COMBATING OPIOID ABUSE FOR CARE IN HOSPITALS ACT OF 2018

June 19, 2018.—Committed to the Committee of the Whole House on the State of the Union and Ordered to be printed

Mr. Brady of Texas, from the Committee on Ways and Means, submitted the following

REPORT

[To accompany H.R. 5774]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 5774) to require the Secretary of Health and Human Services to develop guidance on pain management and opioid use disorder prevention for hospitals receiving payment under part A of the Medicare program, provide for opioid quality measures development, and provide for a technical expert panel on reducing surgical setting opioid use and data collection on perioperative opioid use, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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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 "Combating Opioid Abuse for Care in Hospitals Act of 2018" or the "COACH Act of 2018".

SEC. 2. DEVELOPING GUIDANCE ON PAIN MANAGEMENT AND OPIOID USE DISORDER PRE-VENTION FOR HOSPITALS RECEIVING PAYMENT UNDER PART A OF THE MEDI-CARE PROGRAM.

- (a) IN GENERAL.—Not later than January 1, 2019, the Secretary of Health and Human Services (in this section referred to as the "Secretary") shall develop and publish on the public website of the Centers for Medicare & Medicaid Services guidance for hospitals receiving payment under part A of title XVIII of the Social Security Act (42 U.S.C. 1395c et seq.) on pain management strategies and opioid use disorder prevention strategies with respect to individuals entitled to benefits under such part.
- (b) CONSULTATION.—In developing the guidance described in subsection (a), the Secretary shall consult with relevant stakeholders, including—

(1) medical professional organizations;

- (2) providers and suppliers of services (as such terms are defined in section 1861 of the Social Security Act (42 U.S.C. 1395x));
 - (3) health care consumers or groups representing such consumers; and

(4) other entities determined appropriate by the Secretary.

- (c) CONTENTS.—The guidance described in subsection (a) shall include, with respect to hospitals and individuals described in such subsection, the following:
 - (1) Best practices regarding evidence-based screening and practitioner education initiatives relating to screening and treatment protocols for opioid use disorder, including—
 - (A) methods to identify such individuals at-risk of opioid use disorder, including risk stratification;

(B) ways to prevent, recognize, and treat opioid overdoses; and

(C) resources available to such individuals, such as opioid treatment programs, peer support groups, and other recovery programs.

- (2) Best practices for such hospitals to educate practitioners furnishing items and services at such hospital with respect to pain management and substance use disorders, including education on—
 - (A) the adverse effects of prolonged opioid use;
 - (B) non-opioid, evidence-based, non-pharmacological pain management treatments;
 - (C) monitoring programs for individuals who have been prescribed opioids; and
- (D) the prescribing of naloxone along with an initial opioid prescription.
 (3) Best practices for such hospitals to make such individuals aware of the risks associated with opioid use (which may include use of the notification template described in paragraph (4)).

(4) A notification template developed by the Secretary, for use as appropriate, for such individuals who are prescribed an opioid that—

- (A) explains the risks and side effects associated with opioid use (including the risks of addiction and overdose) and the importance of adhering to the prescribed treatment regimen, avoiding medications that may have an adverse interaction with such opioid, and storing such opioid safely and securely:
- (B) highlights multimodal and evidence-based non-opioid alternatives for pain management;
- (C) encourages such individuals to talk to their health care providers about such alternatives;

(D) provides for a method (through signature or otherwise) for such an individual, or person acting on such individual's behalf, to acknowledge receipt of such notification template;

(E) is worded in an easily understandable manner and made available in

multiple languages determined appropriate by the Secretary; and

(F) includes any other information determined appropriate by the Sec-

(5) Best practices for such hospital to track opioid prescribing trends by prac-

titioners furnishing items and services at such hospital, including-

(A) ways for such hospital to establish target levels, taking into account the specialties of such practitioners and the geographic area in which such hospital is located, with respect to opioids prescribed by such practitioners;

(B) guidance on checking the medical records of such individuals against

information included in prescription drug monitoring programs;

(C) strategies to reduce long-term opioid prescriptions; and

(D) methods to identify such practitioners who may be over-prescribing opioids.

(6) Other information the Secretary determines appropriate, including any such information from the Opioid Safety Initiative established by the Department of Veterans Affairs or the Opioid Overdose Prevention Toolkit published by the Substance Abuse and Mental Health Services Administration.

SEC. 3. REQUIRING THE REVIEW OF QUALITY MEASURES RELATING TO OPIOIDS AND OPIOID JSE DISORDER TREATMENTS FURNISHED UNDER THE MEDICARE PROGRAM AND OTHER FEDERAL HEALTH CARE PROGRAMS.

(a) In General.—Section 1890A of the Social Security Act (42 U.S.C. 1395aaa–1) is amended by adding at the end the following new subsection:

"(g) TECHNICAL EXPERT PANEL REVIEW OF OPIOID AND OPIOID USE DISORDER

QUALITY MEASURES.

"(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this subsection, the Secretary shall establish a technical expert panel for purposes of reviewing quality measures relating to opioids and opioid use disorders, including care, prevention, diagnosis, health outcomes, and treatment furnished to individuals with opioid use disorders. The Secretary may use the entity with a contract under section 1890(a) and amend such contract as necessary to provide for the establishment of such technical expert panel.

"(2) REVIEW AND ASSESSMENT.—Not later than 1 year after the date the technical expert panel described in paragraph (1) is established (and periodically thereafter as the Secretary determines appropriate), the technical expert panel

"(A) review quality measures that relate to opioids and opioid use disorders, including existing measures and those under development;

(B) identify gaps in areas of quality measurement that relate to opioids and opioid use disorders, and identify measure development priorities for

such measure gaps; and

"(C) make recommendations to the Secretary on quality measures with respect to opioids and opioid use disorders for purposes of improving care, prevention, diagnosis, health outcomes, and treatment, including recmemendations for revisions of such measures, need for development of new measures, and recommendations for including such measures in the Merit-Based Incentive Payment System under section 1848(q), the alternative payment models under section 1833(z)(3)(C), the shared savings program under section 1899, the quality reporting requirements for inpatient hospitals under section 1886(b)(3)(B)(viii), the hospital value-based purchasing program under section 1886(o), and under other value-based purchasing programs under this title.

"(3) Consideration of measures by secretary.—The Secretary shall con-

sider-

"(A) using opioid and opioid use disorder measures (including measures used under the Merit-Based Incentive Payment System under section 1848(q), measures recommended under paragraph (2)(C), and other such measures identified by the Secretary) in alternative payment models under section 1833(z)(3)(C) and in the shared savings program under section 1899;

"(B) using opioid measures described in subparagraph (A), as applicable, in the quality reporting requirements for inpatient hospitals under section 1886(b)(3)(B)(viii), in the hospital value-based purchasing program under section 1886(o), and under other value-based purchasing programs under

this title.

"(4) Prioritization of measure development.—The Secretary shall prioritize for measure development the gaps in quality measures identified under paragraph (2)(B).".

(b) EXPEDITED ENDORSEMENT PROCESS FOR OPIOID MEASURES.—Section 1890(b)(2) of the Social Security Act (42 U.S.C. 1395aaa(b)(2)) is amended by adding at the end

the following new flush sentence:

Such endorsement process shall, as determined practicable by the entity, provide for an expedited process with respect to the endorsement of such measures relating to opioids and opioid use disorders.".

SEC. 4. TECHNICAL EXPERT PANEL ON REDUCING SURGICAL SETTING OPIOID USE; DATA COLLECTION ON PERIOPERATIVE OPIOID USE.

(a) TECHNICAL EXPERT PANEL ON REDUCING SURGICAL SETTING OPIOID USE.—

(1) IN GENERAL.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall convene a technical expert panel, including medical and surgical specialty societies and hospital organizations, to provide recommendations on reducing opioid use in the inpatient and outpatient surgical settings and on best practices for pain management, including with respect to the following:

(A) Approaches that limit patient exposure to opioids during the perioperative period, including pre-surgical and post-surgical injections, and that identify such patients at risk of opioid use disorder pre-operation.

- (B) Shared decision making with patients and families on pain management, including recommendations for the development of an evaluation and management code for purposes of payment under the Medicare program under title XVIII of the Social Security Act that would account for time spent on shared decision making.
 - (C) Education on the safe use, storage, and disposal of opioids. (D) Prevention of opioid misuse and abuse after discharge.

(E) Development of a clinical algorithm to identify and treat at-risk, opiate-tolerant patients and reduce reliance on opiodes for acute pain during

the perioperative period.

(2) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to Congress and make public a report containing the recommendations developed under paragraph (1) and recommendations for broader implementation of pain management protocols that limit the use of opioids in the perioperative setting and upon discharge from such setting.

(b) DATA COLLECTION ON PERIOPERATIVE OPIOID USE.—Not later than 1 year after

the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report that contains the following:

(1) The diagnosis-related group codes identified by the Secretary as having the highest volume of surgeries.

(2) With respect to each of such diagnosis-related group codes so identified, a determination by the Secretary of the data that is both available and reported on opioid use following such surgeries, such as with respect to-

(A) surgical volumes, practices, and opioid prescribing patterns;

(B) opioid consumption, including-

(i) perioperative days of therapy;

- (ii) average daily dose at the hospital, including dosage greater than 90 milligram morphine equivalent;
- (iii) post-discharge prescriptions and other combination drugs that are used before intervention and after intervention;

(iv) quantity and duration of opioid prescription at discharge; and

(v) quantity consumed and number of refills;

(C) regional anesthesia and analgesia practices, including pre-surgical and post-surgical injections;

(D) naloxone reversal;

(E) post-operative respiratory failure;

(F) information about storage and disposal; and

(G) such other information as the Secretary may specify.

(3) Recommendations for improving data collection on perioperative opioid use, including an analysis to identify barriers to collecting, reporting, and analyzing the data described in paragraph (2), including barriers related to technological availability.

SEC. 5. REQUIRING THE POSTING AND PERIODIC UPDATE OF OPIOID PRESCRIBING GUIDANCE FOR MEDICARE BENEFICIARIES.

(a) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Šervices (in this section referred to as the "Secretary") shall post on the public website of the Centers for Medicare & Medicaid Services all guidance published by the Department of Health and Human Services on or after January 1, 2016, relating to the prescribing of opioids and applicable to opioid prescriptions for individuals entitled to benefits under part A of title XVIII of the Social Security Act (42 U.S.C. 1395c et seq.) or enrolled under part B of such title of such Act (42 U.S.C. 1395j et seq.).

(b) UPDATE OF GUIDANCE.—

- (1) PERIODIC UPDATE.—The Secretary shall, in consultation with the entities specified in paragraph (2), periodically (as determined appropriate by the Secretary) update guidance described in subsection (a) and revise the posting of such guidance on the website described in such subsection.
 - (2) CONSULTATION.—The entities specified in this paragraph are the following:

(A) Medical professional organizations.

- (B) Providers and suppliers of services (as such terms are defined in section 1861 of the Social Security Act (42 U.S.C. 1395x)).
 - (C) Health care consumers or groups representing such consumers.
 - (D) Other entities determined appropriate by the Secretary.

I. SUMMARY AND BACKGROUND

A. Purpose and Summary

The bill, H.R. 5774, the "Combatting Opioid Abuse for Care in Hospitals (COACH) Act of 2018" as ordered reported by the Committee on Ways and Means on May 16, 2018, focuses on preventing opioid overuse by improving education for providers and beneficiaries. It realigns incentives to expand evidence-based, high-quality health care that reduces reliance on opioids for pain management.

This legislation requires the Centers for Medicare & Medicaid Services (CMS) to develop and publish a toolkit by January 1, 2019, that provides best practices to hospitals for reducing opioid use. This toolkit will include a template notice of opioid risks for patients who are prescribed opioids in a hospital setting. The toolkit will also include best practices regarding evidence-based provider education for pain management and screening at-risk individuals and those with opioid use disorders. Among other guidance, the toolkit will include best practices for patient education and tracking opioid prescribing trends within a hospital setting. This guidance will be developed in consultation with relevant stakeholders.

Additionally, within 180 days of enactment, the Department of Health and Human Services (HHS) is required to convene at least two Technical Expert Panels (TEPs). The first TEP is required to review quality measures related to opioids and opioid use disorders and identify gaps in such measures, prioritize such measures for development in gap areas, and make recommendations for adopting such measures under physician and hospital quality reporting programs. The legislation requires, as practicable, the creation of a fast-track endorsement process for such measures by the National Quality Forum (NQF). Within one year of the TEP's establishment, the Secretary will report on the quality measures (and gaps), including those related to care, prevention, diagnosis, health outcomes, and treatment furnished to individuals with opioid use disorders.

The second TEP is required to make recommendations on best practices for pain management and reducing opioid use within the surgical setting; it also must analyze post-surgical opioid prescribing. HHS must report to Congress based on the TEP's work, while also describing the available data on perioperative opioid use,

as well as identifying barriers to data collection and recommendations to improve data collection. HHS will publish the recommendations under the report (or reports) to Congress within one year of enactment.

Finally, within 180 days of enactment, the Secretary will publish on the CMS website all opioid prescribing guidance published after January 1, 2016, applicable to Medicare beneficiaries. CMS is required to periodically update the posted guidance in consultation with medical professional organizations, providers and suppliers of services, health care consumers, and other stakeholder organizations the Secretary identifies.

B. Background and Need for Legislation

Currently, while there is some guidance available through HHS and other entities aimed at helping health care providers reduce the prevalence of opioid use disorders, it is incomplete. There is no guidance that comprehensively addresses screening for opioid use disorder, provider and beneficiary education regarding opioid risks and non-opioid pain management alternatives, and best practices for tracking trends in opioid prescribing. In particular, CMS has not made available opioid guidance for Medicare beneficiaries in a hospital setting and has not published such guidance in one location that is easily accessible to beneficiaries and providers.

Presently, Medicare reimbursement to providers participating in the Medicare Merit-Based Incentive Program System (MIPS) for physicians, alternative payment models, shared savings programs, hospital inpatient quality reporting, and hospital value-based purchasing are based on quality ratings and measures with little or no

impact on reducing opioid use and abuse.

Lastly, more than 80 percent of Americans who undergo low-risk inpatient surgery receive opioids, and the majority of those patients have opioids that go unused after surgery. Ensuring appropriate use of opioids post-surgery, specific to patients' conditions and needs, is critical.

C. Legislative History

Background

H.R. 5774 was introduced on May 11, 2018, and was referred to the Committee on Ways and Means and additionally the Committee on Energy and Commerce.

Committee hearings

On January 17, 2018, the Subcommittee on Oversight held a hearing on the current landscape and CMS actions to prevent opioid misuse.

On February 6, 2018, the Subcommittee on Health held a hearing on removing barriers to prevent and treat opioid abuse and de-

pendence in Medicare.

On April 12, 2018, the Subcommittee on Human Resources held a hearing on local perspectives on the jobs gap that discussed problems the opioid epidemic is creating in finding qualified workers.

On April 25, 2018, the Subcommittee on Trade held a hearing on stopping the flow of synthetic opioids in the international mail system.

Committee action

The Committee on Ways and Means marked up H.R. 5774, the "Combatting Opioid Abuse for Care in Hospitals (COACH) Act of 2018," on May 16, 2018, and ordered the bill, as amended, favorably reported (with a quorum being present) by voice vote.

II. EXPLANATION OF THE BILL

A. Combatting Opioid Abuse for Care in Hospitals (COACH) Act of 2018

PRESENT LAW

There are no requirements in current law for CMS to develop and provide best practices on opioids to hospitals participating in Medicare, to publish such guidance on the CMS website, to assess opioid quality measures and consider such measures for adoption, or to study perioperative opioid prescribing best practices and data.

REASONS FOR CHANGE

The purposes of this legislation is to prevent opioid misuse by improving education for providers and beneficiaries and to realign incentives to expand evidence-based, high-quality health care that reduces reliance on opioids for pain management.

EXPLANATION OF PROVISIONS

Section 1: Short Title: This section states the short title as the "Combatting Opioid Abuse for Care in Hospitals (COACH) Act of 2018."

Section 2: Developing Guidance on Pain Management and Opioid Use Disorder Prevention for Hospitals Receiving Payment under Part A of the Medicare Program

Toolkit Creation for Hospitals Receiving Part A Medicare Payment: Requires CMS to develop a toolkit that provides best practices to Medicare participating hospitals for reducing opioid use by January 1, 2019, and to post the guidance that is developed on the CMS website.

Stakeholder Consultation: CMS is required to develop this guidance in consultation with medical professional organizations, providers and suppliers of services (including hospitals), health care consumers (including patient advocacy organizations), and other stakeholder organizations identified by the Secretary of HHS.

Contents of Toolkit: The toolkit is intended to provide a number of resources for hospitals to adopt. The toolkit will include the following resources:

- 1. Best practices regarding evidence-based provider education;
- 2. Best practices for provider education including treatment for pain management and prevention of drug diversion through proper storage and disposal;
 - 3. Best practices for patient education;
- 4. Creation of a clearly worded notification template for hospital staff to better inform patients prescribed opioids of potential risks and non-opioid pain management alternatives;
- 5. Best practices for tracking and controlling opioid prescribing trends within a hospital setting; and

6. Best practices from opioid toolkits developed by other federal agencies, including the Department of Veterans Affairs and the Substance Abuse and Mental Health Services Administration (SAMHSA).

Section 3: Requiring the Review of Quality Measures Relating to Opioids and Opioid Use Disorder Treatments Furnished Under the Medicare Program and Other Federal Health Care Programs

Technical Expert Panel Review of Opioid and Opioid Use Disorder Quality Measures: Within 180 days, the Secretary is required to convene a TEP to review quality measures related to opioids and opioid use disorders including care, prevention, diagnosis, health outcomes, and treatments furnished to individuals with opioid use disorder. The Secretary may elect to establish the TEP through a

contract with the consensus-based entity (i.e., NQF).

Review and Assessments: Within one year of the TEP's creation, the TEP will review existing measures related to opioids as well as those under development, and identify gaps in areas of quality measurement and establish priorities for development of opioid measures in gap areas; and make recommendations to the Secretary regarding revisions to existing measures, development of new measures, and recommendations for adoption of such measures. The TEP should be mindful of administrative burden on providers when undergoing this assessment and making recommenda-

Consideration of Measures by Secretary: The Secretary is required to consider the adoption of measures identified by the TEP, as well as those used under the Merit-Based Incentive Payment System (MIPS) for physicians, for adoption in alternative payment models, shared savings programs, hospital inpatient quality reporting, and the hospital value-based purchasing program. The Committee also expects the Secretary to avoid creating undue administrative burden and consider methods to offset burden by streamlining or reducing measures unrelated to opioids. The Secretary cannot recommend additional quality measures for adoption in post-acute care quality reporting and value-based purchasing

Prioritization of Measure Development for Expedited Endorsement: The Secretary is required to prioritize measures for expedited endorsement and the consensus-based entity is required, as practicable, to expedite the process for endorsing opioid-related quality measures. The Committee also expects that measures that do not have sufficient reliability, validity, or evidence behind them

should not be endorsed, but instead should be rejected.

Section 4: Technical Expert Panel on Reducing Surgical Setting

Opioid Use; Data Collection on Perioperative Opioid Use

Technical Expert Panel on Reducing Surgical Setting Opioid Use: Within six months, the Secretary is required to convene a TEP consisting of medical and surgical specialty societies, which may also encompass non-physician therapy societies, and hospital organizations to provide recommendations on best practices for pain management in surgical settings. Recommendations are required to include approaches to limit patient exposure to opioids (such approaches may include pre- and post-surgical injections), consideration of creating a code to pay for shared decision-making, and development of a clinical algorithm to identify patients at-risk of or suffering from opioid use disorder.

TEP Recommendations: Within one year of enactment, the Secretary is required to issue a public report on recommendations for broad implementation of pain management protocols that limit the

use of opioids in the perioperative setting.

Secretary Report: Within one year of enactment, the Secretary is required to issue a report analyzing perioperative opioid prescribing data for high-volume surgeries. Specifically, the Secretary is required to analyze the quantity and duration of opioid prescriptions; opioid-related surgical complications (such as the need for naloxone reversal associated with these surgeries); and will include recommendations to improve data and remove barriers to data collection.

Section 5: Requiring the Posting of Periodic Updates of Opioid

Prescribing Guidance for Medicare Beneficiaries

Within 180 days of enactment, the Secretary is required to publish on the CMS website all opioid prescribing guidance published after January 1, 2016 applicable to Medicare beneficiaries. CMS is required to periodically update the posted guidance in consultation with medical professional organizations, providers and suppliers of services, health care consumers, and other stakeholder organizations identified by the Secretary.

EFFECTIVE DATE

Developing Guidance on Pain Management and Opioid Use Disorder Prevention for Hospitals Receiving Payment under Part A of the Medicare Program: By January 1, 2019, CMS is required to have completed and published a hospital toolkit on the CMS website.

Requiring the Review of Quality Measures Relating to Opioids and Opioid Use Disorder Treatments Furnished Under the Medicare Program and Other Federal Health Care Programs: The Secretary is required to establish the Technical Expert Panel within 180 days of enactment and to publish recommendations within one year of the TEP's creation.

Technical Expert Panel on Reducing Surgical Setting Opioid Use; Data Collection on Perioperative Opioid Use: The Secretary is required to establish the Technical Expert Panel within six months of enactment and to publish recommendations within one year of

enactment.

Requiring the Posting of Periodic Updates of Opioid Prescribing Guidance for Medicare Beneficiaries: The Secretary is required to publish opioid prescribing guidance applicable to Medicare beneficiaries within 180 days of enactment and periodically update the posted guidance thereafter.

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. 5774, the COACH Act of 2018, on May 16, 2018.

The Chairman's amendment in the nature of a substitute was

adopted by a voice vote (with a quorum being present).

The bill, H.R. 5774, was ordered favorably reported as amended by voice vote (with a quorum being present).

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. 5774, 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, Congressional Budget Office, Washington, DC, June 6, 2018.

Hon. KEVIN BRADY, 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 the opioid-related legislation ordered to be reported on May 16, 2018.

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

Sincerely,

MARK P. HADLEY (For Keith Hall, Director).

Enclosure.

Opioid Legislation

Summary: On May 16, 2018, the House Committee on Ways and Means ordered seven bills to be reported related to the nation's response to the opioid epidemic. Generally, the bills would:

- Expand Medicare coverage of treatment for opioid use disorder:
- Give Medicare providers and health plans additional tools to curtail inappropriate prescribing and use of opioids;
- Require the completion of studies and reports related to opioid use and misuse in Medicare; and
- Require the United States Postal Service and Customs and Border Protection (CBP) to reduce illegal shipment of opioids across international borders.

Because the bills are related, CBO is publishing a single comprehensive document that includes estimates for each piece of legislation.

CBO estimates that enacting four of the bills would affect direct spending; therefore, pay-as-you-go procedures apply for those bills. None of the bills would affect revenues.

CBO estimates that although enacting one bill of the seven included in this document (H.R. 5776) would increase net direct spending and on-budget deficits over the four consecutive 10-year periods beginning in 2029, those effects would not exceed the threshold established by the Congress for long-term costs. CBO estimates that none of the remaining bills would increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2029.

None of the bills contain intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

Estimated cost to the Federal Government: The estimates in this document do not include the effects of interactions among the bills. If all seven bills were combined and enacted as one piece of legislation, the budgetary effects would be different from the sum of the estimates in this document, although CBO expects that those differences would be small. The effects of this legislation fall within functions 550 (health), 570 (Medicare), and 750 (administration of justice).

Basis of estimate: For this estimate, CBO assumes that all of the legislation will be enacted late in 2018 and that authorized and estimated amounts will be appropriated each year. Outlays for discretionary programs are estimated based on historical spending patterns for similar programs.

Uncertainty

CBO aims to produce estimates that generally reflect the middle of a range of the most likely budgetary outcomes that would result if the legislation was enacted. Because data on the utilization of mental health and substance abuse treatment under Medicaid and Medicare is scarce, CBO cannot precisely predict how patients or providers would respond to some policy changes or what budgetary effects would result. In addition, several of the bills would give the Department of Health and Human Services (HHS) considerable latitude in designing and implementing policies. Budgetary effects could differ from those provided in CBO's analyses depending on those decisions.

Direct spending

Table 1 lists the four bills included in this estimate that would affect direct spending.

H.R. 5676, the Stop Excessive Narcotics in our Retirement Communities Protection Act of 2018, would allow prescription drug plans to suspend payments to pharmacies while fraud investigations are pending. CBO expects that enacting the legislation would reduce payments by those plans to pharmacies and result in lower premiums for benefits under Medicare's Part D. CBO estimates that the reduction in premiums would lower federal spending for Part D by \$9 million over the 2019–2028 period.

TABLE 1.—ESTIMATED CHANGES IN MANDATORY SPENDING

					S S	nscal year,	n millions	By Tiscal year, in millions of dollars-					
	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2019– 2023	2019–2028
	INCREASE	S OR DECF	REASES (-	INCREASES OR DECREASES ($-$) IN DIRECT SPENDING	CT SPENDI	NG							
$\rm H.R.~5676$, Stop Excessive Narcotics in our Retirement Communities Protection Act of 2018:													
Budget Authority	0	0	-1	-	-1	-1	-1	-1	-1	-1	-1	-4	6 –
Outlays	0	0	-1	-	-	-1	-	-	ī	ï	-	4 –	6 –
H.R. 5773, Preventing Addiction for Susceptible Seniors Act of 2018: a													
Budget Authority	0	0	0	9-	_ 7	_7		%	6-	6-	- 11	-20	- 64
Outlays	0	0	0	9 –	_ 7			∞ 	6 –	6-	- 11	-20	- 64
H.R. 5776, the Medicare and Opioid Safe Treatment Act of 2018: ^a													
Budget Authority	0	∞	0	20	20	25	30	30	35	35	40	73	243
Outlays	0	2	4	22	70	25	30	30	35	35	40	73	243
H.R. 5788, Securing the International Mail Against Opioids Act of 2018: a													
Budget Authority	0	0	*	*	*	*	*	*	*	*	*	*	*
Outlays	0	0	*	*	*	*	*	*	*	*	*	*	*

Annual amounts may not sum to totals because of rounding. * = between -\$500,000 and \$500,000 a This bill also would affect spending subject to appropriation.

H.R. 5773, the Preventing Addiction for Susceptible Seniors Act of 2018, would require Part D prescription drug plans to provide drug management programs for Medicare beneficiaries who are at risk for prescription drug abuse. (Under current law, Part D plans are permitted but not required to establish such programs as of 2019.) Based on an analysis of the number of plans currently providing those programs, CBO estimates that enacting H.R. 5773 would lower federal spending by \$64 million over the 2019-2028 period by reducing the number of prescriptions filled and Medicare's payments for controlled substances.

Two provisions of H.R. 5773 would have no significant budgetary

effect; they are described later in this document.

H.R. 5776, the Medicare and Opioid Safe Treatment Act of 2018, would appropriate \$8 million in 2019, which would be available until expended, for Federally Qualified Health Centers and Rural Health Clinics to support training in the treatment of opioid use disorder. CBO expects that \$8 million would be spent between 2019 and 2021.

H.R. 5776 also would expand the availability of medication-assisted treatment (MAT) for Medicare beneficiaries with opioid use disorder. The bill would allow treatment programs certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) to become Medicare-participating providers. H.R. 5776 also would direct the Secretary of HHS to create a new schedule of bundled payments for MAT through certified programs and grant the Secretary considerable discretion for defining bundles

and establishing payment rates.

CBO projects that, beginning in 2021, about 3,000 Medicare beneficiaries who would not be treated for opioid abuse under current law would newly enroll each year in treatment offered by SAMHSA-certified programs and that the annual cost per participant would range from about \$6,000 to about \$10,000, depending largely on the medications dispensed and the period for which beneficiaries adhered to the protocol. CBO's projection of the number of beneficiaries who would receive treatment takes into consideration the number of beneficiaries estimated to have opioid-use disorder, the number already receiving some form of treatment, and the availability of providers to treat those who newly enroll in MAT. To develop a per capita treatment cost, CBO analyzed rates for MAT paid by other payers, as well as Medicare spending for health care services typically used by people receiving MAT. CBO estimates that the new MAT benefit would increase direct spending by \$235 million over the 2019–2028 period.

CBO estimates that enacting H.R. 5776 would increase net Medicare spending by \$243 million over the 2019-2028 period. (If enacted, H.R. 5776 would also affect spending subject to appropria-

tion; CBO has not completed an estimate of that amount.)

H.R. 5788, the Securing the International Mail Against Opioids Act of 2018, would establish a new fee for certain items mailed to the United States from overseas, beginning January 1, 2020. Ini-

¹MAT combines behavioral therapy and pharmaceutical treatment for substance use disorders. Under current law, methadone (an opioid used to treat and manage dependence on other drugs, such as heroin) can be dispensed only by SAMHSA-certified treatment programs, which do not participate in Medicare. Other drugs used in MAT, including buprenorphine and naltrexone, can be dispensed more widely.

tially, the fee for most such items would be one dollar, but the amount could be adjusted annually thereafter. Using information provided by CBP, CBO estimates that about \$100 million in new fees would be collected over the 2020–2028 period. The collections would be divided equally between CBP and the Postal Service and spent by those agencies on activities related to the processing of inbound mail. CBO estimates that the net effect on federal spending in each year would be insignificant. (If enacted, H.R. 5788 would also affect spending subject to appropriation; those effects are described below.)

Spending subject to appropriation: For this document, CBO has grouped bills with spending that would be subject to appropriation

into three general categories:

Bills with provisions that would have no budgetary effect;
Bills with provisions for which CBO has estimated an au-

thorization of appropriations (see Table 2); and

• Bills with provisions that would affect spending subject to appropriation for which CBO has not yet completed an estimate.

No Budgetary Effect. CBO estimates that three of the bills have provisions that would not significantly affect direct spending, reve-

nues, or spending subject to appropriation.

H.R. 5773, the Preventing Addiction for Susceptible Seniors Act of 2018, would require health care professionals to submit prior authorization requests electronically, starting on January 1, 2021, for drugs covered under Medicare Part D. Taking into account that many prescribers already use electronic methods to submit such requests, CBO estimates that enacting that Section 3 of H.R. 5773 would not significantly affect direct spending for Part D.

Section 5 of that bill would expand medication therapy management programs under Medicare Part D to include beneficiaries who are at risk for prescription drug abuse. Because relatively few beneficiaries would be affected by this provision, CBO estimates that its enactment would not significantly affect direct spending for

Part D.

Section 6 of that bill would require the Secretary of HHS on an annual basis to identify high prescribers of opioids and furnish them with information about proper prescribing methods. Because HHS already has the capacity to meet those requirements, CBO estimates that enacting that provision would not impose additional

administrative costs on the agency.

H.R. 5775, the Providing Reliable Options for Patients and Educational Resources Act of 2018, would require prescription drug plans that provide coverage under Medicare Part D to furnish information to beneficiaries about the risks of opioid use and the availability of alternative treatments for pain. The bill also would require Medicare Advantage plans and prescription drug plans to provide information regarding safe disposal of controlled substances in home health risk assessments and medication therapy management programs, respectively. In CBO's estimation, neither proposal would have a budgetary effect because those activities would not impose significant administrative costs on plans or federal agencies.

In addition, H.R. 5775 would restrict the use of certain pain-related questions on the Hospital Consumer Assessment of

Healthcare Providers and Systems (HCAHPS) survey, which is administered by the Centers for Medicare & Medicaid Services (CMS). The survey is one measure used in CMS's Hospital Value-Based Purchasing (VBP) Program, which adjusts payments to acute care hospitals on the basis of the quality of care they provide to Medicare beneficiaries. Because the VBP program is funded by reducing base payments to all hospitals, CBO estimates that changing the HCAHPS survey would not affect the total amount

paid by Medicare.

H.R. 5776, the Medicare and Opioid Safe Treatment Act of 2018, in section 3, would require CMS, beginning on January 1, 2020, to review and possibly modify payments made through Medicare's Hospital Outpatient Prospective Payment System for certain opioid and nonopioid pain management treatments and technologies. CMS could revise payments if the Secretary of HHS determined that there was a financial incentive to use opioids in place of nonopioid medications. The budget neutrality requirement under current law would apply to such revisions, and the rest of the payment rates within the system would be subject to offsetting adjustments. Because the changes would be made in a budget-neutral manner, CBO estimates that this provision would have no budgetary effect.

Section 6 of H.R. 5776 would explicitly authorize the Center for Medicare and Medicaid Innovation (CMMI) to test approaches for expanding beneficiaries' awareness of psychological services and to help those beneficiaries curtail use of hospital-based mental health or behavioral health services. Because CMMI already has that authority, CBO estimates that enacting the legislation would not af-

fect federal spending.

Estimated Authorizations. Table 2 shows CBO's estimates of the authorization of appropriations for provisions in four bills. For those estimates, CBO assumes that appropriated funds would be

available to implement those provisions.

H.R. 5723, the Expanding Oversight of Opioid Prescribing and Payment Act of 2018, would require the Medicare Payment Advisory Commission to report to the Congress on payments for pain treatment, incentives for prescribing opioids in inpatient and outpatient settings, and documented tracking of opioid use from Medicare claims data. CBO estimates that producing such a report would cost less than \$500,000 over the 2019–2023 period.

TABLE 2.—ESTIMATED SPENDING SUBJECT TO APPROPRIATION FOR BILLS WITH ESTIMATED **AUTHORIZATIONS**

		Ву	fiscal year,	in million	s of dollars	S	
	2018	2019	2020	2021	2022	2023	2019–2023
INCREASES IN SPENDIN	G SUBJEC	T TO APP	ROPRIATI	ON			
H.R. 5723, Expanding Oversight of Opioid Prescribing and							
Payment Act of 2018:							
Estimated Authorization Level	0	*	0	0	0	0	*
Estimated Outlays	0	*	0	0	0	0	*
H.R. 5773, Preventing Addiction for Susceptible Seniors							
Act of 2018: a							
Estimated Authorization Level	0	2	2	2	2	2	9
Estimated Outlays	0	2	2	2	2	2	9
H.R. 5776, Medicare and Opioid Safe Treatment Act of							
2018: a							
Estimated Authorization Level	0	1	0	0	0	0	1

TABLE 2.—ESTIMATED SPENDING SUBJECT TO APPROPRIATION FOR BILLS WITH ESTIMATED AUTHORIZATIONS—Continued

		By fiscal year, in millions of dollars——							
	2018	2019	2020	2021	2022	2023	2019–2023		
Estimated Outlays	0	1	0	0	0	0	1		
Estimated Authorization Level Estimated Outlays	0 0	100 40	0 40	0 20	0	0	100 100		

Annual amounts may not sum to totals because of rounding. * = between zero and \$500,000 $^{\rm a}$ This bill also would affect mandatory spending.

H.R. 5773, the Preventing Addiction for Susceptible Seniors Act of 2018, would require the Secretary of HHS to establish a secure Internet portal to allow HHS, Medicare Advantage plans, and Medicare Part D plans to exchange information about fraud, waste, and abuse among providers and suppliers no later than two years after enactment. H.R. 5773 also would require organizations with Medicare Advantage contracts to submit information on investigations related to providers suspected of prescribing large volumes of opioids through a process established by the Secretary no later than January 2021. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5773 would cost approximately \$9 million over the 2019–2023 period.

cost approximately \$9 million over the 2019–2023 period.

H.R. 5776, the Medicare and Opioid Safe Treatment Act of 2018, would direct the Secretary of HHS to report to the Congress on the availability of supplemental benefits to pay for treatment or prevention of substance abuse among enrollees in Medicare Advantage plans. The Secretary also would report on coverage of and payment for pain treatment and substance use disorders under Medicare. CBO estimates that producing those reports would cost \$1 million

over five years.

H.R. 5788, the Securing the International Mail Against Opioids Act of 2018, would direct the Postal Service, CBP, and other federal agencies to collaborate to develop technology to detect opioids and other drugs that enter the United States in the mail. Using information provided by CBP, CBO estimates that it would cost roughly \$100 million over the 2019–2021 period to deploy drug detection systems at international mail facilities.

Other Authorizations. CBO has determined that provisions in two bills—H.R. 5774, Combating Opioid Abuse for Care in Hospitals Act of 2018; and H.R. 5776, the Medicare and Safe Opioid Treatment Act of 2018—would increase authorization levels, but has not completed estimates of amounts. Any spending that would result from those authorizations would be subject to future appropriation action

action.

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. Four of the bills discussed in this document contain direct spending and are subject to pay-as-you-go procedures. Details about the amount of direct spending in those bills can be found in Table 1.

Increase in long-term direct spending and deficits: CBO estimates that although enacting H.R. 5776, the Medicare and Opioid Safe Treatment Act of 2018, would increase net direct spending and on-budget deficits over the four consecutive 10-year periods be-

ginning in 2029, those effects would not exceed the threshold established by the Congress for long-term costs (\$2.5 billion for net direct spending and \$5 billion for on-budget deficits). CBO estimates that none of the remaining bills would increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2029.

Mandates: None of the bills contains intergovernmental or pri-

vate-sector mandates as defined in UMRA.

Previous CBO estimate: On June 6, 2018, CBO issued an estimate for 59 opioid-related bills ordered reported by the House Committee on Energy and Commerce on May 9 and May 17, 2018. Several of those bills contain provisions that are identical or similar to those in the legislation ordered reported by the Committee on Ways and Means, and for those provisions, CBO's estimates are the

In particular, several sections in H.R. 5773, the Preventing Addiction for Susceptible Seniors Act of 2018, contain provisions that are identical or similar to those in five bills listed in the other esti-

- Section 2, which would require prescription drug plans to implement drug management programs, is identical to a provision in H.R. 5675.
- Section 3, regarding electronic prior authorization for prescriptions under Medicare's Part D, is similar to a provision in H.R.
- Section 4, which would mandate the creation of a new Internet portal to allow various stakeholders to exchange information, is identical to a provision in H.R. 5715.
- Section 5, which would expand medication therapy management, is the same as a provision in H.R. 5684.
- Section 6, regarding prescriber notification, is identical to H.R.

In addition, in this estimate, a provision related to Medicare beneficiary education in section 2 of H.R. 5775, the Providing Reliable Options for Patients and Educational Resources Act of 2018, is the same as a provision in H.R. 5686, the Medicare Clear Health Options in Care for Enrollees Act of 2018, in CBO's estimate for the Committee on Energy and Commerce.

Estimate prepared by: Federal costs, Medicare: Philippa Haven, Lori Housman, Jamease Kowalczyk, Lara Robillard, Sarah Sajewski, Colin Yee, and Rebecca Yip; U.S. Postal Service and Customs and Border Protection: Mark Grabowicz; Mandates: Andrew

Laughlin; Fact Checking: Zachary Byrum and Kate Kelly.

Estimate reviewed by: Tom Bradley, Chief, Health Systems and Medicare Cost Estimates Unit; Kim P. Cawley, Chief, Natural Resources Cost Estimates Unit; Susan Willie, Chief, Mandates Unit; Leo Lex, Deputy Assistant Director for Budget Analysis; Theresa A. Gullo, 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 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 not contain Federal mandates on the private sector. The Committee has determined that the bill does not contain the private sector.

Federal mandates on the private sector. 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. DUPLICATION OF FEDERAL PROGRAMS

In compliance with Sec. 3(g)(2) of H. Res. 5 (114th Congress), 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 from the Government Accountability Office 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 to the Federal Program Information Act (Pub. L. No. 95–220, as amended by Pub. L. No. 98–169).

F. DISCLOSURE OF DIRECTED RULE MAKINGS

In compliance with Sec. 3(i) of H. Res. 5 (114th Congress), the following statement is made concerning directed rule makings: The Committee estimates that the bill requires no directed rule makings within the meaning of such section.

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 italic, 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 (new matter is printed in italic 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

* * * * * *

CONTRACT WITH A CONSENSUS-BASED ENTITY REGARDING PERFORMANCE MEASUREMENT

Sec. 1890. (a) Contract.—

(1) IN GENERAL.—For purposes of activities conducted under this Act, the Secretary shall identify and have in effect a contract with a consensus-based entity, such as the National Quality Forum, that meets the requirements described in subsection (c). Such contract shall provide that the entity will perform the duties described in subsection (b).

(2) TIMING FOR FIRST CONTRACT.—As soon as practicable after the date of the enactment of this subsection, the Secretary shall enter into the first contract under paragraph (1).

(3) PERIOD OF CONTRACT.—A contract under paragraph (1) shall be for a period of 4 years (except as may be renewed after a subsequent bidding process).

(4) COMPETITIVE PROCEDURES.—Competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5))) shall be used to enter into a contract under paragraph (1).

tract under paragraph (1).

(b) DUTIES.—The duties described in this subsection are the following:

(1) PRIORITY SETTING PROCESS.—The entity shall synthesize evidence and convene key stakeholders to make recommendations, with respect to activities conducted under this Act, on an integrated national strategy and priorities for health care performance measurement in all applicable settings. In making such recommendations, the entity shall—

(A) ensure that priority is given to measures-

(i) that address the health care provided to patients

with prevalent, high-cost chronic diseases;

(ii) with the greatest potential for improving the quality, efficiency, and patient-centeredness of health care; and

(iii) that may be implemented rapidly due to existing evidence, standards of care, or other reasons; and (B) take into account measures that-

(i) may assist consumers and patients in making informed health care decisions;

(ii) address health disparities across groups and

areas; and

- (iii) address the continuum of care a patient receives, including services furnished by multiple health care providers or practitioners and across multiple set-
- (2) Endorsement of measures.—The entity shall provide for the endorsement of standardized health care performance measures. The endorsement process under the preceding sentence shall consider whether a measure-
 - (A) is evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver level, feasible to collect and report, and responsive to variations in patient characteristics, such as health status, language capabilities, race or ethnicity, and income level; and

(B) is consistent across types of health care providers, including hospitals and physicians.

Such endorsement process shall, as determined practicable by the entity, provide for an expedited process with respect to the endorsement of such measures relating to opioids and opioid use disorders.

- (3) MAINTENANCE OF MEASURES.—The entity shall establish and implement a process to ensure that measures endorsed under paragraph (2) are updated (or retired if obsolete) as new evidence is developed.
- (5) Annual report to congress and the secretary; sec-RETARIAL PUBLICATION AND COMMENT.-
 - (A) ANNUAL REPORT.—By not later than March 1 of each year (beginning with 2009), the entity shall submit to Congress and the Secretary a report containing the following:

(i) A description of-

(I) the implementation of quality measurement initiatives under this Act and the coordination of such initiatives with quality initiatives implemented by other payers;

(II) the recommendations made under para-

(III) the performance by the entity of the duties required under the contract entered into with the Secretary under subsection (a);

(IV) gaps in endorsed quality measures, which shall include measures that are within priority areas identified by the Secretary under the national strategy established under section 399HH of the Public Health Service Act, and where quality measures are unavailable or inadequate to

identify or address such gaps;

(V) areas in which evidence is insufficient to support endorsement of quality measures in priority areas identified by the Secretary under the national strategy established under section 399HH of the Public Health Service Act and where targeted research may address such gaps; and

(VI) the matters described in clauses (i) and (ii)

of paragraph (7)(A).

(ii) An itemization of financial information for the fiscal year ending September 30 of the preceding year, including—

(I) annual revenues of the entity (including any government funding, private sector contributions, grants, membership revenues, and investment

revenue);

(II) annual expenses of the entity (including grants paid, benefits paid, salaries or other compensation, fundraising expenses, and overhead costs); and

(III) a breakdown of the amount awarded per contracted task order and the specific projects funded in each task order assigned to the entity.

(iii) Any updates or modifications of internal policies and procedures of the entity as they relate to the duties of the entity under this section, including—

(I) specifically identifying any modifications to the disclosure of interests and conflicts of interests for committees, work groups, task forces, and

advisory panels of the entity; and

(II) information on external stakeholder participation in the duties of the entity under this section (including complete rosters for all committees, work groups, task forces, and advisory panels funded through government contracts, descriptions of relevant interests and any conflicts of interest for members of all committees, work groups, task forces, and advisory panels, and the total percentage by health care sector of all convened committees, work groups, task forces, and advisory panels.

(B) SECRETARIAL REVIEW AND PUBLICATION OF ANNUAL REPORT.—Not later than 6 months after receiving a report under subparagraph (A) for a year, the Secretary shall—

(i) review such report; and

(ii) publish such report in the Federal Register, together with any comments of the Secretary on such report.

(6) REVIEW AND ENDORSEMENT OF EPISODE GROUPER UNDER THE PHYSICIAN FEEDBACK PROGRAM.—The entity shall provide for the review and, as appropriate, the endorsement of the epi-

sode grouper developed by the Secretary under section 1848(n)(9)(A). Such review shall be conducted on an expedited basis.

(7) CONVENING MULTI-STAKEHOLDER GROUPS.—

(A) IN GENERAL.—The entity shall convene multi-stake-holder groups to provide input on—

(i) the selection of quality and efficiency measures

described in subparagraph (B), from among-

(I) such measures that have been endorsed by

the entity; and

(II) such measures that have not been considered for endorsement by such entity but are used or proposed to be used by the Secretary for the collection or reporting of quality and efficiency measures; and

(ii) national priorities (as identified under section 399HH of the Public Health Service Act) for improvement in population health and in the delivery of health care services for consideration under the national strategy established under section 399HH of the Public Health Service Act.

(B) QUALITY MEASURES.—

(i) In general.—Subject to clause (ii), the quality and efficiency measures described in this subpara-

graph are quality and efficiency measures—

(I) for use pursuant to sections 1814(i)(5)(D), 1833(i)(7), 1833(t)(17), 1848(k)(2)(C), 1866(k)(3), 1881(h)(2)(A)(iii), 1886(b)(3)(B)(viii), 1886(j)(7)(D), 1886(m)(5)(D), 1886(o)(2), 1886(s)(4)(D), and 1895(b)(3)(B)(v);

(II) for use in reporting performance information to the public; and

(III) for use in health care programs other than

for use under this Act.

(ii) EXCLUSION.—Data sets (such as the outcome and assessment information set for home health services and the minimum data set for skilled nursing facility services) that are used for purposes of classification systems used in establishing payment rates under this title shall not be quality and efficiency measures described in this subparagraph.

(C) REQUIREMENT FOR TRANSPARENCY IN PROCESS.—

(i) IN GENERAL.—In convening multi-stakeholder groups under subparagraph (A) with respect to the selection of quality and efficiency measures, the entity shall provide for an open and transparent process for the activities conducted pursuant to such convening.

(ii) SELECTION OF ORGANIZATIONS PARTICIPATING IN MULTI-STAKEHOLDER GROUPS.—The process described in clause (i) shall ensure that the selection of representatives comprising such groups provides for public nominations for, and the opportunity for public comment on, such selection.

(D) MULTI-STAKEHOLDER GROUP DEFINED.—In this paragraph, the term "multi-stakeholder group" means, with re-

spect to a quality and efficiency measure, a voluntary collaborative of organizations representing a broad group of stakeholders interested in or affected by the use of such quality and efficiency measure.

(8) Transmission of multi-stakeholder input.—Not later than February 1 of each year (beginning with 2012), the entity shall transmit to the Secretary the input of multi-stakeholder groups provided under paragraph (7).

(c) REQUIREMENTS DESCRIBED.—The requirements described in

this subsection are the following:
(1) PRIVATE NONPROFIT.—The entity is a private nonprofit entity governed by a board.

(2) BOARD MEMBERSHIP.—The members of the board of the entity include-

- (A) representatives of health plans and health care providers and practitioners or representatives of groups representing such health plans and health care providers and practitioners;
- (B) health care consumers or representatives of groups representing health care consumers; and
- (C) representatives of purchasers and employers or representatives of groups representing purchasers or employ-
- (3) Entity membership.—The membership of the entity includes persons who have experience with-
 - (A) urban health care issues;
 - (B) safety net health care issues;
 - (C) rural and frontier health care issues; and
 - (D) health care quality and safety issues.
- (4) OPEN AND TRANSPARENT.—With respect to matters related to the contract with the Secretary under subsection (a), the entity conducts its business in an open and transparent manner and provides the opportunity for public comment on its
- (5) Voluntary consensus standards setting organiza-TION.—The entity operates as a voluntary consensus standards setting organization as defined for purposes of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Public Law 104–113) and Office of Management and Budget Revised Circular A-119 (published in the Federal Register on February 10, 1998).

(6) EXPERIENCE.—The entity has at least 4 years of experi-

ence in establishing national consensus standards.

- (7) MEMBERSHIP FEES.—If the entity requires a membership fee for participation in the functions of the entity, such fees shall be reasonable and adjusted based on the capacity of the potential member to pay the fee. In no case shall membership fees pose a barrier to the participation of individuals or groups with low or nominal resources to participate in the functions of the entity.
- (d) FUNDING.—(1) For purposes of carrying out this section, 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 such proportion as the Secretary determines appropriate), of \$10,000,000

to the Centers for Medicare & Medicaid Services Program Management Account for each of fiscal years 2009 through 2013. Amounts transferred under the preceding sentence shall remain available

until expended.

(2) For purposes of carrying out this section and section 1890A (other than subsections (e) and (f)), 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 such proportion as the Secretary determines appropriate, to the Centers for Medicare & Medicaid Services Program Management Account of \$5,000,000 for fiscal year 2014, \$30,000,000 for each of fiscal years 2015 through 2017, and \$7,500,000 for each of fiscal years 2018 and 2019. Amounts transferred under the preceding sentence shall remain available until expended. For purposes of carrying out this section and section 1890A (other than subsections (e) and (f)), 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 such proportion as the Secretary determines appropriate, to the Centers for Medicare & Medicaid Services Program Management Account of \$5,000,000 for fiscal year 2014 and \$30,000,000 for each of fiscal years 2015 through 2017. Amounts transferred under the preceding sentence shall remain available until expended. Amounts transferred for each of fiscal years 2018 and 2019 shall be in addition to any unobligated funds transferred for a preceding fiscal year that are available under the preceding sentence.

(e) ANNUAL REPORT BY SECRETARY TO CONGRESS.—By not later than March 1 of each year (beginning with 2019), the Secretary

shall submit to Congress a report containing the following:

(1) A comprehensive plan that identifies the quality measurement needs of programs and initiatives of the Secretary and provides a strategy for using the entity with a contract under subsection (a) and any other entity the Secretary has contracted with or may contract with to perform work associated with section 1890A to help meet those needs, specifically with respect to the programs under this title and title XIX. In years after the first plan under this paragraph is submitted, the requirements of this paragraph may be met by providing an update to the plan.

(2) The amount of funding provided under subsection (d) for purposes of carrying out this section and section 1890A that has been obligated by the Secretary, the amount of funding provided that has been expended, and the amount of funding

provided that remains unobligated.

(3) With respect to the activities described under this section or section 1890A, a description of how the funds described in paragraph (2) have been obligated or expended, including how much of that funding has been obligated or expended for work performed by the Secretary, the entity with a contract under subsection (a), and any other entity the Secretary has contracted with to perform work.

(4) A description of the activities for which the funds described in paragraph (2) were used, including task orders and activities assigned to the entity with a contract under sub-

section (a), activities performed by the Secretary, and task orders and activities assigned to any other entity the Secretary has contracted with to perform work related to carrying out section 1890A.

(5) The amount of funding described in paragraph (2) that has been obligated or expended for each of the activities de-

scribed in paragraph (4).

(6) Estimates for, and descriptions of, obligations and expenditures that the Secretary anticipates will be needed in the succeeding two year period to carry out each of the quality measurement activities required under this section and section 1890A, including any obligations that will require funds to be expended in a future year.

QUALITY MEASUREMENT

Sec. 1890A. (a) Multi-stakeholder Group Input Into Selection of Quality Measures.—The Secretary shall establish a pre-rulemaking process under which the following steps occur with respect to the selection of quality and efficiency measures described in section 1890(b)(7)(B):

(1) INPUT.—Pursuant to section 1890(b)(7), the entity with a contract under section 1890 shall convene multi-stakeholder groups to provide input to the Secretary on the selection of quality and efficiency measures described in subparagraph (B)

of such paragraph.

(2) PUBLIC AVAILABILITY OF MEASURES CONSIDERED FOR SELECTION.—Not later than December 1 of each year (beginning with 2011), the Secretary shall make available to the public a list of quality and efficiency measures described in section 1890(b)(7)(B) that the Secretary is considering under this title.

(3) Transmission of multi-stakeholder input.—Pursuant to section 1890(b)(8), not later than February 1 of each year (beginning with 2012), the entity shall transmit to the Secretary the input of multi-stakeholder groups described in para-

graph (1).

- (4) Consideration of Multi-Stakeholder input.—The Secretary shall take into consideration the input from multi-stakeholder groups described in paragraph (1) in selecting quality and efficiency measures described in section 1890(b)(7)(B) that have been endorsed by the entity with a contract under section 1890 and measures that have not been endorsed by such entity.
- (5) RATIONALE FOR USE OF QUALITY MEASURES.—The Secretary shall publish in the Federal Register the rationale for the use of any quality and efficiency measure described in section 1890(b)(7)(B) that has not been endorsed by the entity with a contract under section 1890.
- (6) ASSESSMENT OF IMPACT.—Not later than March 1, 2012, and at least once every three years thereafter, the Secretary shall—
 - (A) conduct an assessment of the quality and efficiency impact of the use of endorsed measures described in section 1890(b)(7)(B); and
 - (B) make such assessment available to the public.

(b) Process for Dissemination of Measures Used by the Secretary.—

(1) IN GENERAL.—The Secretary shall establish a process for disseminating quality and efficiency measures used by the Sec-

retary. Such process shall include the following:

(A) The incorporation of such measures, where applicable, in workforce programs, training curricula, and any other means of dissemination determined appropriate by the Secretary.

(B) The dissemination of such quality and efficiency measures through the national strategy developed under

section 399HH of the Public Health Service Act.

(2) EXISTING METHODS.—To the extent practicable, the Secretary shall utilize and expand existing dissemination methods in disseminating quality and efficiency measures under the process established under paragraph (1).

(c) REVIEW OF QUALITY MEASURES USED BY THE SECRETARY.—

(1) IN GENERAL.—The Secretary shall—

- (A) periodically (but in no case less often than once every 3 years) review quality and efficiency measures described in section 1890(b)(7)(B); and
- (B) with respect to each such measure, determine whether to—
 - (i) maintain the use of such measure; or

(ii) phase out such measure.

(2) CONSIDERATIONS.—In conducting the review under paragraph (1), the Secretary shall take steps to—

(A) seek to avoid duplication of measures used; and

(B) take into consideration current innovative methodologies and strategies for quality and efficiency improvement practices in the delivery of health care services that represent best practices for such quality and efficiency improvement and measures endorsed by the entity with a contract under section 1890 since the previous review by the Secretary.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall preclude a State from using the quality and efficiency measures identified under sections 1139A and 1139B.

- (e) DEVELOPMENT OF QUALITY MEASURES.—The Administrator of the Center for Medicare & Medicaid Services shall through contracts develop quality measures (as determined appropriate by the Administrator) for use under this Act. In developing such measures, the Administrator shall consult with the Director of the Agency for Healthcare Research and Quality.
- (f) Hospital Acquired Conditions.—The Secretary shall, to the extent practicable, publicly report on measures for hospital-acquired conditions that are currently utilized by the Centers for Medicare & Medicaid Services for the adjustment of the amount of payment to hospitals based on rates of hospital-acquired infections.

(g) TECHNICAL EXPERT PANEL REVIEW OF OPIOID AND OPIOID USE

DISORDER QUALITY MEASURES.—

(1) In general.—Not later than 180 days after the date of the enactment of this subsection, the Secretary shall establish a technical expert panel for purposes of reviewing quality measures relating to opioids and opioid use disorders, including care, prevention, diagnosis, health outcomes, and treatment furnished to individuals with opioid use disorders. The Secretary may use the entity with a contract under section 1890(a) and amend such contract as necessary to provide for the establishment of such technical expert panel.

(2) REVIEW AND ASSESSMENT.—Not later than 1 year after the date the technical expert panel described in paragraph (1) is established (and periodically thereafter as the Secretary deter-

mines appropriate), the technical expert panel shall-

(A) review quality measures that relate to opioids and opioid use disorders, including existing measures and those under development;

(B) identify gaps in areas of quality measurement that relate to opioids and opioid use disorders, and identify measure development priorities for such measure gaps; and

- (C) make recommendations to the Secretary on quality measures with respect to opioids and opioid use disorders for purposes of improving care, prevention, diagnosis, health outcomes, and treatment, including recommendations for revisions of such measures, need for development of new measures, and recommendations for including such measures in the Merit-Based Incentive Payment System under section 1848(q), the alternative payment models under section 1833(z)(3)(C), the shared savings program under section 1899, the quality reporting requirements for inpatient hospitals under section $1886(b)(\bar{3})(B)(viii)$, the hospital value-based purchasing program under section 1886(o), and under other value-based purchasing programs under this title.
- (3) Consideration of measures by secretary.—The Secretary shall consider-
 - (A) using opioid and opioid use disorder measures (including measures used under the Merit-Based Incentive Payment System under section 1848(q), measures recommended under paragraph (2)(C), and other such measures identified by the Secretary) in alternative payment models under section 1833(z)(3)(C) and in the shared savings program under section 1899; and

(B) using opioid measures described in subparagraph (A), as applicable, in the quality reporting requirements for inpatient hospitals under section 1886(b)(3)(B)(viii), in the hospital value-based purchasing program under section 1886(o), and under other value-based purchasing programs

under this title.

(4) Prioritization of measure development.—The Secretary shall prioritize for measure development the gaps in quality measures identified under paragraph (2)(B).

LETTERS OF EXCHANGE

KEVIN BRADY, TEXAS, CHAIRMAN

Congress of the United States H.S. House of Representatives

COMMITTEE ON WAYS AND MEANS 1102 Longworth House Office Building (202) 225–3625

Washington, ₽€ 20515-6548

http://waysandmeans.house.gov

June 8, 2018

The Honorable Greg Walden Chairman Committee on Energy and Commerce 2125 Rayburn House Office Building Washington, DC 20515

Dear Chairman Walden,

I write to you regarding several opioid bills the Committee on Ways and Means ordered favorably reported to address the opioid epidemic. The following bills were also referred to the Committee on Energy and Commerce.

I ask that the Committee on Energy and Commerce waive formal consideration of the following bills so that they may proceed expeditiously to the House Floor:

- H.R. 5774, Combatting Opioid Abuse for Care in Hospitals (COACH) Act;
- . H.R. 5775, Providing Reliable Options for Patients and Educations Resources (PROPER) Act;
- H.R. 5776, Medicare and Opioid Safe Treatment (MOST) Act;
- H.R. 5773, Preventing Addition for Susceptible Seniors (PASS) Act;
- H.R. 5676, Stop Excessive Narcotics in our Retirement (SENIOR) Communities Protection Act; and
- H.R. 5723, Expanding Oversight of Opioid Prescribing and Payment Act.

I acknowledge that by waiving formal consideration of the bills, the Committee on Energy and Commerce is in no way waiving its jurisdiction over the subject matter contained in those provisions of the bills that fall within your Rule X jurisdiction. I would support your effort to seek appointment of an appropriate number of conferees on any House-Senate conference involving this legislation.

I will include a copy of our letters in the Congressional Record during consideration of this legislation on the House floor.

Sincerely,

Chairman

cc:

The Honorable Paul Ryan, Speaker The Honorable Richard E. Neal The Honorable Frank Pallone

Thomas J. Wickham, Jr., Parliamentarian

GREG WALDEN, OREGON CHAIRMAN FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE 2125 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6115 Majority (20) 279-2927 Milecity (20) 279-3841

June 8, 2018

The Honorable Kevin Brady Chairman Committee on Ways and Means 1102 Longworth House Office Building Washington, DC 20515

Dear Chairman Brady:

Thank you for your letter regarding the following bills, which were also referred to the Committee on Energy and Commerce:

- H.R. 5774, Combatting Opioid Abuse for Care in Hospitals (COACH) Act;
- H.R. 5775, Providing Reliable Options for Patients and Educations Resources (PROPER) Act;
- H.R. 5776, Medicare and Opioid Safe Treatment (MOST) Act;
- H.R. 5773, Preventing Addition for Susceptible Seniors (PASS) Act;
- H.R. 5676, Stop Excessive Narcotics in our Retirement (SENIOR) Communities Protection Act; and

H.R. 5723, Expanding Oversight of Opioid Prescribing and Payment Act.

I wanted to notify you that the Committee will forgo action on these bills so that they may proceed expeditiously to the House floor.

I appreciate your acknowledgment that by forgoing formal consideration of these bills, the Committee on Energy and Commerce is in no way waiving its jurisdiction over the subject matter contained in those provisions of the bills that fall within its Rule X jurisdiction. I also

Letter to the Honorable Kevin Brady Page 2

appreciate your offer to support the Committee's request for the appointment of conferees in the event of a House-Senate conference involving this legislation.

Thank you for your assistance on this matter.

Sincerely,

Mes blilden Greg Walden Chairman

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