

STOP EXCESSIVE NARCOTICS IN OUR RETIREMENT
 COMMUNITIES PROTECTION ACT OF 2018

JUNE 19, 2018.—Ordered to be printed

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

R E P O R T

[To accompany H.R. 5676]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 5676) to amend title XVIII of the Social Security Act to authorize the suspension of payments by Medicare prescription drug plans and MA-PD plans pending investigations of credible allegations of fraud by pharmacies, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

	Page
I. SUMMARY AND BACKGROUND	2
A. Purpose and Summary	2
B. Background and Need for Legislation	2
C. Legislative History	3
II. EXPLANATION OF THE BILL	3
A. Stop Excessive Narcotics in our Retirement Communities Protec- tion Act	3
III. VOTES OF THE COMMITTEE	4
IV. BUDGET EFFECTS OF THE BILL	4
A. Committee Estimate of Budgetary Effects	4
B. Statement Regarding New Budget Authority and Tax Expendi- tures Budget Authority	4
C. Cost Estimate Prepared by the Congressional Budget Office	4
V. OTHER MATTERS TO BE DISCUSSED UNDER THE RULES OF THE HOUSE	13
A. Committee Oversight Findings and Recommendations	13
B. Statement of General Performance Goals and Objectives	13
C. Information Relating to Unfunded Mandates	13
D. Congressional Earmarks, Limited Tax Benefits, and Limited Tariff Benefits	13
E. Duplication of Federal Programs	13

F. Disclosure of Directed Rule Makings	13
VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED	14
A. Text of Existing Law Amended or Repealed by the Bill, as Reported	14
B. Changes in Existing Law Proposed by the Bill, as Reported	14

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 “Stop Excessive Narcotics in our Retirement Communities Protection Act of 2018” or the “SENIOR Communities Protection Act of 2018”.

SEC. 2. SUSPENSION OF PAYMENTS BY MEDICARE PRESCRIPTION DRUG PLANS AND MA-PD PLANS PENDING INVESTIGATIONS OF CREDIBLE ALLEGATIONS OF FRAUD BY PHARMACIES.

(a) **IN GENERAL.**—Section 1860D–12(b) of the Social Security Act (42 U.S.C. 1395w–112(b)) is amended by adding at the end the following new paragraph:

“(7) **SUSPENSION OF PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD BY PHARMACIES.**—

“(A) **IN GENERAL.**—The provisions of section 1862(o) shall apply with respect to a PDP sponsor with a contract under this part, a pharmacy, and payments to such pharmacy under this part in the same manner as such provisions apply with respect to the Secretary, a provider of services or supplier, and payments to such provider of services or supplier under this title.

“(B) **RULE OF CONSTRUCTION.**—Nothing in this paragraph shall be construed as limiting the authority of a PDP sponsor to conduct postpayment review.”.

(b) **APPLICATION TO MA–PD PLANS.**—Section 1857(f)(3) of the Social Security Act (42 U.S.C. 1395w–27(f)(3)) is amended by adding at the end the following new subparagraph:

“(D) **SUSPENSION OF PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD BY PHARMACIES.**—Section 1860D–12(b)(7).”.

(c) **CONFORMING AMENDMENT.**—Section 1862(o)(3) of the Social Security Act (42 U.S.C. 1395y(o)(3)) is amended by inserting “, section 1860D–12(b)(7) (including as applied pursuant to section 1857(f)(3)(D)),” after “this subsection”.

(d) **CLARIFICATION RELATING TO CREDIBLE ALLEGATION OF FRAUD.**—Section 1862(o) of the Social Security Act (42 U.S.C. 1395y(o)) is amended by adding at the end the following new paragraph:

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

(e) **EFFECTIVE DATE.**—The amendments made by this section shall apply with respect to plan years beginning on or after January 1, 2020.

I. SUMMARY AND BACKGROUND

A. PURPOSE AND SUMMARY

The bill, H.R. 5676, the Stop Excessive Narcotics in our Retirement (SENIOR) Communities Protection Act of 2018, as ordered reported by the Committee on Ways and Means on May 16, 2018, grants the Part D prescription drug plans the authority to suspend payments to a provider or supplier pending an investigation of a credible allegation of fraud against the provider or supplier.

B. BACKGROUND AND NEED FOR LEGISLATION

Currently, the Secretary of the Department of Health and Human Services (HHS) has the authority to suspend payments to a provider or supplier pending an investigation of a credible allegation of fraud against the provider or supplier. The Secretary is required to consult with the Inspector General of HHS in determining whether there is a credible allegation of fraud against a

provider of services or a supplier. However, this authority is not provided to Medicare Advantage and Prescription Drug Plans.

C. LEGISLATIVE HISTORY

Background

H.R. 5676 was introduced on May 3, 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 dependence in Medicare.

On April 12, 2018, the Subcommittee on Human Resources held a hearing on local perspective 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. 5676, the Stop Excessive Narcotics in our Retirement (SENIOR) Communities Protection Act of 2018, on May 16, 2018, and ordered the bill, as amended, favorably reported (with a quorum being present).

II. EXPLANATION OF THE BILL

A. STOP EXCESSIVE NARCOTICS IN OUR RETIREMENT COMMUNITIES PROTECTION ACT OF 2018

PRESENT LAW

Section 1862(o) of the Social Security Act grants the Secretary of the Department of Health and Human Services (HHS) the authority to suspend payments to a provider or supplier pending an investigation of a credible allegation of fraud against the provider or supplier.

REASONS FOR CHANGE

This bill extends the authority of Medicare Advantage and Prescription Drug Plans, in the same manner already provided to HHS under Medicare Fee-for-Service, to suspend payments pending credible allegations of fraud.

EXPLANATION OF PROVISIONS

Section 1: Short Title: “Stop Excessive Narcotics in our Retirement (SENIOR) Communities Protection Act of 2018.”

Section 2: Suspension of Payments by Medicare Prescription Drug Plans and MA–PD Plans Pending Investigations of Credible Allegations of Fraud by Pharmacies.

Applies provisions of Section 1862(o) of the Social Security Act to a Prescription Drug Plan sponsor in the same manner as such provisions apply to the Secretary of the Department of Health and Human Services (HHS).

Rule of Construction: Nothing in this bill should be construed as limiting the authority of a Prescription Drug Plan sponsor to conduct post-payment review.

Clarification Relating to Credible Allegations of Fraud: A fraud hotline tip is not considered as sufficient evidence for a credible allegation of fraud unless further evidence is provided.

Effective Date: Beginning on or after January 1, 2020.

EFFECTIVE DATE

Effective Date: Beginning on or after January 1, 2020.

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. 5676, the SENIOR Communities Protection 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. 5676, 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. 5676, 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

	By fiscal year, in millions of dollars—												
	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2019– 2023	2019– 2028
INCREASES OR DECREASES (–) IN DIRECT SPENDING													
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	–1	–4	–9
Outlays	0	0	–1	–1	–1	–1	–1	–1	–1	–1	–1	–4	–9
H.R. 5773, Preventing Addiction for Susceptible Seniors Act of 2018: ^a													
Budget Authority	0	0	0	–6	–7	–7	–7	–8	–9	–9	–11	–20	–64
Outlays	0	0	0	–6	–7	–7	–7	–8	–9	–9	–11	–20	–64
H.R. 5776, the Medicare and Opioid Safe Treatment Act of 2018: ^a													
Budget Authority	0	8	0	20	20	25	30	30	35	35	40	73	243
Outlays	0	2	4	22	20	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

^aThis 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.¹ 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 appropriation; 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 authorization 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, revenues, 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 affect 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

	By fiscal year, in millions of dollars—						
	2018	2019	2020	2021	2022	2023	2019–2023
INCREASES IN SPENDING SUBJECT TO APPROPRIATION							
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

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
H.R. 5776, Medicare and Opioid Safe Treatment Act of 2018: ^a							
Estimated Authorization Level	0	1	0	0	0	0	1
Estimated Outlays	0	1	0	0	0	0	1
H.R. 5788, Securing the International Mail Against Opioids Act of 2018: ^a							
Estimated Authorization Level	0	100	0	0	0	0	100
Estimated Outlays	0	40	40	20	0	0	100

Annual amounts may not sum to totals because of rounding. * = between zero and \$500,000

^aThis 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.

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.

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 beginning 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 private-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 same.

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 estimate:

- 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. 4841.
- 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. 5716.

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 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 C—MEDICARE+CHOICE PROGRAM

* * * * *

CONTRACTS WITH MEDICARE+CHOICE ORGANIZATIONS

SEC. 1857. (a) IN GENERAL.—The Secretary shall not permit the election under section 1851 of a Medicare+Choice plan offered by a Medicare+Choice organization under this part, and no payment shall be made under section 1853 to an organization, unless the Secretary has entered into a contract under this section with the organization with respect to the offering of such plan. Such a contract with an organization may cover more than 1 Medicare+Choice plan. Such contract shall provide that the organization agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

(b) MINIMUM ENROLLMENT REQUIREMENTS.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary may not enter into a contract under this section with a Medicare+Choice organization unless the organization has—

(A) at least 5,000 individuals (or 1,500 individuals in the case of an organization that is a provider-sponsored organization) who are receiving health benefits through the organization, or

(B) at least 1,500 individuals (or 500 individuals in the case of an organization that is a provider-sponsored organization) who are receiving health benefits through the organization if the organization primarily serves individuals residing outside of urbanized areas.

(2) APPLICATION TO MSA PLANS.—In applying paragraph (1) in the case of a Medicare+Choice organization that is offering

an MSA plan, paragraph (1) shall be applied by substituting covered lives for individuals.

(3) ALLOWING TRANSITION.—The Secretary may waive the requirement of paragraph (1) during the first 3 contract years with respect to an organization.

(c) CONTRACT PERIOD AND EFFECTIVENESS.—

(1) PERIOD.—Each contract under this section shall be for a term of at least 1 year, as determined by the Secretary, and may be made automatically renewable from term to term in the absence of notice by either party of intention to terminate at the end of the current term.

(2) TERMINATION AUTHORITY.—In accordance with procedures established under subsection (h), the Secretary may at any time terminate any such contract if the Secretary determines that the organization—

(A) has failed substantially to carry out the contract;

(B) is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part; or

(C) no longer substantially meets the applicable conditions of this part.

(3) EFFECTIVE DATE OF CONTRACTS.—The effective date of any contract executed pursuant to this section shall be specified in the contract, except that in no case shall a contract under this section which provides for coverage under an MSA plan be effective before January 1999 with respect to such coverage.

(4) PREVIOUS TERMINATIONS.—

(A) IN GENERAL.—The Secretary may not enter into a contract with a Medicare+Choice organization if a previous contract with that organization under this section was terminated at the request of the organization within the preceding 2-year period, except as provided in subparagraph (B) and except in such other circumstances which warrant special consideration, as determined by the Secretary.

(B) EARLIER RE-ENTRY PERMITTED WHERE CHANGE IN PAYMENT POLICY.—Subparagraph (A) shall not apply with respect to the offering by a Medicare+Choice organization of a Medicare+Choice plan in a Medicare+Choice payment area if during the 6-month period beginning on the date the organization notified the Secretary of the intention to terminate the most recent previous contract, there was a legislative change enacted (or a regulatory change adopted) that has the effect of increasing payment amounts under section 1853 for that Medicare+Choice payment area.

(5) CONTRACTING AUTHORITY.—The authority vested in the Secretary by this part may be performed without regard to such provisions of law or regulations relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the furtherance of the purpose of this title.

(d) PROTECTIONS AGAINST FRAUD AND BENEFICIARY PROTECTIONS.—

(1) PERIODIC AUDITING.—The Secretary shall provide for the annual auditing of the financial records (including data relating to medicare utilization and costs, including allowable costs under section 1858(c)) of at least one-third of the Medicare+Choice organizations offering Medicare+Choice plans under this part. The Comptroller General shall monitor auditing activities conducted under this subsection.

(2) INSPECTION AND AUDIT.—Each contract under this section shall provide that the Secretary, or any person or organization designated by the Secretary—

(A) shall have the right to timely inspect or otherwise evaluate (i) the quality, appropriateness, and timeliness of services performed under the contract, and (ii) the facilities of the organization when there is reasonable evidence of some need for such inspection, and

(B) shall have the right to timely audit and inspect any books and records of the Medicare+Choice organization that pertain (i) to the ability of the organization to bear the risk of potential financial losses, or (ii) to services performed or determinations of amounts payable under the contract.

(3) ENROLLEE NOTICE AT TIME OF TERMINATION.—Each contract under this section shall require the organization to provide (and pay for) written notice in advance of the contract's termination, as well as a description of alternatives for obtaining benefits under this title, to each individual enrolled with the organization under this part.

(4) DISCLOSURE.—

(A) IN GENERAL.—Each Medicare+Choice organization shall, in accordance with regulations of the Secretary, report to the Secretary financial information which shall include the following:

(i) Such information as the Secretary may require demonstrating that the organization has a fiscally sound operation.

(ii) A copy of the report, if any, filed with the Secretary containing the information required to be reported under section 1124 by disclosing entities.

(iii) A description of transactions, as specified by the Secretary, between the organization and a party in interest. Such transactions shall include—

(I) any sale or exchange, or leasing of any property between the organization and a party in interest;

(II) any furnishing for consideration of goods, services (including management services), or facilities between the organization and a party in interest, but not including salaries paid to employees for services provided in the normal course of their employment and health services provided to members by hospitals and other providers and by staff, medical group (or groups), individual practice association (or associations), or any combination thereof; and

(III) any lending of money or other extension of credit between an organization and a party in interest.

The Secretary may require that information reported respecting an organization which controls, is controlled by, or is under common control with, another entity be in the form of a consolidated financial statement for the organization and such entity.

(B) PARTY IN INTEREST DEFINED.—For the purposes of this paragraph, the term “party in interest” means—

(i) any director, officer, partner, or employee responsible for management or administration of a Medicare+Choice organization, any person who is directly or indirectly the beneficial owner of more than 5 percent of the equity of the organization, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 percent of the organization, and, in the case of a Medicare+Choice organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law;

(ii) any entity in which a person described in clause (i)—

(I) is an officer or director;

(II) is a partner (if such entity is organized as a partnership);

(III) has directly or indirectly a beneficial interest of more than 5 percent of the equity; or

(IV) has a mortgage, deed of trust, note, or other interest valuing more than 5 percent of the assets of such entity;

(iii) any person directly or indirectly controlling, controlled by, or under common control with an organization; and

(iv) any spouse, child, or parent of an individual described in clause (i).

(C) ACCESS TO INFORMATION.—Each Medicare+Choice organization shall make the information reported pursuant to subparagraph (A) available to its enrollees upon reasonable request.

(5) LOAN INFORMATION.—The contract shall require the organization to notify the Secretary of loans and other special financial arrangements which are made between the organization and subcontractors, affiliates, and related parties.

(6) REVIEW TO ENSURE COMPLIANCE WITH CARE MANAGEMENT REQUIREMENTS FOR SPECIALIZED MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS INDIVIDUALS.—In conjunction with the periodic audit of a specialized Medicare Advantage plan for special needs individuals under paragraph (1), the Secretary shall conduct a review to ensure that such organization offering the plan meets the requirements described in section 1859(f)(5).

(e) ADDITIONAL CONTRACT TERMS.—

(1) IN GENERAL.—The contract shall contain such other terms and conditions not inconsistent with this part (including

requiring the organization to provide the Secretary with such information) as the Secretary may find necessary and appropriate.

(2) COST-SHARING IN ENROLLMENT-RELATED COSTS.—

(A) IN GENERAL.—A Medicare+Choice organization and a PDP sponsor under part D shall pay the fee established by the Secretary under subparagraph (B).

(B) AUTHORIZATION.—The Secretary is authorized to charge a fee to each Medicare+Choice organization with a contract under this part and each PDP sponsor with a contract under part D that is equal to the organization' or sponsor's pro rata share (as determined by the Secretary) of the aggregate amount of fees which the Secretary is directed to collect in a fiscal year. Any amounts collected shall be available without further appropriation to the Secretary for the purpose of carrying out section 1851 (relating to enrollment and dissemination of information), section 1860D-1(c), and section 4360 of the Omnibus Budget Reconciliation Act of 1990 (relating to the health insurance counseling and assistance program).

(C) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for the purposes described in subparagraph (B) for each fiscal year beginning with fiscal year 2001 and ending with fiscal year 2005 an amount equal to \$100,000,000, and for each fiscal year beginning with fiscal year 2006 an amount equal to \$200,000,000, reduced by the amount of fees authorized to be collected under this paragraph and section 1860D-12(b)(3)(D) for the fiscal year.

(D) LIMITATION.—In any fiscal year the fees collected by the Secretary under subparagraph (B) shall not exceed the lesser of—

(i) the estimated costs to be incurred by the Secretary in the fiscal year in carrying out the activities described in section 1851 and section 1860D-1(c) and section 4360 of the Omnibus Budget Reconciliation Act of 1990; or

(ii)(I) \$200,000,000 in fiscal year 1998;

(II) \$150,000,000 in fiscal year 1999;

(III) \$100,000,000 in fiscal year 2000;

(IV) the Medicare+Choice portion (as defined in subparagraph (E)) of \$100,000,000 in fiscal year 2001 and each succeeding fiscal year before fiscal year 2006; and

(V) the applicable portion (as defined in subparagraph (F)) of \$200,000,000 in fiscal year 2006 and each succeeding fiscal year.

(E) MEDICARE+CHOICE PORTION DEFINED.—In this paragraph, the term "Medicare+Choice portion" means, for a fiscal year, the ratio, as estimated by the Secretary, of—

(i) the average number of individuals enrolled in Medicare+Choice plans during the fiscal year, to

(ii) the average number of individuals entitled to benefits under part A, and enrolled under part B, during the fiscal year.

(F) APPLICABLE PORTION DEFINED.—In this paragraph, the term “applicable portion” means, for a fiscal year—

(i) with respect to MA organizations, the Secretary’s estimate of the total proportion of expenditures under this title that are attributable to expenditures made under this part (including payments under part D that are made to such organizations); or

(ii) with respect to PDP sponsors, the Secretary’s estimate of the total proportion of expenditures under this title that are attributable to expenditures made to such sponsors under part D.

(3) AGREEMENTS WITH FEDERALLY QUALIFIED HEALTH CENTERS.—

(A) PAYMENT LEVELS AND AMOUNTS.—A contract under this section with an MA organization shall require the organization to provide, in any written agreement described in section 1853(a)(4) between the organization and a federally qualified health center, for a level and amount of payment to the federally qualified health center for services provided by such health center that is not less than the level and amount of payment that the plan would make for such services if the services had been furnished by a entity providing similar services that was not a federally qualified health center.

(B) COST-SHARING.—Under the written agreement referred to in subparagraph (A), a federally qualified health center must accept the payment amount referred to in such subparagraph plus the Federal payment provided for in section 1833(a)(3)(B) as payment in full for services covered by the agreement, except that such a health center may collect any amount of cost-sharing permitted under the contract under this section, so long as the amounts of any deductible, coinsurance, or copayment comply with the requirements under section 1854(e).

(4) REQUIREMENT FOR MINIMUM MEDICAL LOSS RATIO.—If the Secretary determines for a contract year (beginning with 2014) that an MA plan has failed to have a medical loss ratio of at least .85—

(A) the MA plan shall remit to the Secretary an amount equal to the product of—

(i) the total revenue of the MA plan under this part for the contract year; and

(ii) the difference between .85 and the medical loss ratio;

(B) for 3 consecutive contract years, the Secretary shall not permit the enrollment of new enrollees under the plan for coverage during the second succeeding contract year; and

(C) the Secretary shall terminate the plan contract if the plan fails to have such a medical loss ratio for 5 consecutive contract years.

(f) PROMPT PAYMENT BY MEDICARE+CHOICE ORGANIZATION.—

(1) REQUIREMENT.—A contract under this part shall require a Medicare+Choice organization to provide prompt payment (consistent with the provisions of sections 1816(c)(2) and

1842(c)(2)) of claims submitted for services and supplies furnished to enrollees pursuant to the contract, if the services or supplies are not furnished under a contract between the organization and the provider or supplier (or in the case of a Medicare+Choice private fee-for-service plan, if a claim is submitted to such organization by an enrollee).

(2) SECRETARY'S OPTION TO BYPASS NONCOMPLYING ORGANIZATION.—In the case of a Medicare+Choice eligible organization which the Secretary determines, after notice and opportunity for a hearing, has failed to make payments of amounts in compliance with paragraph (1), the Secretary may provide for direct payment of the amounts owed to providers and suppliers (or, in the case of a Medicare+Choice private fee-for-service plan, amounts owed to the enrollees) for covered services and supplies furnished to individuals enrolled under this part under the contract. If the Secretary provides for the direct payments, the Secretary shall provide for an appropriate reduction in the amount of payments otherwise made to the organization under this part to reflect the amount of the Secretary's payments (and the Secretary's costs in making the payments).

(3) INCORPORATION OF CERTAIN PRESCRIPTION DRUG PLAN CONTRACT REQUIREMENTS.—The following provisions shall apply to contracts with a Medicare Advantage organization offering an MA-PD plan in the same manner as they apply to contracts with a PDP sponsor offering a prescription drug plan under part D:

(A) PROMPT PAYMENT.—Section 1860D-12(b)(4).

(B) SUBMISSION OF CLAIMS BY PHARMACIES LOCATED IN OR CONTRACTING WITH LONG-TERM CARE FACILITIES.—Section 1860D-12(b)(5).

(C) REGULAR UPDATE OF PRESCRIPTION DRUG PRICING STANDARD.—Section 1860D-12(b)(6).

(D) *SUSPENSION OF PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD BY PHARMACIES.*—Section 1860D-12(b)(7).

(g) INTERMEDIATE SANCTIONS.—

(1) IN GENERAL.—If the Secretary determines that a Medicare+Choice organization with a contract under this section—

(A) fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(B) imposes premiums on individuals enrolled under this part in excess of the amount of the Medicare+Choice monthly basic and supplemental beneficiary premiums permitted under section 1854;

(C) acts to expel or to refuse to re-enroll an individual in violation of the provisions of this part;

(D) engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or his-

tory indicates a need for substantial future medical services;

(E) misrepresents or falsifies information that is furnished—

(i) to the Secretary under this part, or

(ii) to an individual or to any other entity under this part;

(F) fails to comply with the applicable requirements of section 1852(j)(3) or 1852(k)(2)(A)(ii);

(G) employs or contracts with any individual or entity that is excluded from participation under this title under section 1128 or 1128A for the provision of health care, utilization review, medical social work, or administrative services or employs or contracts with any entity for the provision (directly or indirectly) through such an excluded individual or entity of such services;

(H) except as provided under subparagraph (C) or (D) of section 1860D-1(b)(1), enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual;

(I) transfers an individual enrolled under this part from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission;

(J) fails to comply with marketing restrictions described in subsections (h) and (j) of section 1851 or applicable implementing regulations or guidance; or

(K) employs or contracts with any individual or entity who engages in the conduct described in subparagraphs (A) through (J) of this paragraph;

the Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in paragraph (2). The Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in paragraph (2), if the Secretary determines that any employee or agent of such organization, or any provider or supplier who contracts with such organization, has engaged in any conduct described in subparagraphs (A) through (K) of this paragraph.

(2) REMEDIES.—The remedies described in this paragraph are—

(A) civil money penalties of not more than \$25,000 for each determination under paragraph (1) or, with respect to a determination under subparagraph (D) or (E)(i) of such paragraph, of not more than \$100,000 for each such determination, except with respect to a determination under subparagraph (E), an assessment of not more than the amount claimed by such plan or plan sponsor based upon the misrepresentation or falsified information involved, plus, with respect to a determination under paragraph (1)(B), double the excess amount charged in violation of such paragraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and plus, with respect to a determination

under paragraph (1)(D), \$15,000 for each individual not enrolled as a result of the practice involved,

(B) suspension of enrollment of individuals under this part after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur, or

(C) suspension of payment to the organization under this part for individuals enrolled after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur.

(3) OTHER INTERMEDIATE SANCTIONS.—In the case of a Medicare+Choice organization for which the Secretary makes a determination under subsection (c)(2) the basis of which is not described in paragraph (1), the Secretary may apply the following intermediate sanctions:

(A) Civil money penalties of not more than \$25,000 for each determination under subsection (c)(2) if the deficiency that is the basis of the determination has directly adversely affected (or has the substantial likelihood of adversely affecting) an individual covered under the organization's contract.

(B) Civil money penalties of not more than \$10,000 for each week beginning after the initiation of civil money penalty procedures by the Secretary during which the deficiency that is the basis of a determination under subsection (c)(2) exists.

(C) Suspension of enrollment of individuals under this part after the date the Secretary notifies the organization of a determination under subsection (c)(2) and until the Secretary is satisfied that the deficiency that is the basis for the determination has been corrected and is not likely to recur.

(D) Civil monetary penalties of not more than \$100,000, or such higher amount as the Secretary may establish by regulation, where the finding under subsection (c)(2)(A) is based on the organization's termination of its contract under this section other than at a time and in a manner provided for under subsection (a).

(4) CIVIL MONEY PENALTIES.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under paragraph (2) or (3) in the same manner as they apply to a civil money penalty or proceeding under section 1128A(a).

(h) PROCEDURES FOR TERMINATION.—

(1) IN GENERAL.—The Secretary may terminate a contract with a Medicare+Choice organization under this section in accordance with formal investigation and compliance procedures established by the Secretary under which—

(A) the Secretary provides the organization with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis

of the Secretary’s determination under subsection (c)(2); and

(B) the Secretary provides the organization with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before terminating the contract.

(2) EXCEPTION FOR IMMINENT AND SERIOUS RISK TO HEALTH.—Paragraph (1) shall not apply if the Secretary determines that a delay in termination, resulting from compliance with the procedures specified in such paragraph prior to termination, would pose an imminent and serious risk to the health of individuals enrolled under this part with the organization.

(3) DELAY IN CONTRACT TERMINATION AUTHORITY FOR PLANS FAILING TO ACHIEVE MINIMUM QUALITY RATING.—During the period beginning on the date of the enactment of this paragraph and through the end of plan year 2018, the Secretary may not terminate a contract under this section with respect to the offering of an MA plan by a Medicare Advantage organization solely because the MA plan has failed to achieve a minimum quality rating under the 5-star rating system under section 1853(o)(4).

(i) MEDICARE+CHOICE PROGRAM COMPATIBILITY WITH EMPLOYER OR UNION GROUP HEALTH PLANS.—

(1) CONTRACTS WITH MA ORGANIZATIONS.—To facilitate the offering of Medicare+Choice plans under contracts between Medicare+Choice organizations and employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity’s employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in such Medicare+Choice plans.

(2) EMPLOYER SPONSORED MA PLANS.—To facilitate the offering of MA plans by employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity’s employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in such MA plans. Notwithstanding section 1851(g), an MA plan described in the previous sentence may restrict the enrollment of individuals under this part to individuals who are beneficiaries and participants in such plan.

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PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

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Subpart 2—Prescription Drug Plans; PDP Sponsors; Financing

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REQUIREMENTS FOR AND CONTRACTS WITH PRESCRIPTION DRUG PLAN
(PDP) SPONSORS

SEC. 1860D-12. (a) GENERAL REQUIREMENTS.—Each PDP sponsor of a prescription drug plan shall meet the following requirements:

(1) LICENSURE.—Subject to subsection (c), the sponsor is organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan.

(2) ASSUMPTION OF FINANCIAL RISK FOR UNSUBSIDIZED COVERAGE.—

(A) IN GENERAL.—Subject to subparagraph (B), to the extent that the entity is at risk the entity assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under section 1860D-15(b).

(B) REINSURANCE PERMITTED.—The plan sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing such coverage.

(3) SOLVENCY FOR UNLICENSED SPONSORS.—In the case of a PDP sponsor that is not described in paragraph (1) and for which a waiver has been approved under subsection (c), such sponsor shall meet solvency standards established by the Secretary under subsection (d).

(b) CONTRACT REQUIREMENTS.—

(1) IN GENERAL.—The Secretary shall not permit the enrollment under section 1860D-1 in a prescription drug plan offered by a PDP sponsor under this part, and the sponsor shall not be eligible for payments under section 1860D-14 or 1860D-15, unless the Secretary has entered into a contract under this subsection with the sponsor with respect to the offering of such plan. Such a contract with a sponsor may cover more than one prescription drug plan. Such contract shall provide that the sponsor agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

(2) LIMITATION ON ENTITIES OFFERING FALLBACK PRESCRIPTION DRUG PLANS.—The Secretary shall not enter into a contract with a PDP sponsor for the offering of a prescription drug plan (other than a fallback prescription drug plan) in a PDP region for a year if the sponsor—

(A) submitted a bid under section 1860D-11(g) for such year (as the first year of a contract period under such section) to offer a fallback prescription drug plan in any PDP region;

(B) offers a fallback prescription drug plan in any PDP region during the year; or

(C) offered a fallback prescription drug plan in that PDP region during the previous year.

For purposes of this paragraph, an entity shall be treated as submitting a bid with respect to a prescription drug plan or offering a fallback prescription drug plan if the entity is acting as a subcontractor of a PDP sponsor that is offering such a

plan. The previous sentence shall not apply to entities that are subcontractors of an MA organization except insofar as such organization is acting as a PDP sponsor with respect to a prescription drug plan.

(3) INCORPORATION OF CERTAIN MEDICARE ADVANTAGE CONTRACT REQUIREMENTS.—Except as otherwise provided, the following provisions of section 1857 shall apply to contracts under this section in the same manner as they apply to contracts under section 1857(a):

(A) MINIMUM ENROLLMENT.—Paragraphs (1) and (3) of section 1857(b), except that—

(i) the Secretary may increase the minimum number of enrollees required under such paragraph (1) as the Secretary determines appropriate; and

(ii) the requirement of such paragraph (1) shall be waived during the first contract year with respect to an organization in a region.

(B) CONTRACT PERIOD AND EFFECTIVENESS.—Section 1857(c), except that in applying paragraph (4)(B) of such section any reference to payment amounts under section 1853 shall be deemed payment amounts under section 1860D–15.

(C) PROTECTIONS AGAINST FRAUD AND BENEFICIARY PROTECTIONS.—Section 1857(d).

(D) ADDITIONAL CONTRACT TERMS.—Section 1857(e); except that section 1857(e)(2) shall apply as specified to PDP sponsors and payments under this part to an MA–PD plan shall be treated as expenditures made under part D. Notwithstanding any other provision of law, information provided to the Secretary under the application of section 1857(e)(1) to contracts under this section under the preceding sentence—

(i) may be used for the purposes of carrying out this part, improving public health through research on the utilization, safety, effectiveness, quality, and efficiency of health care services (as the Secretary determines appropriate); and

(ii) shall be made available to Congressional support agencies (in accordance with their obligations to support Congress as set out in their authorizing statutes) for the purposes of conducting Congressional oversight, monitoring, making recommendations, and analysis of the program under this title.

(E) INTERMEDIATE SANCTIONS.—Section 1857(g) (other than paragraph (1)(F) of such section), except that in applying such section the reference in section 1857(g)(1)(B) to section 1854 is deemed a reference to this part.

(F) PROCEDURES FOR TERMINATION.—Section 1857(h).

(4) PROMPT PAYMENT OF CLEAN CLAIMS.—

(A) PROMPT PAYMENT.—

(i) IN GENERAL.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to all clean claims sub-

mitted by pharmacies (other than pharmacies that dispense drugs by mail order only or are located in, or contract with, a long-term care facility) under this part within the applicable number of calendar days after the date on which the claim is received.

(ii) CLEAN CLAIM DEFINED.—In this paragraph, the term “clean claim” means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this part.

(iii) DATE OF RECEIPT OF CLAIM.—In this paragraph, a claim is considered to have been received—

(I) with respect to claims submitted electronically, on the date on which the claim is transferred; and

(II) with respect to claims submitted otherwise, on the 5th day after the postmark date of the claim or the date specified in the time stamp of the transmission.

(B) APPLICABLE NUMBER OF CALENDAR DAYS DEFINED.—In this paragraph, the term “applicable number of calendar days” means—

(i) with respect to claims submitted electronically, 14 days; and

(ii) with respect to claims submitted otherwise, 30 days.

(C) INTEREST PAYMENT.—

(i) IN GENERAL.—Subject to clause (ii), if payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days (as defined in subparagraph (B)) after a clean claim is received, the PDP sponsor shall pay interest to the pharmacy that submitted the claim at a rate equal to the weighted average of interest on 3-month marketable Treasury securities determined for such period, increased by 0.1 percentage point for the period beginning on the day after the required payment date and ending on the date on which payment is made (as determined under subparagraph (D)(iv)). Interest amounts paid under this subparagraph shall not be counted against the administrative costs of a prescription drug plan or treated as allowable risk corridor costs under section 1860D–15(e).

(ii) AUTHORITY NOT TO CHARGE INTEREST.—The Secretary may provide that a PDP sponsor is not charged interest under clause (i) in the case where there are exigent circumstances, including natural disasters and other unique and unexpected events, that prevent the timely processing of claims.

(D) PROCEDURES INVOLVING CLAIMS.—

(i) CLAIM DEEMED TO BE CLEAN.—A claim is deemed to be a clean claim if the PDP sponsor involved does not provide notice to the claimant of any deficiency in the claim—

(I) with respect to claims submitted electronically, within 10 days after the date on which the claim is received; and

(II) with respect to claims submitted otherwise, within 15 days after the date on which the claim is received.

(ii) CLAIM DETERMINED TO NOT BE A CLEAN CLAIM.—

(I) IN GENERAL.—If a PDP sponsor determines that a submitted claim is not a clean claim, the PDP sponsor shall, not later than the end of the period described in clause (i), notify the claimant of such determination. Such notification shall specify all defects or improprieties in the claim and shall list all additional information or documents necessary for the proper processing and payment of the claim.

(II) DETERMINATION AFTER SUBMISSION OF ADDITIONAL INFORMATION.—A claim is deemed to be a clean claim under this paragraph if the PDP sponsor involved does not provide notice to the claimant of any defect or impropriety in the claim within 10 days of the date on which additional information is received under subclause (I).

(iii) OBLIGATION TO PAY.—A claim submitted to a PDP sponsor that is not paid or contested by the sponsor within the applicable number of days (as defined in subparagraph (B)) after the date on which the claim is received shall be deemed to be a clean claim and shall be paid by the PDP sponsor in accordance with subparagraph (A).

(iv) DATE OF PAYMENT OF CLAIM.—Payment of a clean claim under such subparagraph is considered to have been made on the date on which—

(I) with respect to claims paid electronically, the payment is transferred; and

(II) with respect to claims paid otherwise, the payment is submitted to the United States Postal Service or common carrier for delivery.

(E) ELECTRONIC TRANSFER OF FUNDS.—A PDP sponsor shall pay all clean claims submitted electronically by electronic transfer of funds if the pharmacy so requests or has so requested previously. In the case where such payment is made electronically, remittance may be made by the PDP sponsor electronically as well.

(F) PROTECTING THE RIGHTS OF CLAIMANTS.—

(i) IN GENERAL.—Nothing in this paragraph shall be construed to prohibit or limit a claim or action not covered by the subject matter of this section that any individual or organization has against a provider or a PDP sponsor.

(ii) ANTI-RETALIATION.—Consistent with applicable Federal or State law, a PDP sponsor shall not retaliate against an individual or provider for exercising a right of action under this subparagraph.

(G) **RULE OF CONSTRUCTION.**—A determination under this paragraph that a claim submitted by a pharmacy is a clean claim shall not be construed as a positive determination regarding eligibility for payment under this title, nor is it an indication of government approval of, or acquiescence regarding, the claim submitted. The determination shall not relieve any party of civil or criminal liability with respect to the claim, nor does it offer a defense to any administrative, civil, or criminal action with respect to the claim.

(5) **SUBMISSION OF CLAIMS BY PHARMACIES LOCATED IN OR CONTRACTING WITH LONG-TERM CARE FACILITIES.**—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that a pharmacy located in, or having a contract with, a long-term care facility shall have not less than 30 days (but not more than 90 days) to submit claims to the sponsor for reimbursement under the plan.

(6) **REGULAR UPDATE OF PRESCRIPTION DRUG PRICING STANDARD.**—If the PDP sponsor of a prescription drug plan uses a standard for reimbursement of pharmacies based on the cost of a drug, each contract entered into with such sponsor under this part with respect to the plan shall provide that the sponsor shall update such standard not less frequently than once every 7 days, beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug.

(7) **SUSPENSION OF PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD BY PHARMACIES.**—

(A) **IN GENERAL.**—*The provisions of section 1862(o) shall apply with respect to a PDP sponsor with a contract under this part, a pharmacy, and payments to such pharmacy under this part in the same manner as such provisions apply with respect to the Secretary, a provider of services or supplier, and payments to such provider of services or supplier under this title.*

(B) **RULE OF CONSTRUCTION.**—*Nothing in this paragraph shall be construed as limiting the authority of a PDP sponsor to conduct postpayment review.*

(c) **WAIVER OF CERTAIN REQUIREMENTS TO EXPAND CHOICE.**—

(1) **AUTHORIZING WAIVER.**—

(A) **IN GENERAL.**—In the case of an entity that seeks to offer a prescription drug plan in a State, the Secretary shall waive the requirement of subsection (a)(1) that the entity be licensed in that State if the Secretary determines, based on the application and other evidence presented to the Secretary, that any of the grounds for approval of the application described in paragraph (2) have been met.

(B) **APPLICATION OF REGIONAL PLAN WAIVER RULE.**—In addition to the waiver available under subparagraph (A), the provisions of section 1858(d) shall apply to PDP sponsors under this part in a manner similar to the manner in which such provisions apply to MA organizations under part C, except that no application shall be required under

- paragraph (1)(B) of such section in the case of a State that does not provide a licensing process for such a sponsor.
- (2) GROUNDS FOR APPROVAL.—
- (A) IN GENERAL.—The grounds for approval under this paragraph are—
- (i) subject to subparagraph (B), the grounds for approval described in subparagraphs (B), (C), and (D) of section 1855(a)(2); and
 - (ii) the application by a State of any grounds other than those required under Federal law.
- (B) SPECIAL RULES.—In applying subparagraph (A)(i)—
- (i) the ground of approval described in section 1855(a)(2)(B) is deemed to have been met if the State does not have a licensing process in effect with respect to the PDP sponsor; and
 - (ii) for plan years beginning before January 1, 2008, if the State does have such a licensing process in effect, such ground for approval described in such section is deemed to have been met upon submission of an application described in such section.
- (3) APPLICATION OF WAIVER PROCEDURES.—With respect to an application for a waiver (or a waiver granted) under paragraph (1)(A) of this subsection, the provisions of subparagraphs (E), (F), and (G) of section 1855(a)(2) shall apply, except that clauses (i) and (ii) of such subparagraph (E) shall not apply in the case of a State that does not have a licensing process described in paragraph (2)(B)(i) in effect.
- (4) REFERENCES TO CERTAIN PROVISIONS.—In applying provisions of section 1855(a)(2) under paragraphs (2) and (3) of this subsection to prescription drug plans and PDP sponsors—
- (A) any reference to a waiver application under section 1855 shall be treated as a reference to a waiver application under paragraph (1)(A) of this subsection; and
 - (B) any reference to solvency standards shall be treated as a reference to solvency standards established under subsection (d) of this section.
- (d) SOLVENCY STANDARDS FOR NON-LICENSED ENTITIES.—
- (1) ESTABLISHMENT AND PUBLICATION.—The Secretary, in consultation with the National Association of Insurance Commissioners, shall establish and publish, by not later than January 1, 2005, financial solvency and capital adequacy standards for entities described in paragraph (2).
 - (2) COMPLIANCE WITH STANDARDS.—A PDP sponsor that is not licensed by a State under subsection (a)(1) and for which a waiver application has been approved under subsection (c) shall meet solvency and capital adequacy standards established under paragraph (1). The Secretary shall establish certification procedures for such sponsors with respect to such solvency standards in the manner described in section 1855(c)(2).
- (e) LICENSURE DOES NOT SUBSTITUTE FOR OR CONSTITUTE CERTIFICATION.—The fact that a PDP sponsor is licensed in accordance with subsection (a)(1) or has a waiver application approved under subsection (c) does not deem the sponsor to meet other requirements imposed under this part for a sponsor.
- (f) PERIODIC REVIEW AND REVISION OF STANDARDS.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary may periodically review the standards established under this section and, based on such review, may revise such standards if the Secretary determines such revision to be appropriate.

(2) PROHIBITION OF MIDYEAR IMPLEMENTATION OF SIGNIFICANT NEW REGULATORY REQUIREMENTS.—The Secretary may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

(g) PROHIBITION OF STATE IMPOSITION OF PREMIUM TAXES; RELATION TO STATE LAWS.—The provisions of sections 1854(g) and 1856(b)(3) shall apply with respect to PDP sponsors and prescription drug plans under this part in the same manner as such sections apply to MA organizations and MA plans under part C.

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PART E—MISCELLANEOUS PROVISIONS

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EXCLUSIONS FROM COVERAGE AND MEDICARE AS SECONDARY PAYER

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(13) where such expenses are for—

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

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

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

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

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

use of such an assistant in the surgical procedure based on the existence of a complicating medical condition, or

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

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

(17) where the expenses are for an item or service furnished in a competitive acquisition area (as established by the Secretary under section 1847(a)) by an entity other than an entity with which the Secretary has entered into a contract under section 1847(b) for the furnishing of such an item or service in that area, unless the Secretary finds that the expenses were incurred in a case of urgent need, or in other circumstances specified by the Secretary;

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

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

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

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

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

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

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

made under such section to a provider of services or a renal dialysis facility for such services; or

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

Paragraph (7) shall not apply to Federally qualified health center services described in section 1861(aa)(3)(B). In making a national coverage determination (as defined in paragraph (1)(B) of section 1869(f)) the Secretary shall ensure consistent with subsection (l) that the public is afforded notice and opportunity to comment prior to implementation by the Secretary of the determination; meetings of advisory committees with respect to the determination are made on the record; in making the determination, the Secretary has considered applicable information (including clinical experience and medical, technical, and scientific evidence) with respect to the subject matter of the determination; and in the determination, provide a clear statement of the basis for the determination (including responses to comments received from the public), the assumptions underlying that basis, and make available to the public the data (other than proprietary data) considered in making the determination.

(b) MEDICARE AS SECONDARY PAYER.—

(1) REQUIREMENTS OF GROUP HEALTH PLANS.—

(A) WORKING AGED UNDER GROUP HEALTH PLANS.—

(i) IN GENERAL.—A group health plan—

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

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

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

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

this clause shall only apply if the plan elects treatment under this clause.

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

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

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

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

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

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

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

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

(ii) may not differentiate in the benefits it provides between individuals having end stage renal disease and other individuals covered by such plan on the basis of the existence of end stage renal disease, the need for renal dialysis, or in any other manner; except that clause (ii) shall not prohibit a plan from paying benefits secondary to this title when an individual is entitled to or eligible for benefits under this title under section

226A after the end of the 12-month period described in clause (i). Effective for items and services furnished on or after February 1, 1991, and before the date of enactment of the Balanced Budget Act of 1997 (with respect to periods beginning on or after February 1, 1990), this subparagraph shall be applied by substituting “18-month” for “12-month” each place it appears. Effective for items and services furnished on or after the date of enactment of the Balanced Budget Act of 1997, (with respect to periods beginning on or after the date that is 18 months prior to such date), clauses (i) and (ii) shall be applied by substituting “30-month” for “12-month” each place it appears.

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

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

(i) AGGREGATION RULES.—

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

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

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

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

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

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

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

(2) MEDICARE SECONDARY PAYER.—

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

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

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

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

(B) CONDITIONAL PAYMENT.—

(i) AUTHORITY TO MAKE CONDITIONAL PAYMENT.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) ENFORCEMENT.—

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

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

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

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

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

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

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

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

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

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

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

whichever is greater.

(5) IDENTIFICATION OF SECONDARY PAYER SITUATIONS.—

(A) REQUESTING MATCHING INFORMATION.—

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

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

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

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

(C) CONTACTING EMPLOYERS.—

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

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

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

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

(6) SCREENING REQUIREMENTS FOR PROVIDERS AND SUPPLIERS.—

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

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

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

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

(i) secure from the plan sponsor and plan participants such information as the Secretary shall specify for the purpose of identifying situations where the group health plan is or has been a primary plan to the program under this title; and

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

(B) ENFORCEMENT.—

(i) IN GENERAL.—An entity, a plan administrator, or a fiduciary described in subparagraph (A) that fails to comply with the requirements under such subparagraph shall be subject to a civil money penalty of \$1,000 for each day of noncompliance for each individual for which the information under such subparagraph should have been submitted. The provisions of subsections (e) and (k) of section 1128A shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). A civil money penalty under this clause shall be in addition

to any other penalties prescribed by law and in addition to any Medicare secondary payer claim under this title with respect to an individual.

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

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

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

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

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

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

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

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

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

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

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

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

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

Not later than 18 months after the date of enactment of this sentence, the Secretary shall modify the reporting requirements under this paragraph so that an applicable plan in complying with such requirements is permitted but not required to access or report to the Secretary beneficiary social security account numbers or health identification claim numbers, except that the deadline for such

modification shall be extended by one or more periods (specified by the Secretary) of up to 1 year each if the Secretary notifies the committees of jurisdiction of the House of Representatives and of the Senate that the prior deadline for such modification, without such extension, threatens patient privacy or the integrity of the secondary payer program under this subsection. Any such deadline extension notice shall include information on the progress being made in implementing such modification and the anticipated implementation date for such modification.

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

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

- (i) an individual filing a claim directly against the applicable plan; and
- (ii) an individual filing a claim against an individual or entity insured or covered by the applicable plan.

(E) ENFORCEMENT.—

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

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

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

- (i) Liability insurance (including self-insurance).
- (ii) No fault insurance.
- (iii) Workers’ compensation laws or plans.

(G) SHARING OF INFORMATION.—The Secretary may share information collected under this paragraph as necessary for purposes of the proper coordination of benefits.

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

(I) REGULATIONS.—Not later than 60 days after the date of the enactment of this subparagraph, the Secretary shall publish a notice in the Federal Register soliciting proposals, which will be accepted during a 60-day period, for

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

(9) EXCEPTION.—

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

(B) ANNUAL COMPUTATION OF THRESHOLD.—

(i) IN GENERAL.—Not later than November 15 before each year, the Secretary shall calculate and publish a single threshold amount for settlements, judgments, awards, or other payments for obligations arising from liability insurance (including self-insurance) and for alleged physical trauma-based incidents (excluding alleged ingestion, implantation, or exposure cases) subject to this section for that year. The annual single threshold amount for a year shall be set such that the estimated average amount to be credited to the Medicare trust funds of collections of conditional payments from such settlements, judgments, awards, or other payments arising from liability insurance (including self-insurance) and for such alleged incidents subject to this section shall equal the estimated cost of collection incurred by the United States (including payments made to contractors) for a conditional payment arising from liability insurance (including self-insurance) and for such alleged incidents subject to this section for the year. At the time of calculating, but before publishing, the single threshold amount for 2014, the Secretary shall inform, and seek review of, the Comptroller General of the United States with regard to such amount.

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

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

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

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

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

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

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

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

(1) a drug product—

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

(B) which may be dispensed only upon prescription,

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

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

(2) any other drug product—

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

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

until such time as the Secretary withdraws such proposed order.

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

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

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

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

(2) Where an individual eligible for benefits under this title submits a claim for payment for items or services furnished by an individual or entity excluded from participation in the programs under this title, pursuant to section 1128, 1128A, 1156, 1160 (as in effect on September 2, 1982), 1842(j)(2), 1862(d) (as in effect on the date of the enactment of the Medicare and Medicaid Patient and Program Protection Act of 1987), or 1866, and such beneficiary did not know or have reason to know that such individual or entity was so excluded, then, to the extent permitted by this title, and notwithstanding such exclusion, payment shall be made for such items or services. In each such case the Secretary shall notify the beneficiary of the exclusion of the individual or entity furnishing the items or services. Payment shall not be made for items or services furnished by an excluded individual or entity to a beneficiary after a reasonable time (as determined by the Secretary in regulations) after the Secretary has notified the beneficiary of the exclusion of that individual or entity.

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

(g) The Secretary shall, in making the determinations under paragraphs (1) and (9) of subsection (a), and for the purposes of

promoting the effective, efficient, and economical delivery of health care services, and of promoting the quality of services of the type for which payment may be made under this title, enter into contracts with quality improvement organizations pursuant to part B of title XI of this Act.

(h)(1) The Secretary—

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

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

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

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

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

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

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

(i) In order to supplement the activities of the Medicare Payment Advisory Commission under section 1886(e) in assessing the safety, efficacy, and cost-effectiveness of new and existing medical procedures, the Secretary may carry out, or award grants or contracts for, original research and experimentation of the type described in clause (ii) of section 1886(e)(6)(E) with respect to such a procedure if the Secretary finds that—

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

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

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

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

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

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

(2) If an advisory committee described in paragraph (1) organizes into panels of experts according to types of items or services considered by the advisory committee, any such panel of experts may report any recommendation with respect to such items or services di-

rectly to the Secretary without the prior approval of the advisory committee or an executive committee thereof.

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

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

(1) NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS.—

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

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

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

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

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

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

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

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

(i) make a final decision on the request;

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

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

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

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

(5) LOCAL COVERAGE DETERMINATION PROCESS.—

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

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

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

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

(i) Such determination in its entirety.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

* * * * *

LETTERS OF EXCHANGE

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

COMMITTEE ON WAYS AND MEANS

1102 LONGWORTH HOUSE OFFICE BUILDING
(202) 225-3625

Washington, DC 20515-6548

<http://waysandmeans.house.gov>

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GARY J. ANDRES,
STAFF DIRECTOR

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,


Kevin Brady
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 (2017-2018) 225-292 /
Minority (2017-2018) 225-364 /

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,

A handwritten signature in black ink, appearing to read "Greg Walden".

Greg Walden
Chairman