for such plan year shall be equal to the sum of such dollar amount for plan years ending in the previous fiscal year (determined after the application of this subsection), plus an amount equal to the product of—

(1) such dollar amount for plan years ending in the previous fiscal year, multiplied by

(2) the percentage increase in the projected per capita amount of National Health Expenditures, as most recently published by the Secretary before the beginning of the fiscal year.

(e) TERMINATION.—This section shall not apply to plan years ending after September 30, [2019] *2026*.

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Subtitle I—Trust Fund Code

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CHAPTER 98—TRUST FUND CODE

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Subchapter A—ESTABLISHMENT OF TRUST FUNDS

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SEC. 9511. PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND.

(a) CREATION OF TRUST FUND.—There is established in the Treasury of the United States a trust fund to be known as the "Patient-Centered Outcomes Research Trust Fund" (hereafter in this section referred to as the "PCORTF"), consisting of such amounts as may be appropriated or credited to such Trust Fund as provided in this section and section 9602(b).

(b) TRANSFERS TO FUND.—

(1) APPROPRIATION.—There are hereby appropriated to the Trust Fund the following:

(A) For fiscal year 2010, $10,000,000.

(B) For fiscal year 2011, $50,000,000.

(C) For fiscal year 2012, $150,000,000.

(D) For fiscal year 2013—

(i) an amount equivalent to the net revenues received in the Treasury from the fees imposed under subchapter B of chapter 34 (relating to fees on health insurance and self-insured plans) for such fiscal year; and

(ii) $150,000,000.

(E) For each of fiscal years [2014, 2015, 2016, 2017, 2018, and 2019] *2014 through 2026*—

(i) an amount equivalent to the net revenues received in the Treasury from the fees imposed under subchapter B of chapter 34 (relating to fees on health insurance and self-insured plans) for such fiscal year; and

(ii) $150,000,000.

The amounts appropriated under subparagraphs (A), (B), (C), (D)(ii), and (E)(ii) shall be transferred from the general fund of the Treasury, from funds not otherwise appropriated.

(2) TRUST FUND TRANSFERS.—In addition to the amounts appropriated under paragraph (1), there shall be credited to the PCORTF the amounts transferred under section 1183 of the Social Security Act.

(3) LIMITATION ON TRANSFERS TO PCORTF.—No amount may be appropriated or transferred to the PCORTF on and after the date of any expenditure from the PCORTF which is not an expenditure permitted under this section. The determination of whether an expenditure is so permitted shall be made without regard to—

(A) any provision of law which is not contained or referenced in this chapter or in a revenue Act, and

(B) whether such provision of law is a subsequently enacted provision or directly or indirectly seeks to waive the application of this paragraph.

(c) TRUSTEE.—The Secretary of the Treasury shall be a trustee of the PCORTF.

(d) EXPENDITURES FROM FUND.—

(1) AMOUNTS AVAILABLE TO THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE.—Subject to paragraph (2), amounts in the PCORTF are available, without further appropriation, to the Patient-Centered Outcomes Research Institute established under section 1181(b) of the Social Security Act for carrying out part D of title XI of the Social Security Act (as in effect on the date of enactment of such Act).

(2) TRANSFER OF FUNDS.—

(A) IN GENERAL.—The trustee of the PCORTF shall provide for the transfer from the PCORTF of 20 percent of the amounts appropriated or credited to the PCORTF for each of fiscal years 2011 through [2019] *2026* to the Secretary

of Health and Human Services to carry out section 937 of the Public Health Service Act.

(B) AVAILABILITY.—Amounts transferred under subparagraph (A) shall remain available until expended.

(C) REQUIREMENTS.—Of the amounts transferred under subparagraph (A) with respect to a fiscal year, the Secretary of Health and Human Services shall distribute—

(i) 80 percent to the Office of Communication and Knowledge Transfer of the Agency for Healthcare Research and Quality (or any other relevant office designated by Agency for Healthcare Research and Quality) to carry out the activities described in section 937 of the Public Health Service Act; and

(ii) 20 percent to the Secretary to carry out the activities described in such section 937.

(e) NET REVENUES.—For purposes of this section, the term "net revenues" means the amount estimated by the Secretary of the Treasury based on the excess of—

(1) the fees received in the Treasury under subchapter B of chapter 34, over

(2) the decrease in the tax imposed by chapter 1 resulting from the fees imposed by such subchapter.

(f) TERMINATION.—No amounts shall be available for expenditure from the PCORTF after September 30, [2019] *2026*, and any amounts in such Trust Fund after such date shall be transferred to the general fund of the Treasury.

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SOCIAL SECURITY ACT

TITLE XI—GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

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PART D—COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

SEC. 1181. (a) DEFINITIONS.—In this section:

(1) BOARD.—The term "Board" means the Board of Governors established under subsection (f).

(2) COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH; RESEARCH.—

(A) IN GENERAL.—The terms "comparative clinical effectiveness research" and "research" mean research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items described in subparagraph (B).

(B) MEDICAL TREATMENTS, SERVICES, AND ITEMS DESCRIBED.—The medical treatments, services, and items described in this subparagraph are health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), integrative

health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.

(3) CONFLICT OF INTEREST.—The term "conflict of interest" means an association, including a financial or personal association, that have the potential to bias or have the appearance of biasing an individual's decisions in matters related to the Institute or the conduct of activities under this section.

(4) REAL CONFLICT OF INTEREST.—The term "real conflict of interest" means any instance where a member of the Board, the methodology committee established under subsection (d)(6), or an advisory panel appointed under subsection (d)(4), or a close relative of such member, has received or could receive either of the following:

(A) A direct financial benefit of any amount deriving from the result or findings of a study conducted under this section.

(B) A financial benefit from individuals or companies that own or manufacture medical treatments, services, or items to be studied under this section that in the aggregate exceeds $10,000 per year. For purposes of the preceding sentence, a financial benefit includes honoraria, fees, stock, or other financial benefit and the current value of the member or close relative's already existing stock holdings, in addition to any direct financial benefit deriving from the results or findings of a study conducted under this section.

(b) PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE.—

(1) ESTABLISHMENT.—There is authorized to be established a nonprofit corporation, to be known as the "Patient-Centered Outcomes Research Institute" (referred to in this section as the "Institute") which is neither an agency nor establishment of the United States Government.

(2) APPLICATION OF PROVISIONS.—The Institute shall be subject to the provisions of this section, and, to the extent consistent with this section, to the District of Columbia Nonprofit Corporation Act.

(3) FUNDING OF COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH.—For fiscal year 2010 and each subsequent fiscal year, amounts in the Patient-Centered Outcomes Research Trust Fund (referred to in this section as the "PCORTF") under section 9511 of the Internal Revenue Code of 1986 shall be available, without further appropriation, to the Institute to carry out this section.

(c) PURPOSE.—The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items described in subsection (a)(2)(B).

(d) DUTIES.—

(1) IDENTIFYING RESEARCH PRIORITIES AND ESTABLISHING RESEARCH PROJECT AGENDA.—

(A) IDENTIFYING RESEARCH PRIORITIES.—The Institute shall identify national priorities for research, taking into account factors of disease incidence, prevalence, and burden in the United States (with emphasis on chronic conditions), gaps in evidence in terms of clinical outcomes, practice variations and health disparities in terms of delivery and outcomes of care, the potential for new evidence to improve patient health, well-being, and the quality of care, the effect on national expenditures associated with a health care treatment, strategy, or health conditions, as well as patient needs, outcomes, and preferences, the relevance to patients and clinicians in making informed health decisions, and priorities in the National Strategy for quality care established under section 399H of the Public Health Service Act that are consistent with this section. *Such national priorities shall include research with respect to substance use (including opioid use disorders), mental health, and maternal morbidity and mortality.*

(B) ESTABLISHING RESEARCH PROJECT AGENDA.—The Institute shall establish and update a research project agenda for research to address the priorities identified under subparagraph (A), taking into consideration the types of research that might address each priority and the relative value (determined based on the cost of conducting research compared to the potential usefulness of the information produced by research) associated with the different types of research, and such other factors as the Institute determines appropriate.

(2) CARRYING OUT RESEARCH PROJECT AGENDA.—

(A) RESEARCH.—The Institute shall carry out the research project agenda established under paragraph (1)(B) in accordance with the methodological standards adopted under paragraph (9) using methods, including the following:

(i) Systematic reviews and assessments of existing and future research and evidence including original research conducted subsequent to the date of the enactment of this section.

(ii) Primary research, such as randomized clinical trials, molecularly informed trials, and observational studies.

(iii) Any other methodologies recommended by the methodology committee established under paragraph (6) that are adopted by the Board under paragraph (9).

(B) CONTRACTS FOR THE MANAGEMENT OF FUNDING AND CONDUCT OF RESEARCH.—

(i) CONTRACTS.—

(I) IN GENERAL.—In accordance with the research project agenda established under paragraph (1)(B), the Institute shall enter into contracts for the management of funding and conduct of research in accordance with the following:

(aa) Appropriate agencies and instrumentalities of the Federal Government.

(bb) Appropriate academic research, private sector research, or study-conducting entities.

(II) PREFERENCE.—In entering into contracts under subclause (I), the Institute shall give preference to the Agency for Healthcare Research and Quality and the National Institutes of Health, but only if the research to be conducted or managed under such contract is authorized by the governing statutes of such Agency or Institutes.

(ii) CONDITIONS FOR CONTRACTS.—A contract entered into under this subparagraph shall require that the agency, instrumentality, or other entity—

(I) abide by the transparency and conflicts of interest requirements under subsection (h) that apply to the Institute with respect to the research managed or conducted under such contract;

(II) comply with the methodological standards adopted under paragraph (9) with respect to such research;

(III) consult with the expert advisory panels for clinical trials and rare disease appointed under clauses (ii) and (iii), respectively, of paragraph (4)(A);

(IV) subject to clause (iv), permit a researcher who conducts original research, as described in subparagraph (A)(ii), under the contract for the agency, instrumentality, or other entity to have such research published in a peer-reviewed journal or other publication, as long as the researcher enters into a data use agreement with the Institute for use of the data from the original research, as appropriate;

(V) have appropriate processes in place to manage data privacy and meet ethical standards for the research;

(VI) comply with the requirements of the Institute for making the information available to the public under paragraph (8); and

(VII) comply with other terms and conditions determined necessary by the Institute to carry out the research agenda adopted under paragraph (2).

(iii) COVERAGE OF COPAYMENTS OR COINSURANCE.—A contract entered into under this subparagraph may allow for the coverage of copayments or coinsurance, or allow for other appropriate measures, to the extent that such coverage or other measures are necessary to preserve the validity of a research project, such as in the case where the research project must be blinded.

(iv) SUBSEQUENT USE OF THE DATA.—The Institute shall not allow the subsequent use of data from original research in work-for-hire contracts with individuals, entities, or instrumentalities that have a finan-

cial interest in the results, unless approved under a data use agreement with the Institute.

(C) REVIEW AND UPDATE OF EVIDENCE.—The Institute shall review and update evidence on a periodic basis as appropriate.

(D) TAKING INTO ACCOUNT POTENTIAL DIFFERENCES.—Research shall be designed, as appropriate, to take into account the potential for differences in the effectiveness of health care treatments, services, and items as used with various subpopulations, such as racial and ethnic minorities, women, age, and groups of individuals with different comorbidities, genetic and molecular sub-types, or quality of life preferences and include members of such subpopulations as subjects in the research as feasible and appropriate.

(E) DIFFERENCES IN TREATMENT MODALITIES.—Research shall be designed, as appropriate, to take into account different characteristics of treatment modalities that may affect research outcomes, such as the phase of the treatment modality in the innovation cycle and the impact of the skill of the operator of the treatment modality.

(3) DATA COLLECTION.—

(A) IN GENERAL.—The Secretary shall, with appropriate safeguards for privacy, make available to the Institute such data collected by the Centers for Medicare & Medicaid Services under the programs under titles XVIII, XIX, and XXI, as well as provide access to the data networks developed under section 937(f) of the Public Health Service Act, as the Institute and its contractors may require to carry out this section. The Institute may also request and obtain data from Federal, State, or private entities, including data from clinical databases and registries.

(B) USE OF DATA.—The Institute shall only use data provided to the Institute under subparagraph (A) in accordance with laws and regulations governing the release and use of such data, including applicable confidentiality and privacy standards.

(4) APPOINTING EXPERT ADVISORY PANELS.—

(A) APPOINTMENT.—

(i) IN GENERAL.—The Institute may appoint permanent or ad hoc expert advisory panels as determined appropriate to assist in identifying research priorities and establishing the research project agenda under paragraph (1) and for other purposes.

(ii) EXPERT ADVISORY PANELS FOR CLINICAL TRIALS.—The Institute shall appoint expert advisory panels in carrying out randomized clinical trials under the research project agenda under paragraph (2)(A)(ii). Such expert advisory panels shall advise the Institute and the agency, instrumentality, or entity conducting the research on the research question involved and the research design or protocol, including important patient subgroups and other parameters of the research. Such panels shall be available as a resource for technical

questions that may arise during the conduct of such research.

(iii) EXPERT ADVISORY PANEL FOR RARE DISEASE.—In the case of a research study for rare disease, the Institute shall appoint an expert advisory panel for purposes of assisting in the design of the research study and determining the relative value and feasibility of conducting the research study.

(B) COMPOSITION.—An expert advisory panel appointed under subparagraph (A) shall include representatives of practicing and research clinicians, patients, and experts in scientific and health services research, health services delivery, and evidence-based medicine who have experience in the relevant topic, and as appropriate, experts in integrative health and primary prevention strategies. The Institute may include a technical expert of each manufacturer or each medical technology that is included under the relevant topic, project, or category for which the panel is established.

(5) SUPPORTING PATIENT AND CONSUMER REPRESENTATIVES.—The Institute shall provide support and resources to help patient and consumer representatives effectively participate on the Board and expert advisory panels appointed by the Institute under paragraph (4).

(6) ESTABLISHING METHODOLOGY COMMITTEE.—

(A) IN GENERAL.—The Institute shall establish a standing methodology committee to carry out the functions described in subparagraph (C).

(B) APPOINTMENT AND COMPOSITION.—The methodology committee established under subparagraph (A) shall be composed of not more than 15 members appointed by the Comptroller General of the United States. Members appointed to the methodology committee shall be experts in their scientific field, such as health services research, clinical research, comparative clinical effectiveness research, biostatistics, genomics, and research methodologies. Stakeholders with such expertise may be appointed to the methodology committee. In addition to the members appointed under the first sentence, the Directors of the National Institutes of Health and the Agency for Healthcare Research and Quality (or their designees) shall each be included as members of the methodology committee.

(C) FUNCTIONS.—Subject to subparagraph (D), the methodology committee shall work to develop and improve the science and methods of comparative clinical effectiveness research by, not later than 18 months after the establishment of the Institute, directly or through subcontract, developing and periodically updating the following:

(i) Methodological standards for research. Such methodological standards shall provide specific criteria for internal validity, generalizability, feasibility, and timeliness of research and for health outcomes measures, risk adjustment, and other relevant aspects of research and assessment with respect to the design of research. Any methodological standards developed and

updated under this subclause shall be scientifically based and include methods by which new information, data, or advances in technology are considered and incorporated into ongoing research projects by the Institute, as appropriate. The process for developing and updating such standards shall include input from relevant experts, stakeholders, and decisionmakers, and shall provide opportunities for public comment. Such standards shall also include methods by which patient subpopulations can be accounted for and evaluated in different types of research. As appropriate, such standards shall build on existing work on methodological standards for defined categories of health interventions and for each of the major categories of comparative clinical effectiveness research methods (determined as of the date of enactment of the Patient Protection and Affordable Care Act).

(ii) A translation table that is designed to provide guidance and act as a reference for the Board to determine research methods that are most likely to address each specific research question.

(D) CONSULTATION AND CONDUCT OF EXAMINATIONS.—The methodology committee may consult and contract with the Institute of Medicine of the National Academies and academic, nonprofit, or other private and governmental entities with relevant expertise to carry out activities described in subparagraph (C) and may consult with relevant stakeholders to carry out such activities.

(E) REPORTS.—The methodology committee shall submit reports to the Board on the committee's performance of the functions described in subparagraph (C). Reports shall contain recommendations for the Institute to adopt methodological standards developed and updated by the methodology committee as well as other actions deemed necessary to comply with such methodological standards.

(7) PROVIDING FOR A PEER-REVIEW PROCESS FOR PRIMARY RESEARCH.—

(A) IN GENERAL.—The Institute shall ensure that there is a process for peer review of primary research described in subparagraph (A)(ii) of paragraph (2) that is conducted under such paragraph. Under such process—

(i) evidence from such primary research shall be reviewed to assess scientific integrity and adherence to methodological standards adopted under paragraph (9); and

(ii) a list of the names of individuals contributing to any peer-review process during the preceding year or years shall be made public and included in annual reports in accordance with paragraph (10)(D).

(B) COMPOSITION.—Such peer-review process shall be designed in a manner so as to avoid bias and conflicts of interest on the part of the reviewers and shall be composed of experts in the scientific field relevant to the research under review.

(C) USE OF EXISTING PROCESSES.—

(i) PROCESSES OF ANOTHER ENTITY.—In the case where the Institute enters into a contract or other agreement with another entity for the conduct or management of research under this section, the Institute may utilize the peer-review process of such entity if such process meets the requirements under subparagraphs (A) and (B).

(ii) PROCESSES OF APPROPRIATE MEDICAL JOURNALS.—The Institute may utilize the peer-review process of appropriate medical journals if such process meets the requirements under subparagraphs (A) and (B).

(8) RELEASE OF RESEARCH FINDINGS.—

(A) IN GENERAL.—The Institute shall, not later than 90 days after the conduct or receipt of research findings under this part, make such research findings available to clinicians, patients, and the general public. The Institute shall ensure that the research findings—

(i) convey the findings of research in a manner that is comprehensible and useful to patients and providers in making health care decisions;

(ii) fully convey findings and discuss considerations specific to certain subpopulations, risk factors, and comorbidities, as appropriate;

(iii) include limitations of the research and what further research may be needed as appropriate;

(iv) do not include practice guidelines, coverage recommendations, payment, or policy recommendations; and

(v) not include any data which would violate the privacy of research participants or any confidentiality agreements made with respect to the use of data under this section.

(B) DEFINITION OF RESEARCH FINDINGS.—In this paragraph, the term "research findings" means the results of a study or assessment.

(9) ADOPTION.—Subject to subsection (h)(1), the Institute shall adopt the national priorities identified under paragraph (1)(A), the research project agenda established under paragraph (1)(B), the methodological standards developed and updated by the methodology committee under paragraph (6)(C)(i), and any peer-review process provided under paragraph (7) by majority vote. In the case where the Institute does not adopt such processes in accordance with the preceding sentence, the processes shall be referred to the appropriate staff or entity within the Institute (or, in the case of the methodological standards, the methodology committee) for further review.

(10) ANNUAL REPORTS.—The Institute shall submit an annual report to Congress and the President, and shall make the annual report available to the public. Such report shall contain—

(A) a description of the activities conducted under this section, research priorities identified under paragraph (1)(A) and methodological standards developed and updated by the methodology committee under paragraph

(6)(C)(i) that are adopted under paragraph (9) during the preceding year;

(B) the research project agenda and budget of the Institute for the following year;

(C) any administrative activities conducted by the Institute during the preceding year;

(D) the names of individuals contributing to any peer-review process under paragraph (7), without identifying them with a particular research project; and

(E) any other relevant information (including information on the membership of the Board, expert advisory panels, methodology committee, and the executive staff of the Institute, any conflicts of interest with respect to these individuals, and any bylaws adopted by the Board during the preceding year).

(e) ADMINISTRATION.—

(1) IN GENERAL.—Subject to paragraph (2), the Board shall carry out the duties of the Institute.

(2) NONDELEGABLE DUTIES.—The activities described in subsections (d)(1) and (d)(9) are nondelegable.

(f) BOARD OF GOVERNORS.—

(1) IN GENERAL.—The Institute shall have a Board of Governors, which shall consist of the following members:

(A) The Director of Agency for Healthcare Research and Quality (or the Director's designee).

(B) The Director of the National Institutes of Health (or the Director's designee).

(C) Seventeen members appointed, not later than 6 months after the date of enactment of this section, by the Comptroller General of the United States as follows:

(i) 3 members representing patients and health care consumers.

(ii) 7 members representing physicians and providers, including 4 members representing physicians (at least 1 of whom is a surgeon), 1 nurse, 1 State-licensed integrative health care practitioner, and 1 representative of a hospital.

(iii) 3 members representing private payers, of whom at least 1 member shall represent health insurance issuers and at least 1 member shall represent employers who self-insure employee benefits.

(iv) 3 members representing pharmaceutical, device, and diagnostic manufacturers or developers.

(v) 1 member representing quality improvement or independent health service researchers.

(vi) 2 members representing the Federal Government or the States, including at least 1 member representing a Federal health program or agency.

(2) QUALIFICATIONS.—The Board shall represent a broad range of perspectives and collectively have scientific expertise in clinical health sciences research, including epidemiology, decisions sciences, health economics, and statistics. In appointing the Board, the Comptroller General of the United States shall consider and disclose any conflicts of interest in accordance with subsection (h)(4)(B). Members of the Board shall be

recused from relevant Institute activities in the case where the member (or an immediate family member of such member) has a real conflict of interest directly related to the research project or the matter that could affect or be affected by such participation.

(3) TERMS; VACANCIES.—A member of the Board shall be appointed for a term of 6 years, except with respect to the members first appointed, whose terms of appointment shall be staggered evenly over 2-year increments. No individual shall be appointed to the Board for more than 2 terms. Vacancies shall be filled in the same manner as the original appointment was made.

(4) CHAIRPERSON AND VICE-CHAIRPERSON.—The Comptroller General of the United States shall designate a Chairperson and Vice Chairperson of the Board from among the members of the Board. Such members shall serve as Chairperson or Vice Chairperson for a period of 3 years.

(5) COMPENSATION.—Each member of the Board who is not an officer or employee of the Federal Government shall be entitled to compensation (equivalent to the rate provided for level IV of the Executive Schedule under section 5315 of title 5, United States Code) and expenses incurred while performing the duties of the Board. An officer or employee of the Federal government who is a member of the Board shall be exempt from compensation.

(6) DIRECTOR AND STAFF; EXPERTS AND CONSULTANTS.—The Board may employ and fix the compensation of an Executive Director and such other personnel as may be necessary to carry out the duties of the Institute and may seek such assistance and support of, or contract with, experts and consultants that may be necessary for the performance of the duties of the Institute.

(7) MEETINGS AND HEARINGS.—The Board shall meet and hold hearings at the call of the Chairperson or a majority of its members. Meetings not solely concerning matters of personnel shall be advertised at least 7 days in advance and open to the public. A majority of the Board members shall constitute a quorum, but a lesser number of members may meet and hold hearings.

(g) FINANCIAL AND GOVERNMENTAL OVERSIGHT.—

(1) CONTRACT FOR AUDIT.—The Institute shall provide for the conduct of financial audits of the Institute on an annual basis by a private entity with expertise in conducting financial audits.

(2) REVIEW AND ANNUAL REPORTS.—

(A) REVIEW.—The Comptroller General of the United States shall review the following:

(i) Not less frequently than on an annual basis, the financial audits conducted under paragraph (1).

(ii) Not less frequently than every 5 years, the processes established by the Institute, including the research priorities and the conduct of research projects, in order to determine whether information produced by such research projects is objective and credible, is produced in a manner consistent with the require-

ments under this section, and is developed through a transparent process.

(iii) Not less frequently than every 5 years, the dissemination and training activities and data networks established under section 937 of the Public Health Service Act, including the methods and products used to disseminate research, the types of training conducted and supported, and the types and functions of the data networks established, in order to determine whether the activities and data are produced in a manner consistent with the requirements under such section.

(iv) Not less frequently than every 5 years, the overall effectiveness of activities conducted under this section and the dissemination, training, and capacity building activities conducted under section 937 of the Public Health Service Act. Such review shall include an analysis of the extent to which research findings are used by health care decision-makers, the effect of the dissemination of such findings on reducing practice variation and disparities in health care, and the effect of the research conducted and disseminated on innovation and the health care economy of the United States.

(v) Not later than 8 years after the date of enactment of this section, the adequacy and use of the funding for the Institute and the activities conducted under section 937 of the Public Health Service Act, including a determination as to whether, based on the utilization of research findings by public and private payers, funding sources for the Patient-Centered Outcomes Research Trust Fund under section 9511 of the Internal Revenue Code of 1986 are appropriate and whether such sources of funding should be continued or adjusted.

(B) ANNUAL REPORTS.—Not later than April 1 of each year, the Comptroller General of the United States shall submit to Congress a report containing the results of the review conducted under subparagraph (A) with respect to the preceding year (or years, if applicable), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

(h) ENSURING TRANSPARENCY, CREDIBILITY, AND ACCESS.—The Institute shall establish procedures to ensure that the following requirements for ensuring transparency, credibility, and access are met:

(1) PUBLIC COMMENT PERIODS.—The Institute shall provide for a public comment period of not less than 45 days and not more than 60 days prior to the adoption under subsection (d)(9) of the national priorities identified under subsection (d)(1)(A), the research project agenda established under subsection (d)(1)(B), the methodological standards developed and updated by the methodology committee under subsection (d)(6)(C)(i), and the peer-review process provided under paragraph (7), and

after the release of draft findings with respect to systematic reviews of existing research and evidence.

(2) ADDITIONAL FORUMS.—The Institute shall support forums to increase public awareness and obtain and incorporate public input and feedback through media (such as an Internet website) on research priorities, research findings, and other duties, activities, or processes the Institute determines appropriate.

(3) PUBLIC AVAILABILITY.—The Institute shall make available to the public and disclose through the official public Internet website of the Institute the following:

(A) Information contained in research findings as specified in subsection (d)(9).

(B) The process and methods for the conduct of research, including the identity of the entity and the investigators conducing such research and any conflicts of interests of such parties, any direct or indirect links the entity has to industry, and research protocols, including measures taken, methods of research and analysis, research results, and such other information the Institute determines appropriate) concurrent with the release of research findings.

(C) Notice of public comment periods under paragraph (1), including deadlines for public comments.

(D) Subsequent comments received during each of the public comment periods.

(E) In accordance with applicable laws and processes and as the Institute determines appropriate, proceedings of the Institute.

(4) DISCLOSURE OF CONFLICTS OF INTEREST.—

(A) IN GENERAL.—A conflict of interest shall be disclosed in the following manner:

(i) By the Institute in appointing members to an expert advisory panel under subsection (d)(4), in selecting individuals to contribute to any peer-review process under subsection (d)(7), and for employment as executive staff of the Institute.

(ii) By the Comptroller General in appointing members of the methodology committee under subsection (d)(6);

(iii) By the Institute in the annual report under subsection (d)(10), except that, in the case of individuals contributing to any such peer review process, such description shall be in a manner such that those individuals cannot be identified with a particular research project.

(B) MANNER OF DISCLOSURE.—Conflicts of interest shall be disclosed as described in subparagraph (A) as soon as practicable on the Internet web site of the Institute and of the Government Accountability Office. The information disclosed under the preceding sentence shall include the type, nature, and magnitude of the interests of the individual involved, except to the extent that the individual recuses himself or herself from participating in the consideration of or any other activity with respect to the study as to which the potential conflict exists.

(i) RULES.—The Institute, its Board or staff, shall be prohibited from accepting gifts, bequeaths, or donations of services or property. In addition, the Institute shall be prohibited from establishing a corporation or generating revenues from activities other than as provided under this section.

(j) RULES OF CONSTRUCTION.—

(1) COVERAGE.—Nothing in this section shall be construed—

(A) to permit the Institute to mandate coverage, reimbursement, or other policies for any public or private payer; or

(B) as preventing the Secretary from covering the routine costs of clinical care received by an individual entitled to, or enrolled for, benefits under title XVIII, XIX, or XXI in the case where such individual is participating in a clinical trial and such costs would otherwise be covered under such title with respect to the beneficiary.

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TRUST FUND TRANSFERS TO PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND

SEC. 1183. (a) IN GENERAL.—The Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841, in proportion (as estimated by the Secretary) to the total expenditures during such fiscal year that are made under title XVIII from the respective trust fund, to the Patient-Centered Outcomes Research Trust Fund (referred to in this section as the "PCORTF") under section 9511 of the Internal Revenue Code of 1986, of the following:

(1) For fiscal year 2013, an amount equal to $1 multiplied by the average number of individuals entitled to benefits under part A, or enrolled under part B, of title XVIII during such fiscal year.

(2) For each of fiscal years [2014, 2015, 2016, 2017, 2018, and 2019] *2014 through 2026*, an amount equal to $2 multiplied by the average number of individuals entitled to benefits under part A, or enrolled under part B, of title XVIII during such fiscal year.

(b) ADJUSTMENTS FOR INCREASES IN HEALTH CARE SPENDING.—In the case of any fiscal year beginning after September 30, 2014, the dollar amount in effect under subsection (a)(2) for such fiscal year shall be equal to the sum of such dollar amount for the previous fiscal year (determined after the application of this subsection), plus an amount equal to the product of—

(1) such dollar amount for the previous fiscal year, multiplied by

(2) the percentage increase in the projected per capita amount of National Health Expenditures, as most recently published by the Secretary before the beginning of the fiscal year.

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VII. DISSENTING VIEWS

H.R. 3439, introduced by Representative Beyer (D–VA), amends the Internal Revenue Code of 1986 and Title XI of the Social Security Act to extend appropriations and transfers to the Patient-Centered Outcomes Research Trust Fund and to extend certain health insurance fees for such transfers through fiscal year 2026.

Comparative effectiveness research—research that helps to inform patients and providers of the risks and benefits of different treatment options—has value. But like the National Institutes of Health and the Agency for Healthcare Research and Quality, the Patient-Centered Outcomes Research Institute (PCORI) should be funded primarily by discretionary funding that is subject to annual appropriations. H.R. 3439 adds over $2.8 billion in new taxes on private health insurance. Americans who choose consumer-based savings vehicles, like a flexible savings account, pay PCORI's tax on insurance twice. It also raids $1.3 billion from the Medicare Part A and Part B trust funds. The Medicare Part A trust fund is projected to be exhausted by 2026.

Total spending from PCORI's trust fund has totaled $4 billion since its inception. Some of the spending has not been focused on comparative effectiveness research. In FY 2018, for every study on comparative effectiveness research, it approved nearly two "engagement awards." It gave half a million dollars back to the insurance industry's lobbying group to "build and maintain support from health plan leaders" and to "identify important gaps in availability of health insurance administrative data." It also spent over $19.5 million on "engagement award conferences." It even gave $25,000 to the pharmaceutical trade association's foundation to throw a conference.

Again, PCORI is undoubtedly engaging in some valuable work. But this program can continue to do so with discretionary funding. Congressional oversight is critical to oversee the millions of taxpayer dollars being spent on this program each year. Discretionary funding will ensure that Congressional oversight occurs on an annual basis.

Republicans offered two amendments to H.R. 3439. The first, offered by Representative Brad Wenstrup (R–OH), reauthorized PCORI for five years and made it fully discretionary. The second, offered by Representative George Holding (R–NC), eliminated fees assessed on health insurance issuers. Such "fees"—or taxes—includes the fees collected to fund PCORI and the health insurer tax, which is a more than $160 billion tax hike over the next decade that will increase the average individual market premium by more than $200.

Both commonsense amendments were rejected by Democrats and not adopted. The first amendment, offered by Representative Brad Wenstrup (R–OH), failed by a roll call vote of 16 yeas to 24 nays.

The second amendment, offered by Representative Holding (R–NC), failed by a roll call vote of 16 yeas to 24 nays.

KEVIN BRADY,
Ranking Member, Committee on Ways and Means.

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