

POSTOPERATIVE OPIOID PREVENTION ACT OF 2018

JUNE 13, 2018.—Committed to the Committee of the Whole House on the State of the Union and Ordered to be printed

Mr. WALDEN, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 5809]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 5809) to amend title XVIII of the Social Security Act to encourage the use of non-opioid analgesics for the management of post-surgical pain under the Medicare program, and for other purposes, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

CONTENTS		Page
Purpose and Summary		2
Background and Need for Legislation		2
Committee Action		2
Committee Votes		3
Oversight Findings and Recommendations		6
New Budget Authority, Entitlement Authority, and Tax Expenditures		6
Congressional Budget Office Estimate		6
Federal Mandates Statement		28
Statement of General Performance Goals and Objectives		28
Duplication of Federal Programs		28
Committee Cost Estimate		28
Earmark, Limited Tax Benefits, and Limited Tariff Benefits		29
Disclosure of Directed Rule Makings		29
Advisory Committee Statement		29
Applicability to Legislative Branch		29
Section-by-Section Analysis of the Legislation		29
Changes in Existing Law Made by the Bill, as Reported		29
Dissenting Views		94
Exchange of Letters with Additional Committees of Referral		96

PURPOSE AND SUMMARY

H.R. 5809, Postoperative Opioid Prevention Act of 2018, was introduced on May 15, 2018, by Rep. Scott Peters (D–CA) and Rep. Larry Bucshon (R–IN) to extend pass through payment for certain qualifying drugs to encourage the development of non-opioid drugs for post-surgical pain management under the Medicare program.

BACKGROUND AND NEED FOR LEGISLATION

Medicare serves as a unique population in the context of the opioids conversation. The Medicare program serves as the healthcare coverage provider to over 58 million beneficiaries. This number is projected to rise to over 80 million by 2030. In serving the over age 65 population, Medicare accounts for a large share of total opioid prescriptions. In 2016, one out of every three beneficiaries was prescribed an opioid through Medicare Part D. In total, this equates to almost 80 million prescriptions and \$4 billion in Medicare Part D spending. While many Medicare beneficiaries with serious pain-related conditions are being properly prescribed opioids, there is mounting evidence of opioid misuse in the Medicare system. As more seniors and individuals with disabilities come into the program, the challenges of fraud, misuse, and abuse will only increase.

This bill promotes the development of new, clinically superior non-opioid alternative drugs in order to provide more pain management options for patients and providers.

COMMITTEE ACTION

On April 11 and 12, 2018, the Subcommittee on Health held a hearing entitled “Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients” to review legislation related to the opioid epidemic. The Subcommittee received testimony from:

- Kimberly Brandt, Principal Deputy Administrator for Operations, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services;
- Michael Botticelli, Executive Director, Grayken Center for Addiction, Boston Medical Center;
- Toby Douglas, Senior Vice President, Medicaid Solutions, Centene Corporation;
- David Guth, CEO, Centerstone;
- John Kravitz, CIO, Geisinger Health System; and,
- Sam Srivastava, CEO, Magellan Health.

On April 25, 2018, the Subcommittee on Health met in open markup session and forwarded a discussion draft, entitled “Incentivizing Non-Opioid Drugs,” without amendment, to the full Committee by a record vote of 18 yeas and 11 nays. On May 17, 2018, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 5809, without amendment, favorable reported to the House by a record vote of 34 yeas and 17 nays. H.R. 5809 was similar to the discussion draft forwarded by the Subcommittee.

COMMITTEE VOTES

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

COMMITTEE ON ENERGY AND COMMERCE -- 115TH CONGRESS
ROLL CALL VOTE # 71

BILL: H.R. 5809, Postoperative Opioid Prevention Act of 2018

AMENDMENT: An amendment offered by Mrs. Dingell, No. 1, to provide that, with respect to specified payments for covered OPD services, the Secretary shall conduct a review of payments for opioids and evidence-based non-opioid alternatives for pain management, may conduct subsequent reviews of such payments, and shall consider the extent to which revisions to such payments would reduce payment incentives to use opioids instead of non-opioid alternatives for pain management.

DISPOSITION: NOT AGREED TO, by a roll call vote of 22 yeas and 29 nays

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Walden		X		Mr. Pallone	X		
Mr. Barton		X		Mr. Rush	X		
Mr. Upton		X		Ms. Eshoo	X		
Mr. Shimkus		X		Mr. Engel	X		
Mr. Burgess		X		Mr. Green	X		
Mrs. Blackburn				Ms. DeGette			
Mr. Scalise				Mr. Doyle	X		
Mr. Latta		X		Ms. Schakowsky	X		
Mrs. McMorris Rodgers		X		Mr. Butterfield	X		
Mr. Harper		X		Ms. Matsui	X		
Mr. Lance		X		Ms. Castor	X		
Mr. Guthrie		X		Mr. Sarbanes	X		
Mr. Olson		X		Mr. McNerney	X		
Mr. McKinley		X		Mr. Welch	X		
Mr. Kinzinger		X		Mr. Lujan	X		
Mr. Griffith		X		Mr. Tonko	X		
Mr. Bilirakis		X		Ms. Clarke	X		
Mr. Johnson		X		Mr. Loeb sack	X		
Mr. Long		X		Mr. Schrader	X		
Mr. Bucshon		X		Mr. Kennedy	X		
Mr. Flores		X		Mr. Cardenas	X		
Mrs. Brooks		X		Mr. Ruiz	X		
Mr. Mullin		X		Mr. Peters		X	
Mr. Hudson		X		Ms. Dingell	X		
Mr. Collins		X					
Mr. Cramer							
Mr. Walberg		X					
Mrs. Walters		X					
Mr. Costello		X					
Mr. Carter		X					
Mr. Duncan		X					

5/17/18

COMMITTEE ON ENERGY AND COMMERCE -- 115TH CONGRESS
ROLL CALL VOTE # 72

BILL: H.R. 5809, Postoperative Opioid Prevention Act of 2018

AMENDMENT: A motion by Mr. Walden to order H.R. 5809 favorably reported to the House, as amended.
(Final Passage)

DISPOSITION: AGREED TO, by a roll call vote of 34 yeas and 17 nays

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Walden	X			Mr. Pallone		X	
Mr. Barton	X			Mr. Rush		X	
Mr. Upton	X			Ms. Eshoo	X		
Mr. Shimkus	X			Mr. Engel		X	
Mr. Burgess	X			Mr. Green	X		
Mrs. Blackburn				Ms. DeGette			
Mr. Scalise				Mr. Doyle		X	
Mr. Latta	X			Ms. Schakowsky		X	
Mrs. McMorris Rodgers	X			Mr. Butterfield	X		
Mr. Harper	X			Ms. Matsui		X	
Mr. Lance	X			Ms. Castor		X	
Mr. Guthrie	X			Mr. Sarbanes		X	
Mr. Olson	X			Mr. McNerney		X	
Mr. McKinley	X			Mr. Welch		X	
Mr. Kinzinger	X			Mr. Lujan		X	
Mr. Griffith	X			Mr. Tonko		X	
Mr. Bilirakis	X			Ms. Clarke		X	
Mr. Johnson	X			Mr. Loeb sack		X	
Mr. Long	X			Mr. Schrader		X	
Mr. Bucshon	X			Mr. Kennedy		X	
Mr. Flores	X			Mr. Cardenas	X		
Mrs. Brooks	X			Mr. Ruiz	X		
Mr. Mullin	X			Mr. Peters	X		
Mr. Hudson	X			Ms. Dingell		X	
Mr. Collins	X						
Mr. Cramer							
Mr. Walberg	X						
Mrs. Walters	X						
Mr. Costello	X						
Mr. Carter	X						
Mr. Duncan	X						

5/17/18

OVERSIGHT FINDINGS AND RECOMMENDATIONS

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

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R. 5809 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

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

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 6, 2018.

Hon. GREG WALDEN,
*Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed document with cost estimates for the opioid-related legislation ordered to be reported on May 9 and May 17, 2018.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Tom Bradley and Chad Chirico.

Sincerely,

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

Enclosure.

Opioid Legislation

Summary: On May 9 and May 17, 2018, the House Committee on Energy and Commerce ordered 59 bills to be reported related to the nation's response to the opioid epidemic. Generally, the bills would:

- Provide grants to facilities and providers that treat people with substance use disorders,
- Direct various agencies within the Department of Health and Human Services (HHS) to explore nonopioid approaches to treating pain and to educate providers about those alternatives,
- Modify requirements under Medicaid and Medicare for prescribing controlled substances,
- Expand Medicaid coverage for substance abuse treatment, and
- Direct the Food and Drug Administration (FDA) to modify its oversight of opioid drugs and other medications that are used to manage pain.

Because of the large number of related bills ordered reported by the Committee, CBO is publishing a single comprehensive document that includes estimates for each piece of legislation.

CBO estimates that enacting 20 of the bills would affect direct spending, and 2 of the bills would affect revenues; therefore, pay-as-you-go procedures apply for those bills.

CBO estimates that enacting H.R. 4998, the Health Insurance for Former Foster Youth Act, would increase net direct spending by more than \$2.5 billion and on-budget deficits by more than \$5 billion in at least one of the four consecutive 10-year periods beginning in 2029. None of the remaining 58 bills included in this estimate would increase net direct spending by more than \$2.5 billion or on-budget deficits by more than \$5 billion in any of the four consecutive 10-year periods beginning in 2029.

One of the bills reviewed for this document, H.R. 5795, would impose both intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates that the costs of those mandates on public and private entities would fall below the thresholds in UMRA (\$80 million and \$160 million, respectively, in 2018, adjusted annually for inflation). Five bills, H.R. 5228, H.R. 5333, H.R. 5554, H.R. 5687, and H.R. 5811, would impose private-sector mandates as defined in UMRA. CBO estimates that the costs of the mandates in three of the bills (H.R. 5333, H.R. 5554, and H.R. 5811) would not exceed the UMRA threshold for private entities. Because CBO is uncertain how federal agencies would implement new authority granted in the other two bills, H.R. 5228 and H.R. 5687, CBO cannot determine whether the costs of those mandates would exceed the UMRA threshold.

Estimated cost to the Federal Government: The estimates in this document do not include the effects of interactions among the bills. If all 59 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 any such differences would be small. The costs of this legislation fall within budget functions 550 (health), 570 (Medicare), 750 (administration of justice), and 800 (general government).

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 and revenues

Table 1 lists the 22 bills of the 59 ordered to be reported that would affect direct spending or revenues.

TABLE 1.—ESTIMATED CHANGES IN MANDATORY SPENDING AND REVENUES

	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													
Legislation Primarily Affecting Medicaid:													
H.R. 1925, At-Risk Youth Medicaid Protection Act of 2017	0	*	5	5	5	10	10	10	10	10	10	25	75
H.R. 4998, Health Insurance for Former Foster Youth Act	0	0	0	0	0	*	10	21	33	46	61	*	171
H.R. 5477, Rural Development of Opioid Capacity Services Act	0	13	35	58	68	83	27	9	3	3	3	256	301
H.R. 5583, a bill to amend title XI of the Social Security Act to require States to annually report on certain adult health quality measures, and for other purposes	0	*	*	*	*	*	*	*	*	*	*	*	*
H.R. 5797, IMD CARE Act	0	38	158	251	265	279	0	0	0	0	0	991	991
H.R. 5799, Medicaid DRUG Improvement Act ^a	0	*	*	1	1	1	1	1	1	1	1	2	5
H.R. 5801, Medicaid Providers Are Required To Note Experiences in Record Systems to Help In-Need Patients (PARTNERSHIP) Act ^a	0	*	*	*	*	*	*	*	*	*	*	*	*
H.R. 5808, Medicaid Pharmaceutical Home Act of 2018 ^a	0	*	–1	–1	–1	–1	–2	–2	–2	–2	–2	–4	–13
H.R. 5810, Medicaid Health HOME Act	0	94	58	62	56	52	48	43	38	32	25	323	509
Legislation Primarily Affecting Medicare:													
H.R. 3528, Every Prescription Conveyed Securely Act	0	0	0	–24	–35	–33	–30	–33	–32	–31	–32	–92	–250
H.R. 4841, Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018	0	0	0	*	*	*	*	*	*	*	*	*	*
H.R. 5603, Access to Telehealth Services for Opioid Use Disorders Act	0	2	*	*	*	*	1	1	2	2	2	3	11
H.R. 5605, Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act	0	0	0	15	26	24	23	23	10	1	*	65	122
H.R. 5675, a bill to amend title XVIII of the Social Security Act to require prescription drug plan sponsors under the Medicare program to establish drug management programs for at-risk beneficiaries ...	0	0	0	–6	–7	–7	–7	–8	–9	–9	–11	–20	–64
H.R. 5684, Protecting Seniors From Opioid Abuse Act	0	0	0	*	*	*	*	*	*	*	*	*	*
H.R. 5796, Responsible Education Achieves Care and Healthy Outcomes for Users' Treatment Act of 2018	0	10	25	50	10	5	0	0	0	0	0	100	100
H.R. 5798, Opioid Screening and Chronic Pain Management Alternatives for Seniors Act	0	0	*	1	1	1	1	1	1	1	1	2	5
H.R. 5804, Post-Surgical Injections as an Opioid Alternative Act ^a	0	0	25	30	25	20	10	5	0	0	0	100	115
H.R. 5809, Postoperative Opioid Prevention Act of 2018	0	0	0	0	10	15	20	25	30	35	45	25	180
Legislation Primarily Affecting the Food and Drug Administration:													

TABLE 1.—ESTIMATED CHANGES IN MANDATORY SPENDING AND REVENUES—Continued

	By fiscal year, in millions of dollars—											
	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2019– 2023
H.R. 5333, Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018 ^a	0	0	*	*	*	*	*	*	*	*	*	*
	INCREASES OR DECREASES (–) IN REVENUES ^b											
H.R. 5752, Stop Illicit Drug Importation Act of 2018	0	*	*	*	*	*	*	*	*	*	*	*

Annual amounts may not sum to totals because of rounding. * = between –\$500,000 and \$500,000. Budget authority is equivalent to outlays.

^a This bill also would affect spending subject to appropriation.

^b One additional bill, H.R. 5228, the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act, would have a negligible effect on revenues.

Legislation Primarily Affecting Medicaid. The following nine bills would affect direct spending for the Medicaid program.

H.R. 1925, the At-Risk Youth Medicaid Protection Act of 2017, would require states to suspend, rather than terminate, Medicaid eligibility for juvenile enrollees (generally under 21 years of age) who become inmates of public correctional institutions. States also would have to redetermine those enrollees' Medicaid eligibility before their release and restore their coverage upon release if they qualify for the program. States would be required to process Medicaid applications submitted by or on behalf of juveniles in public correctional institutions who were not enrolled in Medicaid before becoming inmates and ensure that Medicaid coverage is provided when they are released if they are found to be eligible. On the basis of an analysis of juvenile incarceration trends and of the per enrollee spending for Medicaid foster care children, who have a similar health profile to incarcerated juveniles, CBO estimates that implementing the bill would cost \$75 million over the 2019–2028 period.

H.R. 4998, the Health Insurance for Former Foster Youth Act, would require states to provide Medicaid coverage to adults up to age 25 who had aged out of foster care in any state. Under current law, such coverage is mandatory only if the former foster care youth has aged out in the state in which the individual applies for coverage. The policy also would apply to former foster children who had been in foster care upon turning 14 years of age but subsequently left foster care to enter into a legal guardianship with a kinship caregiver. The provisions would take effect respect for foster youth who turn 18 on or after January 1, 2023. On the basis of spending for Medicaid foster care children and data from the Census Bureau regarding annual migration rates between states, CBO estimates that implementing the bill would cost \$171 million over the 2019–2028 period.

H.R. 5477, the Rural Development of Opioid Capacity Services Act, would direct the Secretary of HHS to conduct a five-year demonstration to increase the number and ability of providers participating in Medicaid to provide treatment for substance use disorders. On the basis of an analysis of federal and state spending for treatment of substance use disorders and the prevalence of such disorders, CBO estimates that enacting the bill would increase direct spending by \$301 million over the 2019–2028 period.

H.R. 5583, a bill to amend title XI of the Social Security Act to require States to annually report on certain adult health quality measures, and for other purposes, would require states to include behavioral health indicators in their annual reports on the quality of care under Medicaid. Although the bill would add a requirement for states, CBO estimates that its enactment would not have a significant budgetary effect because most states have systems in place for reporting such measures to the federal government.

H.R. 5797, the IMD CARE Act, would expand Medicaid coverage for people with opioid use disorder who are in institutions for mental disease (IMDs) for up to 30 days per year. Under a current-law policy known as the IMD exclusion, the federal government generally does not make matching payments to state Medicaid programs for most services provided by IMDs to adults between the ages of 21 and 64. Recent administrative changes have made fed-

eral financing for IMDs available in limited circumstances, but the statutory prohibition remains in place. CBO analyzed several data sets, primarily those collected by the Substance Abuse and Mental Health Services Administration (SAMHSA), to estimate current federal spending under Medicaid for IMD services and to estimate spending under H.R. 5797. Using that analysis, CBO estimates that enacting H.R. 5797 would increase direct spending by \$991 million over the 2019–2028 period.

H.R. 5799, the Medicaid DRUG Improvement Act, would require state Medicaid programs to implement additional reviews of opioid prescriptions, monitor concurrent prescribing of opioids and certain other drugs, and monitor use of antipsychotic drugs by children. CBO estimates that the bill would increase direct spending by \$5 million over the 2019–2028 period to cover the administrative costs of complying with those requirements. On the basis of stakeholder feedback, CBO expects that the bill would not have a significant effect on Medicaid spending for prescription drugs because many of the bill's requirements would duplicate current efforts to curb opioid and antipsychotic drug use. (If enacted, H.R. 5799 also would affect spending subject to appropriation; CBO has not completed an estimate of that amount.)

H.R. 5801, the Medicaid Providers Are Required To Note Experiences in Record Systems to Help In-Need Patients (PARTNERSHIP) Act, would require providers who are permitted to prescribe controlled substances and who participate in Medicaid to query prescription drug monitoring programs (PDMPs) before prescribing controlled substances to Medicaid patients. PDMPs are statewide electronic databases that collect data on controlled substances dispensed in the state. The bill also would require PDMPs to comply with certain data and system criteria, and it would provide additional federal matching funds to certain states to help cover administrative costs. On the basis of a literature review and stakeholder feedback, CBO estimates that the net budgetary effect of enacting H.R. 5801 would be insignificant. Costs for states to come into compliance with the systems and administrative requirements would be roughly offset by savings from small reductions in the number of controlled substances paid for by Medicaid under the proposal. (If enacted, H.R. 5801 also would affect spending subject to appropriation; CBO has not completed an estimate of that amount.)

H.R. 5808, the Medicaid Pharmaceutical Home Act of 2018, would require state Medicaid programs to operate pharmacy programs that would identify people at high risk of abusing controlled substances and require those patients to use a limited number of providers and pharmacies. Although nearly all state Medicaid programs currently meet such a requirement, a small number of high-risk Medicaid beneficiaries are not now monitored. Based on an analysis of information about similar state and federal programs, CBO estimates that net Medicaid spending under the bill would decrease by \$13 million over the 2019–2028 period. That amount represents a small increase in administrative costs and a small reduction in the number of controlled substances paid for by Medicaid under the proposal. (If enacted, H.R. 5808 also would affect spending subject to appropriation; CBO has not completed an estimate of that amount.)

H.R. 5810, the Medicaid Health HOME Act, would allow states to receive six months of enhanced federal Medicaid funding for programs that coordinate care for people with substance use disorders. Based on enrollment and spending data from states that currently participate in Medicaid's Health Homes program, CBO estimates that the expansion would cost approximately \$469 million over the 2019–2028 period. The bill also would require states to cover all FDA-approved drugs used in medication-assisted treatment for five years, although states could seek a waiver from that requirement. (Medication-assisted treatment combines behavioral therapy and pharmaceutical treatment for substance use disorders.) Under current law, states already cover most FDA-approved drugs used in such programs in some capacity, although a few exclude methadone dispensed by opioid treatment programs. CBO estimates that a small share of those states would begin to cover methadone if this bill was enacted at a federal cost of about \$39 million over the 2019–2028 period. In sum, CBO estimates that the enacting H.R. 5810 would increase direct spending by \$509 million over the 2019–2028 period.

Legislation Primarily Affecting Medicare. The following ten bills would affect direct spending for the Medicare program.

H.R. 3528, the Every Prescription Conveyed Securely Act, would require prescriptions for controlled substances covered under Medicare Part D to be transmitted electronically, starting on January 1, 2021. Based on CBO's analysis of prescription drug spending, spending for controlled substances is a small share of total drug spending. CBO also assumes a small share of those prescriptions would not be filled because they are not converted to an electronic format. Therefore, CBO expects that enacting H.R. 3528 would reduce the number of prescriptions filled and estimates that Medicare spending would be reduced by \$250 million over the 2019–2028 period.

H.R. 4841, the Standardizing Electronic Prior Authorization for Safe Prescribing 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 H.R. 4841 would not significantly affect direct spending for Part D.

H.R. 5603, the Access to Telehealth Services for Opioid Use Disorders Act, would permit the Secretary of HHS to lift current geographic and other restrictions on coverage of telehealth services under Medicare for treatment of substance use disorders or co-occurring mental health disorders. Under the bill, the Secretary of HHS would be directed to encourage other payers to coordinate payments for opioid use disorder treatments and to evaluate the extent to which the demonstration reduces hospitalizations, increases the use of medication-assisted treatments, and improves the health outcomes of individuals with opioid use disorders during and after the demonstration. Based on current use of Medicare telehealth services for treatment of substance use disorders, CBO estimates that expanding that coverage would increase direct spending by \$11 million over the 2019–2028 period.

H.R. 5605, the Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act, would establish a five-year demonstra-

tion program to increase access to treatment for opioid use disorder. The demonstration would provide incentive payments and funding for care management services based on criteria such as patient engagement, use of evidence-based treatments, and treatment length and intensity. Under the bill, the Secretary of HHS would be directed to encourage other payers to coordinate payments for opioid use disorder treatments and to evaluate the extent to which the demonstration reduces hospitalizations, increases the use of medication-assisted treatments, and improves the health outcomes of individuals with opioid use disorders during and after the demonstration. Based on historical utilization of opioid use disorder treatments and projected spending on incentive payments and care management fees, CBO estimates that increased use of treatment services and the demonstration's incentive payments would increase direct spending by \$122 million over the 2019–2028 period.

H.R. 5675, a bill to amend title XVIII of the Social Security Act to require prescription drug plan sponsors under the Medicare program to establish drug management programs for at-risk beneficiaries, 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. 5675 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.

H.R. 5684, the Protecting Seniors From Opioid Abuse Act, 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 bill, CBO estimates that its enactment would not significantly affect direct spending for Part D.

H.R. 5796, the Responsible Education Achieves Care and Healthy Outcomes for Users' Treatment Act of 2018, would allow the Secretary of HHS to award grants to certain organizations that provide technical assistance and education to high-volume prescribers of opioids. The bill would appropriate \$100 million for fiscal year 2019. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5796 would cost \$100 million over the 2019–2028 period.

H.R. 5798, the Opioid Screening and Chronic Pain Management Alternatives for Seniors Act, would add an assessment of current opioid prescriptions and screening for opioid use disorder to the Welcome to Medicare Initial Preventive Physical Examination. Based on historical use of the examinations and pain management alternatives, CBO expects that enacting the bill would increase use of pain management services and estimates that direct spending would increase by \$5 million over the 2019–2028 period.

H.R. 5804, the Post-Surgical Injections as an Opioid Alternative Act, would freeze the Medicare payment rate for certain analgesic injections provided in ambulatory surgical centers (ASCs). (For injections identified by specific billing codes, Medicare would pay the 2016 rate, which is higher than the current rate, during the 2020–2024 period.) Based on current utilization in the ASC setting, CBO

estimates that enacting the legislation would increase direct spending by about \$115 million over the 2019–2028 period. (If enacted, H.R. 5804 also would affect spending subject to appropriation; see Table 3.)

H.R. 5809, the Postoperative Opioid Prevention Act of 2018, would create an additional payment under Medicare for nonopioid analgesics. Under current law, certain new drugs and devices may receive an additional payment—separate from the bundled payment for a surgical procedure—in outpatient hospital departments and ambulatory surgical centers. The bill would allow nonopioid analgesics to qualify for a five-year period of additional payments. Based on its assessment of current spending for analgesics and on the probability of new nonopioid analgesics coming to market, CBO estimates that H.R. 5809 would increase direct spending by about \$180 million over the 2019–2028 period.

Legislation Primarily Affecting the Food and Drug Administration. One bill related to the FDA would affect direct spending.

H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018, would change the way that the FDA regulates the marketing of over-the-counter (OTC) medicines, and it would authorize that agency to grant 18 months of exclusive market protection for certain qualifying OTC drugs, thus delaying the entry of other versions of the same qualifying OTC product. Medicaid currently provides some coverage for OTC medicines, but only if a medicine is the least costly alternative in its drug class. On the basis of stakeholder feedback, CBO expects that delaying the availability of additional OTC versions of a drug would not significantly affect the average net price paid by Medicaid. As a result, CBO estimates that enacting H.R. 5333 would have a negligible effect on the federal budget. (If enacted, H.R. 5333 also would affect spending subject to appropriation; see Table 3.)

Legislation with Revenue Effects. Two bills would affect revenues. However, CBO estimates that one bill, H.R. 5228, the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act, would have only a negligible effect.

H.R. 5752, the Stop Illicit Drug Importation Act of 2018, would amend the Federal Food, Drug, and Cosmetic Act (FDCA) to strengthen the FDA’s seizure powers and enhance its authority to detain, refuse, seize, or destroy illegal products offered for import. The legislation would subject more people to debarment under the FDCA and thus increase the potential for violations, and subsequently, the assessment of civil penalties, which are recorded in the budget as revenues. CBO estimates that those collections would result in an insignificant increase in revenues. Because H.R. 5752 would prohibit the importation of drugs that are in the process of being scheduled, it also could reduce amounts collected in customs duties. CBO anticipates that the result would be a negligible decrease in revenues. With those results taken together, CBO estimates, enacting H.R. 5752 would generate an insignificant net increase in revenues over the 2019–2028 period.

Spending subject to appropriation

For this document, CBO has grouped bills with spending that would be subject to appropriation into four general categories:

- Bills that would have no budgetary effect,

- Bills with provisions that would authorize specified amounts to be appropriated (see Table 2),
- Bills with provisions for which CBO has estimated an authorization of appropriations (see Table 3), 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 6 of the 59 bills would have no effect on direct spending, revenues, or spending subject to appropriation.

H.R. 3192, the CHIP Mental Health Parity Act, would require all Children’s Health Insurance Program (CHIP) plans to cover mental health and substance abuse treatment. In addition, states would not be allowed to impose financial or utilization limits on mental health treatment that are lower than limits placed on physical health treatment. Based on information from the Centers for Medicare and Medicaid Services, CBO estimates that enacting the bill would have no budgetary effect because all CHIP enrollees are already in plans that meet those requirements.

H.R. 3331, a bill to amend title XI of the Social Security Act to promote testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology, would give the Center for Medicare and Medicaid Innovation (CMMI) explicit authorization to test a program offering incentive payments to behavioral health providers that adopt and use certified electronic health record technology. Because it is already clear to CMMI that it has that authority, CBO estimates that enacting the legislation would not affect federal spending.

H.R. 5202, the Ensuring Patient Access to Substance Use Disorder Treatments Act of 2018, would clarify permission for pharmacists to deliver controlled substances to providers under certain circumstances. Because this provision would codify current practice, CBO estimates that H.R. 5202 would not affect direct spending or revenues during the 2019–2028 period.

H.R. 5685, the Medicare Opioid Safety Education Act of 2018, would require the Secretary of HHS to include information on opioid use, pain management, and nonopioid pain management treatments in future editions of *Medicare & You*, the program’s handbook for beneficiaries, starting on January 1, 2019. Because H.R. 5685 would add information to an existing administrative document, CBO estimates that enacting the bill would have no budgetary effect.

H.R. 5686, the Medicare Clear Health Options in Care for Enrollees 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. CBO estimates that enacting the bill would not affect direct spending because the required activities would not impose significant administrative costs.

H.R. 5716, the Commit to Opioid Medical Prescriber Accountability and Safety for Seniors Act, 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.

Specified Authorizations. Table 2 lists the ten bills that would authorize specified amounts to be appropriated over the 2019–2023 period. Spending from those authorized amounts would be subject to appropriation.

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

	By fiscal year, in millions of dollars—						
	2018	2019	2020	2021	2022	2023	2019–2023
INCREASES IN SPENDING SUBJECT TO APPROPRIATION							
H.R. 4684, Ensuring Access to Quality Sober Living Act:							
Authorization Level	0	3	0	0	0	0	3
Estimated Outlays	0	1	2	*	*	*	3
H.R. 5102, Substance Use Disorder Workforce Loan Repayment Act of 2018:							
Authorization Level	0	25	25	25	25	25	125
Estimated Outlays	0	9	19	23	25	25	100
H.R. 5176, Preventing Overdoses While in Emergency Rooms Act of 2018:							
Authorization Level	0	50	0	0	0	0	50
Estimated Outlays	0	16	26	6	2	1	50
H.R. 5197, Alternatives to Opioids (ALTO) in the Emergency Department Act:							
Authorization Level	0	10	10	10	0	0	30
Estimated Outlays	0	3	8	10	7	2	30
H.R. 5261, Treatment, Education, and Community Help to Combat Addiction Act of 2018:							
Authorization Level	0	4	4	4	4	4	20
Estimated Outlays	0	1	3	4	4	4	16
H.R. 5327, Comprehensive Opioid Recovery Centers Act of 2018:							
Authorization Level	0	10	10	10	10	10	50
Estimated Outlays	0	3	8	10	10	10	41
H.R. 5329, Poison Center Network Enhancement Act of 2018:							
Authorization Level	0	30	30	30	30	30	151
Estimated Outlays	0	12	25	29	29	29	125
H.R. 5353, Eliminating Opioid-Related Infectious Diseases Act of 2018:							
Authorization Level	0	40	40	40	40	40	200
Estimated Outlays	0	15	34	38	39	40	166
H.R. 5580, Surveillance and Testing of Opioids to Prevent Fentanyl Deaths Act of 2018:							
Authorization Level	30	30	30	30	30	0	120
Estimated Outlays	0	11	25	29	29	19	113
H.R. 5587, Peer Support Communities of Recovery Act:							
Authorization Level	0	15	15	15	15	15	75
Estimated Outlays	0	5	13	14	15	15	62

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

H.R. 4684, the Ensuring Access to Quality Sober Living Act, would direct the Secretary of HHS to develop and disseminate best practices for organizations that operate housing designed for people recovering from substance use disorders. The bill would authorize a total of \$3 million over the 2019–2021 period for that purpose. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 4684 would cost \$3 million over the 2019–2023 period.

H.R. 5102, the Substance Use Disorder Workforce Loan Repayment Act of 2018, would establish a loan repayment program for

mental health professionals who practice in areas with few mental health providers or with high rates of death from overdose and would authorize \$25 million per year over the 2019–2028 period for that purpose. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5102 would cost \$100 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5176, the Preventing Overdoses While in Emergency Rooms Act of 2018, would require the Secretary of HHS to develop protocols and a grant program for health care providers to address the needs of people who survive a drug overdose, and it would authorize \$50 million in 2019 for that purpose. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5176 would cost \$50 million over the 2019–2023 period.

H.R. 5197, the Alternatives to Opioids (ALTO) in the Emergency Department Act, would direct the Secretary of HHS to carry out a demonstration program for hospitals and emergency departments to develop alternative protocols for pain management that limit the use of opioids and would authorize \$10 million annually in grants for fiscal years 2019 through 2021. Based on historical spending patterns for similar programs, CBO estimates that implementing H.R. 5197 would cost \$30 million over the 2019–2023 period.

H.R. 5261, the Treatment, Education, and Community Help to Combat Addiction Act of 2018, would direct the Secretary of HHS to designate regional centers of excellence to improve the training of health professionals who treat substance use disorders. The bill would authorize \$4 million annually for grants to those programs over the 2019–2023 period. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5261 would cost \$16 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5327, the Comprehensive Opioid Recovery Centers Act of 2018, would direct the Secretary of HHS to award grants to at least 10 providers that offer treatment services for people with opioid use disorder, and it would authorize \$10 million per year over the 2019–2023 period for that purpose. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5327 would cost \$41 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5329, the Poison Center Network Enhancement Act of 2018, would reauthorize the poison control center toll-free number, national media campaign, and grant program under the Public Health Service Act. Among other actions, H.R. 5329 would increase the share of poison control center funding that could be provided by federal grants. The bill would authorize a total of about \$30 million per year over the 2019–2023 period. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5329 would cost \$125 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5353, the Eliminating Opioid Related Infectious Diseases Act of 2018, would amend the Public Health Service Act by broadening the focus of surveillance and education programs from preventing and treating hepatitis C virus to preventing and treating infections associated with injection drug use. It would authorize

\$40 million per year over 2019–2023 period for that purpose. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5353 would cost \$166 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5580, the Surveillance and Testing of Opioids to Prevent Fentanyl Deaths Act of 2018, would establish a grant program for public health laboratories that conduct testing for fentanyl and other synthetic opioids. It also would direct the Centers for Disease Control and Prevention to expand its drug surveillance program, with a particular focus on collecting data on fentanyl. The bill would authorize a total of \$30 million per year over the 2018–2022 period for those activities. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5580 would cost \$113 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5587, Peer Support Communities of Recovery Act, would direct the Secretary of HHS to award grants to nonprofit organizations that support community-based, peer-delivered support, including technical support for the establishment of recovery community organizations, independent, nonprofit groups led by people in recovery and their families. The bill would authorize \$15 million per year for the 2019–2023 period. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5587 would cost \$62 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

Estimated Authorizations. Table 3 shows CBO’s estimates of the appropriations that would be necessary to implement 19 of the bills. Spending would be subject to appropriation of those amounts.

H.R. 449, the Synthetic Drug Awareness Act of 2018, would require the Surgeon General to report to the Congress on the health effects of synthetic psychoactive drugs on children between the ages of 12 and 18. Based on spending patterns for similar activities, CBO estimates that implementing H.R. 449 would cost approximately \$1 million over the 2019–2023 period.

H.R. 4005, the Medicaid Reentry Act, would direct the Secretary of HHS to convene a group of stakeholders to develop and report to the Congress on best practices for addressing issues related to health care faced by those returning from incarceration to their communities. The bill also would require the Secretary to issue a letter to state Medicaid directors about relevant demonstration projects. Based on an analysis of anticipated workload, CBO estimates that implementing H.R. 4005 would cost less than \$500,000 over the 2018–2023 period.

H.R. 4275, the Empowering Pharmacists in the Fight Against Opioid Abuse Act, would require the Secretary of HHS to develop and disseminate materials for training pharmacists, health care practitioners, and the public about the circumstances under which a pharmacist may decline to fill a prescription. Based on historical spending patterns for similar activities, CBO estimates that costs to the federal government for the development and distribution of those materials would not be significant.

TABLE 3.—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. 449, Synthetic Drug Awareness Act of 2018:							
Estimated Authorization Level	0	*	*	*	0	0	1
Estimated Outlays	0	*	*	*	0	0	1
H.R. 4005, Medicaid Reentry Act:							
Estimated Authorization Level	*	*	0	0	0	0	*
Estimated Outlays	*	*	0	0	0	0	*
H.R. 4275, Empowering Pharmacists in the Fight Against Opioid Abuse Act:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5009, Jessie's Law:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5041, Safe Disposal of Unused Medication Act:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5272, Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse Act of 2018:							
Estimated Authorization Level	0	1	1	1	1	1	4
Estimated Outlays	0	1	1	1	1	1	4
H.R. 5333, Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018: ^a							
Food and Drug Administration:							
Collections from fees:							
Estimated Authorization Level	0	–22	–22	–26	–35	–42	–147
Estimated Outlays	0	–22	–22	–26	–35	–42	–147
Spending of fees:							
Estimated Authorization Level	0	22	22	26	35	42	147
Estimated Outlays	0	6	17	30	44	41	137
Net effect on FDA:							
Estimated Authorization Level	0	0	0	0	0	0	0
Estimated Outlays	0	–17	–6	4	9	*	–10
Government Accountability Office:							
Estimated Authorization Level	0	0	0	0	0	*	*
Estimated Outlays	0	0	0	0	0	*	*
Total, H.R. 5333:							
Estimated Authorization Level	0	0	0	0	0	*	*
Estimated Outlays	0	–17	–6	4	9	*	–10
H.R. 5473, Better Pain Management Through Better Data Act of 2018:							
Estimated Authorization Level	0	*	*	*	*	0	1
Estimated Outlays	0	*	*	*	*	*	1
H.R. 5483, Special Registration for Telemedicine Clarification Act of 2018:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5554, Animal Drug and Animal Generic Drug User Fee Amendments of 2018:							
Collections from fees:							
Animal drug fees	0	–30	–31	–32	–33	–34	–159
Generic animal drug fees	0	–18	–19	–19	–20	–21	–97
Total, Estimated Authorization Level	0	–49	–50	–51	–53	–55	–257
Total, Estimated Outlays	0	–49	–50	–51	–53	–55	–257
Spending of fees:							
Animal drug fees	0	30	31	32	33	34	159
Generic animal drug fees	0	18	19	19	20	21	97
Total, Estimated Authorization Level	0	49	50	51	53	55	257
Total, Estimated Outlays	0	39	47	51	52	54	243

TABLE 3.—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
Net changes in fees:							
Estimated Authorization Level	0	0	0	0	0	0	0
Estimated Outlays	0	–10	–3	*	*	*	–14
Other effects:							
Estimated Authorization Level	0	3	1	1	1	1	6
Estimated Outlays	0	2	1	1	1	1	6
Total, H.R. 5554:							
Estimated Authorization Level	0	3	1	1	1	1	6
Estimated Outlays	0	–8	–2	1	*	*	–8
H.R. 5582, Abuse Deterrent Access Act of 2018:							
Estimated Authorization Level	0	0	*	0	0	0	*
Estimated Outlays	0	0	*	0	0	0	*
H.R. 5590, Opioid Addiction Action Plan Act:							
Estimated Authorization Level	*	*	*	*	*	*	2
Estimated Outlays	*	*	*	*	*	*	2
H.R. 5687, Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5715, Strengthening Partnerships to Prevent Opioid Abuse Act:							
Estimated Authorization Level	0	2	2	2	2	2	9
Estimated Outlays	0	2	2	2	2	2	9
H.R. 5789, a bill to require the Secretary of Health and Human Services to issue guidance to improve care for infants with neonatal abstinence syndrome and their mothers, and to require the Comptroller General of the United States to conduct a study on gaps in Medicaid coverage for pregnant and postpartum women with substance use disorder:							
Estimated Authorization Level	0	2	0	0	0	0	2
Estimated Outlays	0	2	0	0	0	0	2
H.R. 5795, Overdose Prevention and Patient Safety Act:							
Estimated Authorization Level	0	1	0	0	0	0	1
Estimated Outlays	0	1	0	0	0	0	1
H.R. 5800, Medicaid IMD ADDITIONAL INFO Act:							
Estimated Authorization Level	0	1	0	0	0	0	1
Estimated Outlays	0	*	*	0	0	0	1
H.R. 5804, Post-Surgical Injections as an Opioid Alternative Act: ^a							
Estimated Authorization Level	0	0	0	0	1	1	1
Estimated Outlays	0	0	0	0	1	1	1
H.R. 5811, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to postapproval study requirements for certain controlled substances, and for other purposes:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*

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

^a This bill also would affect mandatory spending (see Table 1).

H.R. 5009, Jessie’s Law, would require HHS, in collaboration with outside experts, to develop best practices for displaying information about opioid use disorder in a patient’s medical record. HHS also would be required to develop and disseminate written materials annually to health care providers about what disclosures could be made while still complying with federal laws that govern health care privacy. Based on spending patterns for similar activities, CBO estimates that implementing H.R. 5009 would have an insignificant effect on spending over the 2019–2023 period.

H.R. 5041, the Safe Disposal of Unused Medication Act, would require hospice programs to have written policies and procedures for the disposal of controlled substances after a patient's death. Certain licensed employees of hospice programs would be permitted to assist in the disposal of controlled substances that were lawfully dispensed. Using information from the Department of Justice (DOJ), CBO estimates that implementing the bill would cost less than \$500,000 over the 2019–2023 period.

H.R. 5272, the Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse Act of 2018, would require the newly established National Mental Health and Substance Use Policy Laboratory to issue guidance to applicants for SAMHSA grants that support evidence-based practices. Using information from HHS about the historical cost of similar activities, CBO estimates that enacting this bill would cost approximately \$4 million over the 2019–2023 period.

H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018, would change the FDA's oversight of the commercial marketing of OTC medicines and authorize the collection and spending of fees through 2023 to cover the costs of expediting the FDA's administrative procedures for certain regulatory activities relating to OTC products. Under H.R. 5333, CBO estimates, the FDA would assess about \$147 million in fees over the 2019–2023 period that could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. Because the FDA could spend those fees, CBO estimates that the estimated budget authority for collections and spending would offset each other exactly in each year, although CBO expects that spending initially would lag behind collections. Assuming appropriation action consistent with the bill, CBO estimates that implementing H.R. 5333 would reduce net discretionary outlays by \$10 million over the 2019–2023 period, primarily because of that lag. The bill also would require the Government Accountability Office to study exclusive market protections for certain qualifying OTC drugs authorized by the bill—a provision that CBO estimates would cost less than \$500,000. (If enacted, H.R. 5333 also would affect mandatory spending; see Table 1.)

H.R. 5473, the Better Pain Management Through Better Data Act of 2018, would require that the FDA conduct a public meeting and issue guidance to industry addressing data collection and labeling for medical products that reduce pain while enabling the reduction, replacement, or avoidance of oral opioids. Using information from the agency, CBO estimates that implementing H.R. 5473 would cost about \$1 million over the 2019–2023 period.

H.R. 5483, the Special Registration for Telemedicine Clarification Act of 2018, would direct DOJ, within one year of the bill's enactment, to issue regulations concerning the practice of telemedicine (for remote diagnosis and treatment of patients). Using information from DOJ, CBO estimates that implementing the bill would cost less than \$500,000 over the 2019–2023 period.

H.R. 5554, the Animal Drug and Animal Generic Drug User Fee Amendments of 2018, would authorize the FDA to collect and spend fees to cover the cost of expedited approval for the development and marketing of certain drugs for use in animals. The legislation would extend through fiscal year 2023, and make several changes

to, the FDA's existing approval processes and fee programs for brand-name and generic veterinary drugs, which expire at the end of fiscal year 2018. CBO estimates that implementing H.R. 5554 would reduce net discretionary outlays by \$8 million over the 2019–2023 period, primarily because the spending of fees lags somewhat behind their collection.

Fees authorized under the bill would supplement funds appropriated to cover the FDA's cost of reviewing certain applications and investigational submissions for brand-name and generic drugs for use in animals. Those fees could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. Under H.R. 5554, CBO estimates, the FDA would assess about \$257 million in fees over the 2019–2023 period. Because the FDA could spend those funds, CBO estimates that budget authority for collections and spending would offset each other exactly in each year. CBO estimates that the delay between collecting and spending fees under the reauthorized programs would reduce net discretionary outlays by \$14 million over the 2019–2023 period, assuming appropriation actions consistent with the bill.

Enacting H.R. 5554 would increase the FDA's workload because the legislation would expand eligibility for conditional approval for certain drugs. The agency's administrative costs also would increase because of regulatory activities required by a provision concerning petitions for additives intended for use in animal food. H.R. 5554 also would require the FDA to publish guidance or produce regulations on a range of topics, transmit a report to the Congress, and hold public meetings. CBO expects that the costs associated with those activities would not be covered by fees, and it estimates that implementing such provisions would cost \$6 million over the 2019–2023 period.

H.R. 5582, the Abuse Deterrent Access Act of 2018, would require the Secretary of HHS to report to the Congress on existing barriers to access to "abuse-deterrent opioid formulations" by Medicare Part C and D beneficiaries. Such formulations make the drugs more difficult to dissolve for injection, for example, and thus can impede their abuse. Assuming the availability of appropriated funds and based on historical spending patterns for similar activities, CBO estimates that implementing the legislation would cost less than \$500,000 over the 2019–2023 period.

H.R. 5590, the Opioid Addiction Action Plan Act, would require the Secretary of HHS to develop an action plan by January 1, 2019, for increasing access to medication-assisted treatment among Medicare and Medicaid enrollees. The bill also would require HHS to convene a stakeholder meeting and issue a request for information within three months of enactment, and to submit a report to the Congress by June 1, 2019. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5590 would cost approximately \$2 million over the 2019–2023 period.

H.R. 5687, the Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018, would permit the FDA to require certain packaging and disposal technologies, controls, or measures to mitigate the risk of abuse and misuse of drugs. Based on information from the FDA, CBO estimates that implementing H.R. 5687 would not significantly affect spending over the 2019–

2023 period. This bill would also require that the GAO study the effectiveness and use of packaging technologies for controlled substances—a provision that CBO estimates would cost less than \$500,000.

H.R. 5715, the Strengthening Partnerships to Prevent Opioid Abuse Act, 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. 5715 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. 5715 would cost approximately \$9 million over the 2019–2023 period.

H.R. 5789, a bill to require the Secretary of Health and Human Services to issue guidance to improve care for infants with neonatal abstinence syndrome and their mothers, and to require the Comptroller General of the United States to conduct a study on gaps in Medicaid coverage for pregnant and postpartum women with substance use disorder, would direct the Secretary of HHS to issue guidance to states on best practices under Medicaid and CHIP for treating infants with neonatal abstinence syndrome. H.R. 5789 also would direct the Government Accountability Office to study Medicaid coverage for pregnant and postpartum women with substance use disorders. Based on information from HHS and historical spending patterns for similar activities, CBO estimates that enacting H.R. 5789 would cost approximately \$2 million over the 2019–2023 period.

H.R. 5795, the Overdose Prevention and Patient Safety Act, would amend the Public Health Service Act so that requirements pertaining to the confidentiality and disclosure of medical records relating to substance use disorders align with the provisions of the Health Insurance Portability and Accountability Act of 1996. The bill would require the Office of the Secretary of HHS to issue regulations prohibiting discrimination based on data disclosed from such medical records, to issue regulations requiring covered entities to provide written notice of privacy practices, and to develop model training programs and materials for health care providers and patients and their families. Based on spending patterns for similar activities, CBO estimates that implementing H.R. 5795 would cost approximately \$1 million over the 2019–2023 period.

H.R. 5800, Medicaid IMD ADDITIONAL INFO Act, would direct the Medicaid and CHIP Payment and Access Commission to study institutions for mental diseases in a representative sample of states. Based on information from the commission about the cost of similar work, CBO estimates that implementing H.R. 5800 would cost about \$1 million over the 2019–2023 period.

H.R. 5804, the Post-Surgical Injections as an Opioid Alternative Act, would freeze the Medicare payment rate for certain analgesic injections provided in ambulatory surgical centers. The bill also would mandate two studies of Medicare coding and payments arising from enactment of this legislation. Based on the cost of similar activities, CBO estimates that those reports would cost \$1 million

over the 2019–2023 period. (If enacted, H.R. 5804 also would affect mandatory spending; see Table 1.)

H.R. 5811, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to postapproval study requirements for certain controlled substances, and for other purposes, would allow the FDA to require that pharmaceutical manufacturers study certain drugs after they are approved to assess any potential reduction in those drugs’ effectiveness for the conditions of use prescribed, recommended, or suggested in labeling. CBO anticipates that implementing H.R. 5811 would not significantly affect the FDA’s costs over the 2019–2023 period.

Other Authorizations. The following nine bills would increase authorization levels, but CBO has not completed estimates of amounts. All authorizations would be subject to future appropriation action.

- H.R. 4284, Indexing Narcotics, Fentanyl, and Opioids Act of 2017
- H.R. 5002, Advancing Cutting Edge Research Act
- H.R. 5228, Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act (see Table 1 for an estimate of the revenue effects of H.R. 5228)
- H.R. 5752, Stop Illicit Drug Importation Act of 2018 (see Table 1 for an estimate of the revenue effects of H.R. 5752)
- H.R. 5799, Medicaid DRUG Improvement Act (see Table 1 for an estimate of the direct spending effects of H.R. 5799)
- H.R. 5801, Medicaid Providers and Pharmacists Are Required to Note Experiences in Record Systems to Help In-Need Patients (PARTNERSHIP) Act (see Table 1 for an estimate of the direct spending effects of H.R. 5801)
- H.R. 5806, 21st Century Tools for Pain and Addiction Treatments Act
- H.R. 5808, Medicaid Pharmaceutical Home Act of 2018 (see Table 1 for an estimate of the direct spending effects of H.R. 5808)
- H.R. 5812, Creating Opportunities that Necessitate New and Enhanced Connections That Improve Opioid Navigation Strategies Act (CONNECTIONS) Act

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

Increase in long-term direct spending and deficits: CBO estimates that enacting H.R. 4998, the Health Insurance for Former Foster Youth Act, would increase net direct spending by more than \$2.5 billion and on-budget deficits by more than \$5 billion in at least one of the four consecutive 10-year periods beginning in 2029.

CBO estimates that none of the remaining 58 bills included in this estimate would increase net direct spending by more than \$2.5 billion or on-budget deficits by more than \$5 billion in any of the four consecutive 10-year periods beginning in 2029.

Mandates: One of the 59 bills included in this document, H.R. 5795, would impose both intergovernmental and private-sector

mandates as defined in UMRA. CBO estimates that the costs of that bill's mandates on public and private entities would fall below UMRA's thresholds (\$80 million and \$160 million, respectively, for public- and private-sector entities in 2018, adjusted annually for inflation).

In addition, five bills would impose private-sector mandates as defined in UMRA. CBO estimates that the costs of the mandates in three of those bills (H.R. 5333, H.R. 5554, and H.R. 5811) would fall below the UMRA threshold. Because CBO does not know how federal agencies would implement new authority granted in the other two of those five bills, H.R. 5228 and 5687, CBO cannot determine whether the costs of their mandates would exceed the threshold.

For large entitlement grant programs, including Medicaid and CHIP, UMRA defines an increase in the stringency of conditions on states or localities as an intergovernmental mandate if the affected governments lack authority to offset those costs while continuing to provide required services. Because states possess significant flexibility to alter their responsibilities within Medicaid and CHIP, the requirements imposed by various bills in the markup on state administration of those programs would not constitute mandates as defined in UMRA.

Mandates Affecting Public and Private Entities

H.R. 5795, the Overdose Prevention and Patient Safety Act, would impose intergovernmental and private-sector mandates by requiring entities that provide treatment for substance use disorders to notify patients of their privacy rights and also to notify patients in the event that the confidentiality of their records is breached. In certain circumstances, H.R. 5795 also would prohibit public and private entities from denying entry to treatment on the basis of information in patient health records. Those requirements would either supplant or narrowly expand responsibilities under existing law, and compliance with them would not impose significant additional costs. CBO estimates that the costs of the mandates would fall below the annual thresholds established in UMRA.

Mandates Affecting Private Entities

Five bills included in this document would impose private-sector mandates:

H.R. 5228, the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act, would require drug distributors to cease distributing any drug that the Secretary of HHS determines might present an imminent or substantial hazard to public health. CBO cannot determine what drugs could be subject to such an order nor can it determine how private entities would respond. Consequently, CBO cannot determine whether the aggregate cost of the mandate would exceed the annual threshold for private-sector mandates.

H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018, would require developers and manufacturers of OTC drugs to pay certain fees to the FDA. CBO estimates that about \$30 million would be collected each year, on average, for a total of \$147 million over the 2019–2023 period. Those amounts

would not exceed the annual threshold for private-sector mandates in any year during that period.

H.R. 5554, the Animal Drug and Animal Generic Drug User Fee Amendments of 2018, would require developers and manufacturers of brand-name and generic veterinary drugs to pay application, product, establishment, and sponsor fees to the FDA. CBO estimates that about \$51 million would be collected annually, on average, for a total of \$257 million over the 2019–2023 period. Those amounts would not exceed the annual threshold for private-sector mandates in any year during that period.

H.R. 5687, the Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018, would permit the Secretary of HHS to require drug developers and manufacturers to implement new packaging and disposal technology for certain drugs. Based on information from the agency, CBO expects that the Secretary would use the new regulatory authority provided in the bill; however, it is uncertain how or when those requirements would be implemented. Consequently, CBO cannot determine whether the aggregate cost of the mandate would exceed the annual threshold for private entities.

H.R. 5811, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to postapproval study requirements for certain controlled substances, and for other purposes, would expand an existing mandate that requires drug developers to conduct postapproval studies or clinical trials for certain drugs. Under current law, in certain instances, the FDA can require studies or clinical trials after a drug has been approved. H.R. 5811 would permit the FDA to use that authority if the reduction in a drug's effectiveness meant that its benefits no longer outweighed its costs. CBO estimates that the incremental cost of the mandate would fall below the annual threshold established in UMRA because of the small number of drugs affected and the narrow expansion of the authority that exists under current law.

None of the remaining 53 bills included in this document would impose an intergovernmental or private-sector mandate.

Previous CBO estimate: On June 6, 2018, CBO issued an estimate for seven opioid-related bills ordered reported by the House Committee on Ways and Means on May 16, 2018. Two of those bills contain provisions that are identical or similar to the legislation ordered reported by the Committee on Energy and Commerce, and for those provisions, CBO's estimates are the same.

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

- H.R. 5675, which would require prescription drug plans to implement drug management programs, is identical to section 2 of H.R. 5773.
- H.R. 4841, regarding electronic prior authorization for prescriptions under Medicare's Part D, is similar to section 3 of H.R. 5773.
- H.R. 5715, which would mandate the creation of a new Internet portal to allow various stakeholders to exchange information, is identical to section 4 of H.R. 5773.
- H.R. 5684, which would expand medication therapy management, is the same as section 5 of H.R. 5773.

- H.R. 5716, regarding prescriber notification, is identical to section 6 of H.R. 5773.

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

Estimate prepared by: Federal Costs: Rebecca Yip (Centers for Disease Control and Prevention), Mark Grabowicz (Drug Enforcement Agency), Julia Christensen, Ellen Werble (Food and Drug Administration), Emily King, Andrea Noda, Lisa Ramirez-Branum, Robert Stewart (Medicaid and Children's Health Insurance Program), Philippa Haven, Lara Robillard, Colin Yee, Rebecca Yip (Medicare), Philippa Haven (National Institutes of Health), Alice Burns, Andrea Noda (Office of the Secretary of the Department of Health and Human Services), Philippa Haven, Lori Housman, Emily King (Substance Abuse and Mental Health Services Administration, Health Resources and Services Administration); Federal Revenues: Jacob Fabian, Peter Huether, and Cecilia Pastrone; Fact Checking: Zachary Byrum and Kate Kelly; Mandates: Andrew Laughlin.

Estimate reviewed by: Tom Bradley, Chief, Health Systems and Medicare Cost Estimates Unit; Chad M. Chirico, Chief, Low-Income Health Programs and Prescription Drugs Cost Estimates Unit; Sarah Masi, Special Assistant for Health; Susan Willie, Chief, Mandates Unit; Leo Lex, Deputy Assistant Director for Budget Analysis; Theresa A. Gullo, Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

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

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to extend pass through payment for certain qualifying drugs to encourage the development of non-opioid drugs for post-surgical pain management under the Medicare program.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 5809 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111-139 or the most recent Catalog of Federal Domestic Assistance.

COMMITTEE COST ESTIMATE

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

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 5809 contains no earmarks, limited tax benefits, or limited tariff benefits.

DISCLOSURE OF DIRECTED RULE MAKINGS

Pursuant to section 3(i) of H. Res. 5, the Committee finds that H.R. 3331 contains no directed rule makings.

ADVISORY COMMITTEE STATEMENT

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

APPLICABILITY TO LEGISLATIVE BRANCH

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

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 provides that the Act may be cited as the “Post-operative Opioid Prevention Act of 2018.”

Section 2. Medicare incentives for use of non-opioid analgesics in hospital outpatient departments and ambulatory surgical centers

Section 2 extends the eligibility to receive pass through payments from three years to five years for qualifying drugs. In order to qualify, the drug must be a non-opioid analgesic, demonstrate substantial clinical improvement through a process developed by the Secretary, and either receive pass through payment at the time of enactment or be a new drug coming to market after enactment of the bill.

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 B—SUPPLEMENTARY MEDICAL INSURANCE BENEFITS FOR THE
AGED AND DISABLED

* * * * *

PAYMENT OF BENEFITS

SEC. 1833. (a) Except as provided in section 1876, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to—(1) in the case of services described in section 1832(a)(1)—80 percent of the reasonable charges for the services; except that (A) an organization which provides medical and other health services (or arranges for their availability) on a prepayment basis (and either is sponsored by a union or employer, or does not provide, or arrange for the provision of, any inpatient hospital services) may elect to be paid 80 percent of the reasonable cost of services for which payment may be made under this part on behalf of individuals enrolled in such organization in lieu of 80 percent of the reasonable charges for such services if the organization undertakes to charge such individuals no more than 20 percent of such reasonable cost plus any amounts payable by them as a result of subsection (b), (B) with respect to items and services described in section 1861(s)(10)(A), the amounts paid shall be 100 percent of the reasonable charges for such items and services, (C) with respect to expenses incurred for those physicians' services for which payment may be made under this part that are described in section 1862(a)(4), the amounts paid shall be subject to such limitations as may be prescribed by regulations, (D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i)(I) on the basis of a fee schedule under subsection (h)(1) (for tests furnished before January 1, 2017) or section 1834(d)(1), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B), or the amount of the charges billed for the tests, or (II) under section 1834A (for tests furnished on or after January 1, 2017), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis) of the lesser of the amount determined under such section or the amount of the charges billed for the tests, or (ii) for tests furnished before January 1, 2017, on the basis of a negotiated rate established under subsection (h)(6), the amount paid shall be equal to 100 percent of such negotiated rate,, (E) with respect to services furnished to individuals who have been determined to have end stage renal disease, the amounts paid shall be determined subject to the provisions of section 1881, (F) with respect to clinical social worker services under section 1861(s)(2)(N), the amounts paid shall be 80 percent of the lesser of (i) the actual charge for the services or (ii) 75 percent of the amount determined for payment of a psychologist under clause (L),

(G) with respect to facility services furnished in connection with a surgical procedure specified pursuant to subsection (i)(1)(A) and furnished to an individual in an ambulatory surgical center described in such subsection, for services furnished beginning with the implementation date of a revised payment system for such services in such facilities specified in subsection (i)(2)(D), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under such revised payment system,

(H) with respect to services of a certified registered nurse anesthetist under section 1861(s)(11), the amounts paid shall be 80 percent of the least of the actual charge, the prevailing charge that would be recognized (or, for services furnished on or after January 1, 1992, the fee schedule amount provided under section 1848) if the services had been performed by an anesthesiologist, or the fee schedule for such services established by the Secretary in accordance with subsection (I), (I) with respect to covered items (described in section 1834(a)(13)), the amounts paid shall be the amounts described in section 1834(a)(1), and (J) with respect to expenses incurred for radiologist services (as defined in section 1834(b)(6)), subject to section 1848, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount provided under the fee schedule established under section 1834(b), (K) with respect to certified nurse-midwife services under section 1861(s)(2)(L), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph (but in no event shall such fee schedule exceed 65 percent of the prevailing charge that would be allowed for the same service performed by a physician, or, for services furnished on or after January 1, 1992, 65 percent (or 100 percent for services furnished on or after January 1, 2011) of the fee schedule amount provided under section 1848 for the same service performed by a physician), (L) with respect to qualified psychologist services under section 1861(s)(2)(M), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph, (M) with respect to prosthetic devices and orthotics and prosthetics (as defined in section 1834(h)(4)), the amounts paid shall be the amounts described in section 1834(h)(1), (N) with respect to expenses incurred for physicians' services (as defined in section 1848(j)(3)) other than personalized prevention plan services (as defined in section 1861(hhh)(1)), the amounts paid shall be 80 percent of the payment basis determined under section 1848(a)(1), (O) with respect to services described in section 1861(s)(2)(K) (relating to services furnished by physician assistants, nurse practitioners, or clinic nurse specialists), the amounts paid shall be equal to 80 percent of (i) the lesser of the actual charge or 85 percent of the fee schedule amount provided under section 1848, or (ii) in the case of services as an assistant at surgery, the lesser of the actual charge or 85 percent of the amount that would oth-

erwise be recognized if performed by a physician who is serving as an assistant at surgery, (P) with respect to surgical dressings, the amounts paid shall be the amounts determined under section 1834(i), (Q) with respect to items or services for which fee schedules are established pursuant to section 1842(s), the amounts paid shall be 80 percent of the lesser of the actual charge or the fee schedule established in such section, (R) with respect to ambulance services, (i) the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary under section 1834(l) and (ii) with respect to ambulance services described in section 1834(l)(8), the amounts paid shall be the amounts determined under section 1834(g) for outpatient critical access hospital services, (S) with respect to drugs and biologicals (including intravenous immune globulin (as defined in section 1861(zz))) not paid on a cost or prospective payment basis as otherwise provided in this part (other than items and services described in subparagraph (B)), the amounts paid shall be 80 percent of the lesser of the actual charge or the payment amount established in section 1842(o) (or, if applicable, under section 1847, 1847A, or 1847B), (T) with respect to medical nutrition therapy services (as defined in section 1861(vv)), the amount paid shall be 80 percent (or 100 percent if such services are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual) of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) for the same services if furnished by a physician, (U) with respect to facility fees described in section 1834(m)(2)(B), the amounts paid shall be 80 percent of the lesser of the actual charge or the amounts specified in such section, (V) notwithstanding subparagraphs (I) (relating to durable medical equipment), (M) (relating to prosthetic devices and orthotics and prosthetics), and (Q) (relating to 1842(s) items), with respect to competitively priced items and services (described in section 1847(a)(2)) that are furnished in a competitive area, the amounts paid shall be the amounts described in section 1847(b)(5), (W) with respect to additional preventive services (as defined in section 1861(ddd)(1)), the amount paid shall be (i) in the case of such services which are clinical diagnostic laboratory tests, the amount determined under subparagraph (D) (if such subparagraph were applied, by substituting "100 percent" for "80 percent"), and (ii) in the case of all other such services, 100 percent of the lesser of the actual charge for the service or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph, (X) with respect to personalized prevention plan services (as defined in section 1861(hhh)(1)), the amount paid shall be 100 percent of the lesser of the actual charge for the services or the amount determined under the payment basis determined under section 1848, (Y) with respect to preventive services described in subparagraphs (A) and (B) of section 1861(ddd)(3) that are appropriate for the individual and, in the case of such services de-

scribed in subparagraph (A), are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population, the amount paid shall be 100 percent of (i) except as provided in clause (ii), the lesser of the actual charge for the services or the amount determined under the fee schedule that applies to such services under this part, and (ii) in the case of such services that are covered OPD services (as defined in subsection (t)(1)(B)), the amount determined under subsection (t), (Z) with respect to Federally qualified health center services for which payment is made under section 1834(o), the amounts paid shall be 80 percent of the lesser of the actual charge or the amount determined under such section, (AA) with respect to an applicable disposable device (as defined in paragraph (2) of section 1834(s)) furnished to an individual pursuant to paragraph (1) of such section, the amount paid shall be equal to 80 percent of the lesser of the actual charge or the amount determined under paragraph (3) of such section, and (BB) with respect to home infusion therapy, the amount paid shall be an amount equal to 80 percent of the lesser of the actual charge for the services or the amount determined under section 1834(u);

(2) in the case of services described in section 1832(a)(2) (except those services described in subparagraphs (C), (D), (E), (F), (G), (H), and (I) of such section and unless otherwise specified in section 1881)—

(A) with respect to home health services (other than a covered osteoporosis drug) (as defined in section 1861(kk)), the amount determined under the prospective payment system under section 1895;

(B) with respect to other items and services (except those described in subparagraph (C), (D), or (E) of this paragraph and except as may be provided in section 1886 or section 1888(e)(9))—

(i) furnished before January 1, 1999, the lesser of—

(I) the reasonable cost of such services, as determined under section 1861(v), or

(II) the customary charges with respect to such services,—less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A), but in no case may the payment for such other services exceed 80 percent of such reasonable cost, or

(ii) if such services are furnished before January 1, 1999, by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this clause), free of charge or at nominal charges to the public, 80 percent of the amount determined in accordance with section 1814(b)(2), or

(iii) if such services are furnished on or after January 1, 1999, the amount determined under subsection (t), or

(iv) if (and for so long as) the conditions described in section 1814(b)(3) are met, the amounts determined

under the reimbursement system described in such section;

(C) with respect to services described in the second sentence of section 1861(p), 80 percent of the reasonable charges for such services;

(D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i)(I) on the basis of a fee schedule determined under subsection (h)(1) (for tests furnished before January 1, 2017) or section 1834(d)(1), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1866) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B), or the amount of the charges billed for the tests, or (II) under section 1834A (for tests furnished on or after January 1, 2017), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1866) of the lesser of the amount determined under such section or the amount of the charges billed for the tests, or (ii) for tests furnished before January 1, 2017, on the basis of a negotiated rate established under subsection (h)(6), the amount paid shall be equal to 100 percent of such negotiated rate for such tests;

(E) with respect to—

(i) outpatient hospital radiology services (including diagnostic and therapeutic radiology, nuclear medicine and CAT scan procedures, magnetic resonance imaging, and ultrasound and other imaging services, but excluding screening mammography and, for services furnished on or after January 1, 2005, diagnostic mammography), and

(ii) effective for procedures performed on or after October 1, 1989, diagnostic procedures (as defined by the Secretary) described in section 1861(s)(3) (other than diagnostic x-ray tests and diagnostic laboratory tests), the amount determined under subsection (n) or, for services or procedures performed on or after January 1, 1999, subsection (t);

(F) with respect to a covered osteoporosis drug (as defined in section 1861(kk)) furnished by a home health agency, 80 percent of the reasonable cost of such service, as determined under section 1861(v);

(G) with respect to items and services described in section 1861(s)(10)(A), the lesser of—

(i) the reasonable cost of such services, as determined under section 1861(v), or

(ii) the customary charges with respect to such services; and

(H) with respect to personalized prevention plan services (as defined in section 1861(hhh)(1)) furnished by an out-

patient department of a hospital, the amount determined under paragraph (1)(X), or, if such services are furnished by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this provision), free of charge or at nominal charges to the public, the amount determined in accordance with section 1814(b)(2);

(3) in the case of services described in section 1832(a)(2)(D)—

(A) except as provided in subparagraph (B), the costs which are reasonable and related to the cost of furnishing such services or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations, including those authorized under section 1861(v)(1)(A), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A), but in no case may the payment for such services (other than for items and services described in section 1861(s)(10)(A)) exceed 80 percent of such costs; or

(B) with respect to the services described in clause (ii) of section 1832(a)(2)(D) that are furnished to an individual enrolled with a MA plan under part C pursuant to a written agreement described in section 1853(a)(4), the amount (if any) by which—

(i) the amount of payment that would have otherwise been provided (I) under subparagraph (A) (calculated as if “100 percent” were substituted for “80 percent” in such subparagraph) for such services if the individual had not been so enrolled, or (II) in the case of such services furnished on or after the implementation date of the prospective payment system under section 1834(o), under such section (calculated as if “100 percent” were substituted for “80 percent” in such section) for such services if the individual had not been so enrolled; exceeds

(ii) the amount of the payments received under such written agreement for such services (not including any financial incentives provided for in such agreement such as risk pool payments, bonuses, or withholds),

less the amount the federally qualified health center may charge as described in section 1857(e)(3)(B);

(4) in the case of facility services described in section 1832(a)(2)(F), and outpatient hospital facility services furnished in connection with surgical procedures specified by the Secretary pursuant to section 1833(i)(1)(A), the applicable amount as determined under paragraph (2) or (3) of subsection (i) or subsection (t);

(5) in the case of covered items (described in section 1834(a)(13)) the amounts described in section 1834(a)(1);

(6) in the case of outpatient critical access hospital services, the amounts described in section 1834(g);

(7) in the case of prosthetic devices and orthotics and prosthetics (as described in section 1834(h)(4)), the amounts described in section 1834(h);

(8) in the case of—

(A) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services furnished—

(i) by a rehabilitation agency, public health agency, clinic, comprehensive outpatient rehabilitation facility, or skilled nursing facility,

(ii) by a home health agency to an individual who is not homebound, or

(iii) by another entity under an arrangement with an entity described in clause (i) or (ii); and

(B) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services furnished—

(i) by a hospital to an outpatient or to a hospital inpatient who is entitled to benefits under part A but has exhausted benefits for inpatient hospital services during a spell of illness or is not so entitled to benefits under part A, or

(ii) by another entity under an arrangement with a hospital described in clause (i),

the amounts described in section 1834(k); and

(9) in the case of services described in section 1832(a)(2)(E) that are not described in paragraph (8), the amounts described in section 1834(k).

Paragraph (3)(A) shall not apply to Federally qualified health center services furnished on or after the implementation date of the prospective payment system under section 1834(0).

(b) Before applying subsection (a) with respect to expenses incurred by an individual during any calendar year, the total amount of the expenses incurred by such individual during such year (which would, except for this subsection, constitute incurred expenses from which benefits payable under subsection (a) are determinable) shall be reduced by a deductible of \$75 for calendar years before 1991, \$100 for 1991 through 2004, \$110 for 2005, and for a subsequent year the amount of such deductible for the previous year increased by the annual percentage increase in the monthly actuarial rate under section 1839(a)(1) ending with such subsequent year (rounded to the nearest \$1); except that (1) such total amount shall not include expenses incurred for preventive services described in subparagraph (A) of section 1861(ddd)(3) that are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual, (2) such deductible shall not apply with respect to home health services (other than a covered osteoporosis drug (as defined in section 1861(kk))), (3) such deductible shall not apply with respect to clinical diagnostic laboratory tests for which payment is made under this part (A) under subsection (a)(1)(D)(i) or (a)(2)(D)(i) on an assignment-related basis, or to a provider having an agreement under section 1866, or (B) for tests furnished before January 1, 2017, on the basis of a negotiated rate determined under subsection (h)(6), (4) such deductible shall not apply to Federally qualified health center services, (5) such deductible shall not apply with respect to screening mammography (as described in section 1861(jj)), (6) such deductible shall not apply with respect to

screening pap smear and screening pelvic exam (as described in section 1861(nn)), (7) such deductible shall not apply with respect to ultrasound screening for abdominal aortic aneurysm (as defined in section 1861(bbb)), (8) such deductible shall not apply with respect to colorectal cancer screening tests (as described in section 1861(pp)(1)), (9) such deductible shall not apply with respect to an initial preventive physical examination (as defined in section 1861(ww)), and (10) such deductible shall not apply with respect to personalized prevention plan services (as defined in section 1861(hhh)(1)). The total amount of the expenses incurred by an individual as determined under the preceding sentence shall, after the reduction specified in such sentence, be further reduced by an amount equal to the expenses incurred for the first three pints of whole blood (or equivalent quantities of packed red blood cells, as defined under regulations) furnished to the individual during the calendar year, except that such deductible for such blood shall in accordance with regulations be appropriately reduced to the extent that there has been a replacement of such blood (or equivalent quantities of packed red blood cells, as so defined); and for such purposes blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual shall be deemed replaced when the institution or other person furnishing such blood (or such equivalent quantities of packed red blood cells, as so defined) is given one pint of blood for each pint of blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual with respect to which a deduction is made under this sentence. The deductible under the previous sentence for blood or blood cells furnished an individual in a year shall be reduced to the extent that a deductible has been imposed under section 1813(a)(2) to blood or blood cells furnished the individual in the year. Paragraph (1) of the first sentence of this subsection shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

(c)(1) Notwithstanding any other provision of this part, with respect to expenses incurred in a calendar year in connection with the treatment of mental, psychoneurotic, and personality disorders of an individual who is not an inpatient of a hospital at the time such expenses are incurred, there shall be considered as incurred expenses for purposes of subsections (a) and (b)—

(A) for expenses incurred in years prior to 2010, only 62½ percent of such expenses;

(B) for expenses incurred in 2010 or 2011, only 68¾ percent of such expenses;

(C) for expenses incurred in 2012, only 75 percent of such expenses;

(D) for expenses incurred in 2013, only 81¼ percent of such expenses; and

(E) for expenses incurred in 2014 or any subsequent calendar year, 100 percent of such expenses.

(2) For purposes of subparagraphs (A) through (D) of paragraph (1), the term “treatment” does not include brief office visits (as defined by the Secretary) for the sole purpose of monitoring or chang-

ing drug prescriptions used in the treatment of such disorders or partial hospitalization services that are not directly provided by a physician

(d) No payment may be made under this part with respect to any services furnished an individual to the extent that such individual is entitled (or would be entitled except for section 1813) to have payment made with respect to such services under part A.

(e) No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

(f) In establishing limits under subsection (a) on payment for rural health clinic services provided by rural health clinics (other than such clinics in hospitals with less than 50 beds), the Secretary shall establish such limit, for services provided—

(1) in 1988, after March 31, at \$46 per visit, and

(2) in a subsequent year, at the limit established under this subsection for the previous year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) applicable to primary care services (as defined in section 1842(i)(4)) furnished as of the first day of that year.

(g)(1)(A) Subject to paragraphs (4) and (5), in the case of physical therapy services of the type described in section 1861(p) and speech-language pathology services of the type described in such section through the application of section 1861(l)(2), but (except as provided in paragraph (6)) not described in subsection (a)(8)(B), and physical therapy services and speech-language pathology services of such type which are furnished by a physician or as incident to physicians' services, with respect to expenses incurred in any calendar year, no more than the amount specified in paragraph (2) for the year shall be considered as incurred expenses for purposes of subsections (a) and (b). The preceding sentence shall not apply to expenses incurred with respect to services furnished after December 31, 2017.

(B) With respect to services furnished during 2018 or a subsequent year, in the case of physical therapy services of the type described in section 1861(p), speech-language pathology services of the type described in such section through the application of section 1861(l)(2), and physical therapy services and speech-language pathology services of such type which are furnished by a physician or as incident to physicians' services, with respect to expenses incurred in any calendar year, any amount that is more than the amount specified in paragraph (2) for the year shall not be considered as incurred expenses for purposes of subsections (a) and (b) unless the applicable requirements of paragraph (7) are met.

(2) The amount specified in this paragraph—

(A) for 1999, 2000, and 2001, is \$1,500, and

(B) for a subsequent year is the amount specified in this paragraph for the preceding year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year;

except that if an increase under subparagraph (B) for a year is not a multiple of \$10, it shall be rounded to the nearest multiple of \$10.

(3)(A) Subject to paragraphs (4) and (5), in the case of occupational therapy services (of the type that are described in section 1861(p) (but (except as provided in paragraph (6)) not described in subsection (a)(8)(B)) through the operation of section 1861(g) and of such type which are furnished by a physician or as incident to physicians' services), with respect to expenses incurred in any calendar year, no more than the amount specified in paragraph (2) for the year shall be considered as incurred expenses for purposes of subsections (a) and (b). The preceding sentence shall not apply to expenses incurred with respect to services furnished after December 31, 2017.

(B) With respect to services furnished during 2018 or a subsequent year, in the case of occupational therapy services (of the type that are described in section 1861(p) through the operation of section 1861(g) and of such type which are furnished by a physician or as incident to physicians' services), with respect to expenses incurred in any calendar year, any amount that is more than the amount specified in paragraph (2) for the year shall not be considered as incurred expenses for purposes of subsections (a) and (b) unless the applicable requirements of paragraph (7) are met.

(4) This subsection shall not apply to expenses incurred with respect to services furnished during 2000, 2001, 2002, 2004, and 2005.

(5)(A) With respect to expenses incurred during the period beginning on January 1, 2006, and ending on December 31, 2017, for services, the Secretary shall implement a process under which an individual enrolled under this part may, upon request of the individual or a person on behalf of the individual, obtain an exception from the uniform dollar limitation specified in paragraph (2), for services described in paragraphs (1) and (3) if the provision of such services is determined to be medically necessary and if the requirement of subparagraph (B) is met. Under such process, if the Secretary does not make a decision on such a request for an exception within 10 business days of the date of the Secretary's receipt of the request made in accordance with such requirement, the Secretary shall be deemed to have found the services to be medically necessary.

(B) In the case of outpatient therapy services for which an exception is requested under the first sentence of subparagraph (A), the claim for such services shall contain an appropriate modifier (such as the KX modifier used as of the date of the enactment of this subparagraph) indicating that such services are medically necessary as justified by appropriate documentation in the medical record involved.

(C)(i) In applying this paragraph with respect to a request for an exception with respect to expenses that would be incurred for outpatient therapy services (including services described in subsection (a)(8)(B)) that would exceed the threshold described in clause (ii) for a year, the request for such an exception, for services furnished on or after October 1, 2012, shall be subject to a manual medical review process that, subject to subparagraph (E), is similar to the

manual medical review process used for certain exceptions under this paragraph in 2006.

(ii) The threshold under this clause for a year is \$3,700. Such threshold shall be applied separately—

(I) for physical therapy services and speech-language pathology services; and

(II) for occupational therapy services.

(E)(i) In place of the manual medical review process under subparagraph (C)(i), the Secretary shall implement a process for medical review under this subparagraph under which the Secretary shall identify and conduct medical review for services described in subparagraph (C)(i) furnished by a provider of services or supplier (in this subparagraph referred to as a “therapy provider”) using such factors as the Secretary determines to be appropriate.

(ii) Such factors may include the following:

(I) The therapy provider has had a high claims denial percentage for therapy services under this part or is less compliant with applicable requirements under this title.

(II) The therapy provider has a pattern of billing for therapy services under this part that is aberrant compared to peers or otherwise has questionable billing practices for such services, such as billing medically unlikely units of services in a day.

(III) The therapy provider is newly enrolled under this title or has not previously furnished therapy services under this part.

(IV) The services are furnished to treat a type of medical condition.

(V) The therapy provider is part of group that includes another therapy provider identified using the factors determined under this subparagraph.

(iii) For purposes of carrying out this subparagraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of \$5,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for fiscal years 2015 and 2016, to remain available until expended. Such funds may not be used by a contractor under section 1893(h) for medical reviews under this subparagraph.

(iv) The targeted review process under this subparagraph shall not apply to services for which expenses are incurred beyond the period for which the exceptions process under subparagraph (A) is implemented, except as such process is applied under paragraph (7)(B).

(6)(A) In applying paragraphs (1) and (3) to services furnished during the period beginning not later than October 1, 2012, and ending on December 31, 2017, the exclusion of services described in subsection (a)(8)(B) from the uniform dollar limitation specified in paragraph (2) shall not apply to such services furnished during 2012 through 2017.

(B)(i) With respect to outpatient therapy services furnished beginning on or after January 1, 2013, and before January 1, 2014, for which payment is made under section 1834(g), the Secretary shall count toward the uniform dollar limitations described in paragraphs (1) and (3) and the threshold described in paragraph (5)(C) the amount that would be payable under this part if such services

were paid under section 1834(k)(1)(B) instead of being paid under section 1834(g).

(ii) Nothing in clause (i) shall be construed as changing the method of payment for outpatient therapy services under section 1834(g).

(7) For purposes of paragraphs (1)(B) and (3)(B), with respect to services described in such paragraphs, the requirements described in this paragraph are as follows:

(A) INCLUSION OF APPROPRIATE MODIFIER.—The claim for such services contains an appropriate modifier (such as the KX modifier described in paragraph (5)(B)) indicating that such services are medically necessary as justified by appropriate documentation in the medical record involved.

(B) TARGETED MEDICAL REVIEW FOR CERTAIN SERVICES ABOVE THRESHOLD.—

(i) IN GENERAL.—In the case where expenses that would be incurred for such services would exceed the threshold described in clause (ii) for the year, such services shall be subject to the process for medical review implemented under paragraph (5)(E).

(ii) THRESHOLD.—The threshold under this clause for—

(I) a year before 2028, is \$3,000;

(II) 2028, is the amount specified in subclause (I) increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for 2028; and

(III) a subsequent year, is the amount specified in this clause for the preceding year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year;

except that if an increase under subclause (II) or (III) for a year is not a multiple of \$10, it shall be rounded to the nearest multiple of \$10.

(iii) APPLICATION.—The threshold under clause (ii) shall be applied separately—

(I) for physical therapy services and speech-language pathology services; and

(II) for occupational therapy services.

(iv) FUNDING.—For purposes of carrying out this subparagraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841 to the Centers for Medicare & Medicaid Services Program Management Account, of \$5,000,000 for each fiscal year beginning with fiscal year 2018, to remain available until expended. Such funds may not be used by a contractor under section 1893(h) for medical reviews under this subparagraph.

(8) With respect to services furnished on or after January 1, 2013, where payment may not be made as a result of application of paragraphs (1) and (3), section 1879 shall apply in the same manner as such section applies to a denial that is made by reason of section 1862(a)(1).

(h)(1)(A) Subject to section 1834(d)(1), the Secretary shall establish fee schedules for clinical diagnostic laboratory tests (including prostate cancer screening tests under section 1861(o) consisting of prostate-specific antigen blood tests) for which payment is made

under this part, other than such tests performed by a provider of services for an inpatient of such provider.

(B) In the case of clinical diagnostic laboratory tests performed by a physician or by a laboratory (other than tests performed by a qualified hospital laboratory (as defined in subparagraph (D)) for outpatients of such hospital), the fee schedules established under subparagraph (A) shall be established on a regional, statewide, or carrier service area basis (as the Secretary may determine to be appropriate) for tests furnished on or after July 1, 1984.

(C) In the case of clinical diagnostic laboratory tests performed by a qualified hospital laboratory (as defined in subparagraph (D)) for outpatients of such hospital, the fee schedules established under subparagraph (A) shall be established on a regional, statewide, or carrier service area basis (as the Secretary may determine to be appropriate) for tests furnished on or after July 1, 1984.

(D) In this subsection, the term “qualified hospital laboratory” means a hospital laboratory, in a sole community hospital (as defined in section 1886(d)(5)(D)(iii)), which provides some clinical diagnostic laboratory tests 24 hours a day in order to serve a hospital emergency room which is available to provide services 24 hours a day and 7 days a week.

(2)(A)(i) Except as provided in clause (v), subparagraph (B), and paragraph (4), the Secretary shall set the fee schedules at 60 percent (or, in the case of a test performed by a qualified hospital laboratory (as defined in paragraph (1)(D)) for outpatients of such hospital, 62 percent) of the prevailing charge level determined pursuant to the third and fourth sentences of section 1842(b)(3) for similar clinical diagnostic laboratory tests for the applicable region, State, or area for the 12-month period beginning July 1, 1984, adjusted annually (to become effective on January 1 of each year) by, subject to clause (iv), a percentage increase or decrease equal to the percentage increase or decrease in the Consumer Price Index for All Urban Consumers (United States city average) minus, for each of the years 2009 and 2010, 0.5 percentage points, and, for tests furnished before the date of enactment of section 1834A, subject to such other adjustments as the Secretary determines are justified by technological changes.

(ii) Notwithstanding clause (i)—

(I) any change in the fee schedules which would have become effective under this subsection for tests furnished on or after January 1, 1988, shall not be effective for tests furnished during the 3-month period beginning on January 1, 1988,

(II) the Secretary shall not adjust the fee schedules under clause (i) to take into account any increase in the consumer price index for 1988,

(III) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1991, 1992, and 1993 shall be 2 percent, and

(IV) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1994 and 1995, 1998 through 2002, and 2004 through 2008 shall be 0 percent.

(iii) In establishing fee schedules under clause (i) with respect to automated tests and tests (other than cytopathology tests) which before July 1, 1984, the Secretary made subject to a limit based on lowest charge levels under the sixth sentence of section 1842(b)(3)

performed after March 31, 1988, the Secretary shall reduce by 8.3 percent the fee schedules otherwise established for 1988, and such reduced fee schedules shall serve as the base for 1989 and subsequent years.

(iv) After determining the adjustment to the fee schedules under clause (i), the Secretary shall reduce such adjustment—

(I) for 2011 and each subsequent year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(II) for each of 2011 through 2015, by 1.75 percentage points.

Subclause (I) shall not apply in a year where the adjustment to the fee schedules determined under clause (i) is 0.0 or a percentage decrease for a year. The application of the productivity adjustment under subclause (I) shall not result in an adjustment to the fee schedules under clause (i) being less than 0.0 for a year. The application of subclause (II) may result in an adjustment to the fee schedules under clause (i) being less than 0.0 for a year, and may result in payment rates for a year being less than such payment rates for the preceding year.

(v) The Secretary shall reduce by 2 percent the fee schedules otherwise determined under clause (i) for 2013, and such reduced fee schedules shall serve as the base for 2014 and subsequent years.

(B) The Secretary may make further adjustments or exceptions to the fee schedules to assure adequate reimbursement of (i) emergency laboratory tests needed for the provision of bona fide emergency services, and (ii) certain low volume high-cost tests where highly sophisticated equipment or extremely skilled personnel are necessary to assure quality.

(3) In addition to the amounts provided under the fee schedules (for tests furnished before January 1, 2017) or under section 1834A (for tests furnished on or after January 1, 2017), subject to subsection (b)(5) of such section, the Secretary shall provide for and establish (A) a nominal fee to cover the appropriate costs in collecting the sample on which a clinical diagnostic laboratory test was performed and for which payment is made under this part, except that not more than one such fee may be provided under this paragraph with respect to samples collected in the same encounter, and (B) a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample, except that such a fee may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital). In establishing a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a sample, the Secretary shall provide a method for computing the fee based on the number of miles traveled and the personnel costs associated with the collection of each individual sample, but the Secretary shall only be required to apply such method in the case of tests furnished during the period beginning on April 1, 1989, and ending on December 31, 1990, by a laboratory that establishes to the satisfaction of the Secretary (based on data for the 12-month period ending June 30, 1988) that (i) the laboratory is dependent upon payments under this title for at least 80 percent of its collected revenues for clinical diagnostic laboratory tests, (ii) at least 85 percent of its gross revenues for such tests are attributable to tests performed with respect to individuals who are homebound or who are

residents in a nursing facility, and (iii) the laboratory provided such tests for residents in nursing facilities representing at least 20 percent of the number of such facilities in the State in which the laboratory is located.

(4)(A) In establishing any fee schedule under this subsection, the Secretary may provide for an adjustment to take into account, with respect to the portion of the expenses of clinical diagnostic laboratory tests attributable to wages, the relative difference between a region's or local area's wage rates and the wage rate presumed in the data on which the schedule is based.

(B) For purposes of subsections (a)(1)(D)(i) and (a)(2)(D)(i), the limitation amount for a clinical diagnostic laboratory test performed—

(i) on or after July 1, 1986, and before April 1, 1988, is equal to 115 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(ii) after March 31, 1988, and before January 1, 1990, is equal to the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iii) after December 31, 1989, and before January 1, 1991, is equal to 93 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iv) after December 31, 1990, and before January 1, 1994, is equal to 88 percent of such median,

(v) after December 31, 1993, and before January 1, 1995, is equal to 84 percent of such median,

(vi) after December 31, 1994, and before January 1, 1996, is equal to 80 percent of such median,

(vii) after December 31, 1995, and before January 1, 1998, is equal to 76 percent of such median, and

(viii) after December 31, 1997, is equal to 74 percent of such median (or 100 percent of such median in the case of a clinical diagnostic laboratory test performed on or after January 1, 2001, that the Secretary determines is a new test for which no limitation amount has previously been established under this subparagraph).

(5)(A) In the case of a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part on an assignment-related basis or under a provider agreement under section 1866, payment may be made only to the person or entity which performed or supervised the performance of such test; except that—

(i) if a physician performed or supervised the performance of such test, payment may be made to another physician with whom he shares his practice,

(ii) in the case of a test performed at the request of a laboratory by another laboratory, payment may be made to the referring laboratory but only if—

(I) the referring laboratory is located in, or is part of, a rural hospital,

(II) the referring laboratory is wholly owned by the entity performing such test, the referring laboratory wholly owns the entity performing such test, or both the referring

laboratory and the entity performing such test are wholly-owned by a third entity, or

(III) not more than 30 percent of the clinical diagnostic laboratory tests for which such referring laboratory (but not including a laboratory described in subclause (II)), receives requests for testing during the year in which the test is performed are performed by another laboratory, and

(iii) in the case of a clinical diagnostic laboratory test provided under an arrangement (as defined in section 1861(w)(1)) made by a hospital, critical access hospital, or skilled nursing facility, payment shall be made to the hospital or skilled nursing facility.

(B) In the case of such a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part, and which is not described in subparagraph (A), payment may be made to the beneficiary only on the basis of the itemized bill of the person or entity which performed or supervised the performance of the test.

(C) Payment for a clinical diagnostic laboratory test, including a test performed in a physician's office but excluding a test performed by a rural health clinic may only be made on an assignment-related basis or to a provider of services with an agreement in effect under section 1866.

(D) A person may not bill for a clinical diagnostic laboratory test, including a test performed in a physician's office but excluding a test performed by a rural health clinic, other than on an assignment-related basis. If a person knowingly and willfully and on a repeated basis bills for a clinical diagnostic laboratory test in violation of the previous sentence, the Secretary may apply sanctions against the person in the same manner as the Secretary may apply sanctions against a physician in accordance with paragraph (2) of section 1842(j) in the same manner such paragraphs apply with respect to a physician. Paragraph (4) of such section shall apply in this subparagraph in the same manner as such paragraph applies to such section.

(6) For tests furnished before January 1, 2017, in the case of any diagnostic laboratory test payment for which is not made on the basis of a fee schedule under paragraph (1), the Secretary may establish a payment rate which is acceptable to the person or entity performing the test and which would be considered the full charge for such tests. Such negotiated rate shall be limited to an amount not in excess of the total payment that would have been made for the services in the absence of such rate.

(7) Notwithstanding paragraphs (1) and (4) and section 1834A, the Secretary shall establish a national minimum payment amount under this part for a diagnostic or screening pap smear laboratory test (including all cervical cancer screening technologies that have been approved by the Food and Drug Administration as a primary screening method for detection of cervical cancer) equal to \$14.60 for tests furnished in 2000. For such tests furnished in subsequent years, such national minimum payment amount shall be adjusted annually as provided in paragraph (2).

(8)(A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to

which a new or substantially revised HCPCS code is assigned on or after January 1, 2005 (in this paragraph referred to as “new tests”).

(B) Determinations under subparagraph (A) shall be made only after the Secretary—

(i) makes available to the public (through an Internet website and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount under this subsection is being considered for a year;

(ii) on the same day such list is made available, causes to have published in the Federal Register notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis under this subsection for establishing payment amounts for the tests on such list;

(iii) not less than 30 days after publication of such notice convenes a meeting, that includes representatives of officials of the Centers for Medicare & Medicaid Services involved in determining payment amounts, to receive such comments and recommendations (and data on which the recommendations are based);

(iv) taking into account the comments and recommendations (and accompanying data) received at such meeting, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under this subsection for each such code, together with an explanation of the reasons for each such determination, the data on which the determinations are based, and a request for public written comments on the proposed determination; and

(v) taking into account the comments received during the public comment period, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of final determinations of the payment amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

(C) Under the procedures established pursuant to subparagraph (A), the Secretary shall—

(i) set forth the criteria for making determinations under subparagraph (A); and

(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary deems appropriate.

(E) For purposes of this paragraph:

(i) The term “HCPCS” refers to the Health Care Procedure Coding System.

(ii) A code shall be considered to be “substantially revised” if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or

a new methodology for measuring an existing analyte-specific test).

(9) Notwithstanding any other provision in this part, in the case of any diagnostic laboratory test for HbA1c that is labeled by the Food and Drug Administration for home use and is furnished on or after April 1, 2008, the payment rate for such test shall be the payment rate established under this part for a glycated hemoglobin test (identified as of October 1, 2007, by HCPCS code 83036 (and any succeeding codes)).

(i)(1) The Secretary shall, in consultation with appropriate medical organizations—

(A) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in an ambulatory surgical center (meeting the standards specified under section 1832(a)(2)(F)(i)), critical access hospital, or hospital outpatient department, and

(B) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in a physician's office.

The lists of procedures established under subparagraphs (A) and (B) shall be reviewed and updated not less often than every 2 years, in consultation with appropriate trade and professional organizations.

(2)(A) For services furnished prior to the implementation of the system described in subparagraph (D), subject to subparagraph (E), the amount of payment to be made for facility services furnished in connection with a surgical procedure specified pursuant to paragraph (1)(A) and furnished to an individual in an ambulatory surgical center described in such paragraph shall be equal to 80 percent of a standard overhead amount established by the Secretary (with respect to each such procedure) on the basis of the Secretary's estimate of a fair fee which—

(i) takes into account the costs incurred by such centers, or classes of centers, generally in providing services furnished in connection with the performance of such procedure, as determined in accordance with a survey (based upon a representative sample of procedures and facilities) of the actual audited costs incurred by such centers in providing such services,

(ii) takes such costs into account in such a manner as will assure that the performance of the procedure in such a center will result in substantially less amounts paid under this title than would have been paid if the procedure had been performed on an inpatient basis in a hospital, and

(iii) in the case of insertion of an intraocular lens during or subsequent to cataract surgery includes payment which is reasonable and related to the cost of acquiring the class of lens involved.

Each amount so established shall be reviewed and updated not later than July 1, 1987, and annually thereafter to take account of varying conditions in different areas.

(B) The amount of payment to be made under this part for facility services furnished, in connection with a surgical procedure specified pursuant to paragraph (1)(B), in a physician's office shall be equal to 80 percent of a standard overhead amount established by the Secretary (with respect to each such procedure) on the basis of the Secretary's estimate of a fair fee which—

(i) takes into account additional costs, not usually included in the professional fee, incurred by physicians in securing, maintaining, and staffing the facilities and ancillary services appropriate for the performance of such procedure in the physician's office, and

(ii) takes such items into account in such a manner which will assure that the performance of such procedure in the physician's office will result in substantially less amounts paid under this title than would have been paid if the services had been furnished on an inpatient basis in a hospital.

Each amount so established shall be reviewed and updated not later than July 1, 1987, and annually thereafter to take account of varying conditions in different areas.

(C)(i) Notwithstanding the second sentence of each of subparagraphs (A) and (B), except as otherwise specified in clauses (ii), (iii), and (iv), if the Secretary has not updated amounts established under such subparagraphs or under subparagraph (D), with respect to facility services furnished during a fiscal year (beginning with fiscal year 1986 or a calendar year (beginning with 2006)), such amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(ii) In each of the fiscal years 1998 through 2002, the increase under this subparagraph shall be reduced (but not below zero) by 2.0 percentage points.

(iii) In fiscal year 2004, beginning with April 1, 2004, the increase under this subparagraph shall be the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with March 31, 2003, minus 3.0 percentage points.

(iv) In fiscal year 2005, the last quarter of calendar year 2005, and each of calendar years 2006 through 2009, the increase under this subparagraph shall be 0 percent.

(D)(i) Taking into account the recommendations in the report under section 626(d) of Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Secretary shall implement a revised payment system for payment of surgical services furnished in ambulatory surgical centers.

(ii) In the year the system described in clause (i) is implemented, such system shall be designed to result in the same aggregate amount of expenditures for such services as would be made if this subparagraph did not apply, as estimated by the Secretary and taking into account reduced expenditures that would apply if subparagraph (E) were to continue to apply, as estimated by the Secretary.

(iii) The Secretary shall implement the system described in clause (i) for periods in a manner so that it is first effective begin-

ning on or after January 1, 2006, and not later than January 1, 2008.

(iv) The Secretary may implement such system in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).

(v) In implementing the system described in clause (i) for 2011 and each subsequent year, any annual update under such system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II). The application of the preceding sentence may result in such update being less than 0.0 for a year, and may result in payment rates under the system described in clause (i) for a year being less than such payment rates for the preceding year.

(vi) There shall be no administrative or judicial review under section 1869, 1878, or otherwise, of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, under this subparagraph.

(E) With respect to surgical procedures furnished on or after January 1, 2007, and before the effective date of the implementation of a revised payment system under subparagraph (D), if—

(i) the standard overhead amount under subparagraph (A) for a facility service for such procedure, without the application of any geographic adjustment, exceeds

(ii) the Medicare OPD fee schedule amount established under the prospective payment system for hospital outpatient department services under paragraph (3)(D) of section 1833(t) for such service for such year, determined without regard to geographic adjustment under paragraph (2)(D) of such section, the Secretary shall substitute under subparagraph (A) the amount described in clause (ii) for the standard overhead amount for such service referred to in clause (i).

(3)(A) The aggregate amount of the payments to be made under this part for outpatient hospital facility services or critical access hospital services furnished before January 1, 1999, in connection with surgical procedures specified under paragraph (1)(A) shall be equal to the lesser of—

(i) the amount determined with respect to such services under subsection (a)(2)(B); or

(ii) the blend amount (described in subparagraph (B)).

(B)(i) The blend amount for a cost reporting period is the sum of—

(I) the cost proportion (as defined in clause (ii)(I)) of the amount described in subparagraph (A)(i), and

(II) the ASC proportion (as defined in clause (ii)(II)) of the standard overhead amount payable with respect to the same surgical procedure as if it were provided in an ambulatory surgical center in the same area, as determined under paragraph (2)(A), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A).

(ii) Subject to paragraph (4), in this paragraph:

(I) The term “cost proportion” means 75 percent for cost reporting periods beginning in fiscal year 1988, 50 percent for portions of cost reporting periods beginning on or after October 1, 1988, and ending on or before December 31, 1990, and 42

percent for portions of cost reporting periods beginning on or after January 1, 1991.

(II) The term “ASC proportion” means 25 percent for cost reporting periods beginning in fiscal year 1988, 50 percent for portions of cost reporting periods beginning on or after October 1, 1988, and ending on or before December 31, 1990, and 58 percent for portions of cost reporting periods beginning on or after January 1, 1991.

(4)(A) In the case of a hospital that—

(i) makes application to the Secretary and demonstrates that it specializes in eye services or eye and ear services (as determined by the Secretary),

(ii) receives more than 30 percent of its total revenues from outpatient services, and

(iii) on October 1, 1987—

(I) was an eye specialty hospital or an eye and ear specialty hospital, or

(II) was operated as an eye or eye and ear unit (as defined in subparagraph (B)) of a general acute care hospital which, on the date of the application described in clause (i), operates less than 20 percent of the beds that the hospital operated on October 1, 1987, and has sold or otherwise disposed of a substantial portion of the hospital's other acute care operations,

the cost proportion and ASC proportion in effect under subclauses (I) and (II) of paragraph (3)(B)(ii) for cost reporting periods beginning in fiscal year 1988 shall remain in effect for cost reporting periods beginning on or after October 1, 1988, and before January 1, 1995.

(B) For purposes of this subparagraph (A)(iii)(II), the term “eye or eye and ear unit” means a physically separate or distinct unit containing separate surgical suites devoted solely to eye or eye and ear services.

(5)(A) The Secretary is authorized to provide by regulations that in the case of a surgical procedure, specified by the Secretary pursuant to paragraph (1)(A), performed in an ambulatory surgical center described in such paragraph, there shall be paid (in lieu of any amounts otherwise payable under this part) with respect to the facility services furnished by such center and with respect to all related services (including physicians' services, laboratory, X-ray, and diagnostic services) a single all-inclusive fee established pursuant to subparagraph (B), if all parties furnishing all such services agree to accept such fee (to be divided among the parties involved in such manner as they shall have previously agreed upon) as full payment for the services furnished.

(B) In implementing this paragraph, the Secretary shall establish with respect to each surgical procedure specified pursuant to paragraph (1)(A) the amount of the all-inclusive fee for such procedure, taking into account such factors as may be appropriate. The amount so established with respect to any surgical procedure shall be reviewed periodically and may be adjusted by the Secretary, when appropriate, to take account of varying conditions in different areas.

(6) Any person, including a facility having an agreement under section 1832(a)(2)(F)(i), who knowingly and willfully presents, or

causes to be presented, a bill or request for payment, for an intraocular lens inserted during or subsequent to cataract surgery for which payment may be made under paragraph (2)(A)(iii), is subject to a civil money penalty of not to exceed \$2,000. 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)(A) For purposes of paragraph (2)(D)(iv), the Secretary may provide, in the case of an ambulatory surgical center that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to a year, any annual increase provided under the system established under paragraph (2)(D) for such year shall be reduced by 2.0 percentage points. A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take into account such reduction in computing any annual increase factor for a subsequent year.

(B) Except as the Secretary may otherwise provide, the provisions of subparagraphs (B), (C), (D), and (E) of paragraph (17) of section 1833(t) shall apply with respect to services of ambulatory surgical centers under this paragraph in a similar manner to the manner in which they apply under such paragraph and, for purposes of this subparagraph, any reference to a hospital, outpatient setting, or outpatient hospital services is deemed a reference to an ambulatory surgical center, the setting of such a center, or services of such a center, respectively.

(j) Whenever a final determination is made that the amount of payment made under this part either to a provider of services or to another person pursuant to an assignment under section 1842(b)(3)(B)(ii) was in excess of or less than the amount of payment that is due, and payment of such excess or deficit is not made (or effected by offset) within 30 days of the date of the determination, interest shall accrue on the balance of such excess or deficit not paid or offset (to the extent that the balance is owed by or owing to the provider) at a rate determined in accordance with the regulations of the Secretary of the Treasury applicable to charges for late payments.

(k) With respect to services described in section 1861(s)(10)(B), the Secretary may provide, instead of the amount of payment otherwise provided under this part, for payment of such an amount or amounts as reasonably reflects the general cost of efficiently providing such services.

(l)(1)(A) The Secretary shall establish a fee schedule for services of certified registered nurse anesthetists under section 1861(s)(11).

(B) In establishing the fee schedule under this paragraph the Secretary may utilize a system of time units, a system of base and time units, or any appropriate methodology.

(C) The provisions of this subsection shall not apply to certain services furnished in certain hospitals in rural areas under the provisions of section 9320(k) of the Omnibus Budget Reconciliation Act of 1986, as amended by section 6132 of the Omnibus Budget Reconciliation Act of 1989.

(2) Except as provided in paragraph (3), the fee schedule established under paragraph (1) shall be initially based on audited data

from cost reporting periods ending in fiscal year 1985 and such other data as the Secretary determines necessary.

(3)(A) In establishing the initial fee schedule for those services, the Secretary shall adjust the fee schedule to the extent necessary to ensure that the estimated total amount which will be paid under this title for those services plus applicable coinsurance in 1989 will equal the estimated total amount which would be paid under this title for those services in 1989 if the services were included as inpatient hospital services and payment for such services was made under part A in the same manner as payment was made in fiscal year 1987, adjusted to take into account changes in prices and technology relating to the administration of anesthesia.

(B) The Secretary shall also reduce the prevailing charge of physicians for medical direction of a certified registered nurse anesthetist, or the fee schedule for services of certified registered nurse anesthetists, or both, to the extent necessary to ensure that the estimated total amount which will be paid under this title plus applicable coinsurance for such medical direction and such services in 1989 and 1990 will not exceed the estimated total amount which would have been paid plus applicable coinsurance but for the enactment of the amendments made by section 9320 of the Omnibus Budget Reconciliation Act of 1986. A reduced prevailing charge under this subparagraph shall become the prevailing charge but for subsequent years for purposes of applying the economic index under the fourth sentence of section 1842(b)(3).

(4)(A) Except as provided in subparagraphs (C) and (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, by a certified registered nurse anesthetist who is not medically directed—

(i) the conversion factor shall be—

(I) for services furnished in 1991, \$15.50,

(II) for services furnished in 1992, \$15.75,

(III) for services furnished in 1993, \$16.00,

(IV) for services furnished in 1994, \$16.25,

(V) for services furnished in 1995, \$16.50,

(VI) for services furnished in 1996, \$16.75, and

(VII) for services furnished in calendar years after 1996, the previous year's conversion factor increased by the update determined under section 1848(d) for physician anesthesia services for that year;

(ii) the payment areas to be used shall be the fee schedule areas used under section 1848 (or, in the case of services furnished during 1991, the localities used under section 1842(b)) for purposes of computing payments for physicians' services that are anesthesia services;

(iii) the geographic adjustment factors to be applied to the conversion factor under clause (i) for services in a fee schedule area or locality is—

(I) in the case of services furnished in 1991, the geographic work index value and the geographic practice cost index value specified in section 1842(q)(1)(B) for physicians' services that are anesthesia services furnished in the area or locality, and

(II) in the case of services furnished after 1991, the geographic work index value, the geographic practice cost

index value, and the geographic malpractice index value used for determining payments for physicians' services that are anesthesia services under section 1848, with 70 percent of the conversion factor treated as attributable to work and 30 percent as attributable to overhead for services furnished in 1991 (and the portions attributable to work, practice expenses, and malpractice expenses in 1992 and thereafter being the same as is applied under section 1848).

(B)(i) Except as provided in clause (ii) and subparagraph (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, and before January 1, 1994, by a certified registered nurse anesthetist who is medically directed, the Secretary shall apply the same methodology specified in subparagraph (A).

(ii) The conversion factor used under clause (i) shall be—

(I) for services furnished in 1991, \$10.50,

(II) for services furnished in 1992, \$10.75, and

(III) for services furnished in 1993, \$11.00.

(iii) In the case of services of a certified registered nurse anesthetist who is medically directed or medically supervised by a physician which are furnished on or after January 1, 1994, the fee schedule amount shall be one-half of the amount described in section 1848(a)(5)(B) with respect to the physician.

(C) Notwithstanding subclauses (I) through (V) of subparagraph (A)(i)—

(i) in the case of a 1990 conversion factor that is greater than \$16.50, the conversion factor for a calendar year after 1990 and before 1996 shall be the 1990 conversion factor reduced by the product of the last digit of the calendar year and one-fifth of the amount by which the 1990 conversion factor exceeds \$16.50; and

(ii) in the case of a 1990 conversion factor that is greater than \$15.49 but less than \$16.51, the conversion factor for a calendar year after 1990 and before 1996 shall be the greater of—

(I) the 1990 conversion factor, or

(II) the conversion factor specified in subparagraph (A)(i) for the year involved.

(D) Notwithstanding subparagraph (C), in no case may the conversion factor used to determine payment for services in a fee schedule area or locality under this subsection, as adjusted by the adjustment factors specified in subparagraphs (A)(iii), exceed the conversion factor used to determine the amount paid for physicians' services that are anesthesia services in the area or locality.

(5)(A) Payment for the services of a certified registered nurse anesthetist (for which payment may otherwise be made under this part) may be made on the basis of a claim or request for payment presented by the certified registered nurse anesthetist furnishing such services, or by a hospital, critical access hospital, physician, group practice, or ambulatory surgical center with which the certified registered nurse anesthetist furnishing such services has an employment or contractual relationship that provides for payment to be made under this part for such services to such hospital, critical access hospital, physician, group practice, or ambulatory surgical center.

(B) No hospital or critical access hospital that presents a claim or request for payment for services of a certified nurse anesthetist under this part may treat any uncollected coinsurance amount imposed under this part with respect to such services as a bad debt of such hospital or critical access hospital for purposes of this title.

(6) If an adjustment under paragraph (3)(B) results in a reduction in the reasonable charge for a physicians' service and a non-participating physician furnishes the service to an individual entitled to benefits under this part after the effective date of the reduction, the physician's actual charge is subject to a limit under section 1842(j)(1)(D).

(m)(1) In the case of physicians' services furnished in a year to an individual, who is covered under the insurance program established by this part and who incurs expenses for such services, in an area that is designated (under section 332(a)(1)(A) of the Public Health Service Act) as a health professional shortage area as identified by the Secretary prior to the beginning of such year, in addition to the amount otherwise paid under this part, there also shall be paid to the physician (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6)) (on a monthly or quarterly basis) from the Federal Supplementary Medical Insurance Trust Fund an amount equal to 10 percent of the payment amount for the service under this part.

(2) For each health professional shortage area identified in paragraph (1) that consists of an entire county, the Secretary shall provide for the additional payment under paragraph (1) without any requirement on the physician to identify the health professional shortage area involved. The Secretary may implement the previous sentence using the method specified in subsection (u)(4)(C).

(3) The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a list of the health professional shortage areas identified in paragraph (1) that consist of a partial county to facilitate the additional payment under paragraph (1) in such areas.

(4) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, respecting—

(A) the identification of a county or area;

(B) the assignment of a specialty of any physician under this paragraph;

(C) the assignment of a physician to a county under this subsection; or

(D) the assignment of a postal ZIP Code to a county or other area under this subsection.

(n)(1)(A) The aggregate amount of the payments to be made for all or part of a cost reporting period for services described in subsection (a)(2)(E)(i) furnished under this part on or after October 1, 1988, and before January 1, 1999, and for services described in subsection (a)(2)(E)(ii) furnished under this part on or after October 1, 1989, and before January 1, 1999, shall be equal to the lesser of—

(i) the amount determined with respect to such services under subsection (a)(2)(B), or

(ii) the blend amount for radiology services and diagnostic procedures determined in accordance with subparagraph (B).

(B)(i) The blend amount for radiology services and diagnostic procedures for a cost reporting period is the sum of—

(I) the cost proportion (as defined in clause (ii)) of the amount described in subparagraph (A)(i); and

(II) the charge proportion (as defined in clause (ii)(II)) of 62 percent (for services described in subsection (a)(2)(E)(i)), or (for procedures described in subsection (a)(2)(E)(ii)), 42 percent or such other percent established by the Secretary (or carriers acting pursuant to guidelines issued by the Secretary) based on prevailing charges established with actual charge data, of the prevailing charge or (for services described in subsection (a)(2)(E)(i) furnished on or after January 1, 1989) the fee schedule amount established for participating physicians for the same services as if they were furnished in a physician's office in the same locality as determined under section 1842(b), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A).

(ii) In this subparagraph:

(I) The term "cost proportion" means 50 percent, except that such term means 65 percent in the case of outpatient radiology services for portions of cost reporting periods which occur in fiscal year 1989 and in the case of diagnostic procedures described in subsection (a)(2)(E)(ii) for portions of cost reporting periods which occur in fiscal year 1990, and such term means 42 percent in the case of outpatient radiology services for portions of cost reporting periods beginning on or after January 1, 1991.

(II) The term "charge proportion" means 100 percent minus the cost proportion.

(o)(1) In the case of shoes described in section 1861(s)(12)—

(A) no payment may be made under this part, with respect to any individual for any year, for the furnishing of—

(i) more than one pair of custom molded shoes (including inserts provided with such shoes) and 2 additional pairs of inserts for such shoes, or

(ii) more than one pair of extra-depth shoes (not including inserts provided with such shoes) and 3 pairs of inserts for such shoes, and

(B) with respect to expenses incurred in any calendar year, no more than the amount of payment applicable under paragraph (2) shall be considered as incurred expenses for purposes of subsections (a) and (b).

Payment for shoes (or inserts) under this part shall be considered to include payment for any expenses for the fitting of such shoes (or inserts).

(2)(A) Except as provided by the Secretary under subparagraphs (B) and (C), the amount of payment under this paragraph for custom molded shoes, extra-depth shoes, and inserts shall be the amount determined for such items by the Secretary under section 1834(h).

(B) The Secretary may establish payment amounts for shoes and inserts that are lower than the amount established under section 1834(h) if the Secretary finds that shoes and inserts of an appropriate quality are readily available at or below the amount established under such section.

(C) In accordance with procedures established by the Secretary, an individual entitled to benefits with respect to shoes described in section 1861(s)(12) may substitute modification of such shoes instead of obtaining one (or more, as specified by the Secretary) pair of inserts (other than the original pair of inserts with respect to such shoes). In such case, the Secretary shall substitute, for the payment amount established under section 1834(h), a payment amount that the Secretary estimates will assure that there is no net increase in expenditures under this subsection as a result of this subparagraph.

(3) In this title, the term “shoes” includes, except for purposes of subparagraphs (A)(ii) and (B) of paragraph (2), inserts for extra-depth shoes.

(q)(1) Each request for payment, or bill submitted, for an item or service furnished by an entity for which payment may be made under this part and for which the entity knows or has reason to believe there has been a referral by a referring physician (within the meaning of section 1877) shall include the name and unique physician identification number for the referring physician.

(2)(A) In the case of a request for payment for an item or service furnished by an entity under this part on an assignment-related basis and for which information is required to be provided under paragraph (1) but not included, payment may be denied under this part.

(B) In the case of a request for payment for an item or service furnished by an entity under this part not submitted on an assignment-related basis and for which information is required to be provided under paragraph (1) but not included—

(i) if the entity knowingly and willfully fails to provide such information promptly upon request of the Secretary or a carrier, the entity may be subject to a civil money penalty in an amount not to exceed \$2,000, and

(ii) if the entity knowingly, willfully, and in repeated cases fails, after being notified by the Secretary of the obligations and requirements of this subsection to provide the information required under paragraph (1), the entity may be subject to exclusion from participation in the programs under this Act for a period not to exceed 5 years, in accordance with the procedures of subsections (c), (f), and (g) of section 1128.

The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under clause (i) in the same manner as they apply to a penalty or proceeding under section 1128A(a).

(r)(1) With respect to services described in section 1861(s)(2)(K)(ii) (relating to nurse practitioner or clinical nurse specialist services), payment may be made on the basis of a claim or request for payment presented by the nurse practitioner or clinical nurse specialist furnishing such services, or by a hospital, critical access hospital, skilled nursing facility or nursing facility (as defined in section 1919(a)), physician, group practice, or ambulatory surgical center with which the nurse practitioner or clinical nurse specialist has an employment or contractual relationship that provides for payment to be made under this part for such services to such hospital, physician, group practice, or ambulatory surgical center.

(2) No hospital or critical access hospital that presents a claim or request for payment under this part for services described in section 1861(s)(2)(K)(ii) may treat any uncollected coinsurance amount imposed under this part with respect to such services as a bad debt of such hospital for purposes of this title.

(s) The Secretary may not provide for payment under subsection (a)(1)(A) with respect to an organization unless the organization provides assurances satisfactory to the Secretary that the organization meets the requirement of section 1866(f) (relating to maintaining written policies and procedures respecting advance directives).

(t) PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES.—

(1) AMOUNT OF PAYMENT.—

(A) IN GENERAL.—With respect to covered OPD services (as defined in subparagraph (B)) furnished during a year beginning with 1999, the amount of payment under this part shall be determined under a prospective payment system established by the Secretary in accordance with this subsection.

(B) DEFINITION OF COVERED OPD SERVICES.—For purposes of this subsection, the term “covered OPD services”—

(i) means hospital outpatient services designated by the Secretary;

(ii) subject to clause (iv), includes inpatient hospital services designated by the Secretary that are covered under this part and furnished to a hospital inpatient who (I) is entitled to benefits under part A but has exhausted benefits for inpatient hospital services during a spell of illness, or (II) is not so entitled;

(iii) includes implantable items described in paragraph (3), (6), or (8) of section 1861(s);

(iv) does not include any therapy services described in subsection (a)(8) or ambulance services, for which payment is made under a fee schedule described in section 1834(k) or section 1834(l) and does not include screening mammography (as defined in section 1861(jj)), diagnostic mammography, or personalized prevention plan services (as defined in section 1861(hhh)(1)); and

(v) does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider (as defined in subparagraph (B) of such paragraph).

(2) SYSTEM REQUIREMENTS.—Under the payment system—

(A) the Secretary shall develop a classification system for covered OPD services;

(B) the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified to the group that includes the service to which the item relates;

(C) the Secretary shall, using data on claims from 1996 and using data from the most recent available cost reports, establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs and shall determine projections of the frequency of utilization of each such service (or group of services) in 1999;

(D) subject to paragraph (19), the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner;

(E) the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals;

(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services;

(G) the Secretary shall create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those that do not; and

(H) with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices and for stranded and non-stranded devices furnished on or after July 1, 2007.

For purposes of subparagraph (B), items and services within a group shall not be treated as “comparable with respect to the use of resources” if the highest median cost (or mean cost, if elected by the Secretary under subparagraph (C)) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the group; except that the Secretary may make exceptions in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act.

(3) CALCULATION OF BASE AMOUNTS.—

(A) AGGREGATE AMOUNTS THAT WOULD BE PAYABLE IF DEDUCTIBLES WERE DISREGARDED.—The Secretary shall estimate the sum of—

(i) the total amounts that would be payable from the Trust Fund under this part for covered OPD services

in 1999, determined without regard to this subsection, as though the deductible under section 1833(b) did not apply, and

(ii) the total amounts of copayments estimated to be paid under this subsection by beneficiaries to hospitals for covered OPD services in 1999, as though the deductible under section 1833(b) did not apply.

(B) UNADJUSTED COPAYMENT AMOUNT.—

(i) IN GENERAL.—For purposes of this subsection, subject to clause (ii), the “unadjusted copayment amount” applicable to a covered OPD service (or group of such services) is 20 percent of the national median of the charges for the service (or services within the group) furnished during 1996, updated to 1999 using the Secretary’s estimate of charge growth during the period.

(ii) ADJUSTED TO BE 20 PERCENT WHEN FULLY PHASED IN.—If the pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year would be equal to or exceed 80 percent, then the unadjusted copayment amount shall be 20 percent of amount determined under subparagraph (D).

(iii) RULES FOR NEW SERVICES.—The Secretary shall establish rules for establishment of an unadjusted copayment amount for a covered OPD service not furnished during 1996, based upon its classification within a group of such services.

(C) CALCULATION OF CONVERSION FACTORS.—

(i) FOR 1999.—

(I) IN GENERAL.—The Secretary shall establish a 1999 conversion factor for determining the medicare OPD fee schedule amounts for each covered OPD service (or group of such services) furnished in 1999. Such conversion factor shall be established on the basis of the weights and frequencies described in paragraph (2)(C) and in such a manner that the sum for all services and groups of the products (described in subclause (II) for each such service or group) equals the total projected amount described in subparagraph (A).

(II) PRODUCT DESCRIBED.—The Secretary shall determine for each service or group the product of the medicare OPD fee schedule amounts (taking into account appropriate adjustments described in paragraphs (2)(D) and (2)(E)) and the estimated frequencies for such service or group.

(ii) SUBSEQUENT YEARS.—Subject to paragraph (8)(B), the Secretary shall establish a conversion factor for covered OPD services furnished in subsequent years in an amount equal to the conversion factor established under this subparagraph and applicable to such services furnished in the previous year increased by the OPD fee schedule increase factor specified under clause (iv) for the year involved.

(iii) ADJUSTMENT FOR SERVICE MIX CHANGES.—Insofar as the Secretary determines that the adjustments for service mix under paragraph (2) for a previous year (or estimates that such adjustments for a future year) did (or are likely to) result in a change in aggregate payments under this subsection during the year that are a result of changes in the coding or classification of covered OPD services that do not reflect real changes in service mix, the Secretary may adjust the conversion factor computed under this subparagraph for subsequent years so as to eliminate the effect of such coding or classification changes.

(iv) OPD FEE SCHEDULE INCREASE FACTOR.—For purposes of this subparagraph, subject to paragraph (17) and subparagraph (F) of this paragraph, the “OPD fee schedule increase factor” for services furnished in a year is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) to hospital discharges occurring during the fiscal year ending in such year, reduced by 1 percentage point for such factor for services furnished in each of 2000 and 2002. In applying the previous sentence for years beginning with 2000, the Secretary may substitute for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year.

(D) CALCULATION OF MEDICARE OPD FEE SCHEDULE AMOUNTS.—The Secretary shall compute a medicare OPD fee schedule amount for each covered OPD service (or group of such services) furnished in a year, in an amount equal to the product of—

(i) the conversion factor computed under subparagraph (C) for the year, and

(ii) the relative payment weight (determined under paragraph (2)(C)) for the service or group.

(E) PRE-DEDUCTIBLE PAYMENT PERCENTAGE.—The pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year is equal to the ratio of—

(i) the medicare OPD fee schedule amount established under subparagraph (D) for the year, minus the unadjusted copayment amount determined under subparagraph (B) for the service or group, to

(ii) the medicare OPD fee schedule amount determined under subparagraph (D) for the year for such service or group.

(F) PRODUCTIVITY AND OTHER ADJUSTMENT.—After determining the OPD fee schedule increase factor under subparagraph (C)(iv), the Secretary shall reduce such increase factor—

(i) for 2012 and subsequent years, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(ii) for each of 2010 through 2019, by the adjustment described in subparagraph (G).

The application of this subparagraph may result in the increase factor under subparagraph (C)(iv) being less than 0.0 for a year, and may result in payment rates under the payment system under this subsection for a year being less than such payment rates for the preceding year.

(G) OTHER ADJUSTMENT.—For purposes of subparagraph (F)(ii), the adjustment described in this subparagraph is—

(i) for each of 2010 and 2011, 0.25 percentage point;

(ii) for each of 2012 and 2013, 0.1 percentage point;

(iii) for 2014, 0.3 percentage point;

(iv) for each of 2015 and 2016, 0.2 percentage point;

and

(v) for each of 2017, 2018, and 2019, 0.75 percentage point.

(4) MEDICARE PAYMENT AMOUNT.—The amount of payment made from the Trust Fund under this part for a covered OPD service (and such services classified within a group) furnished in a year is determined, subject to paragraph (7), as follows:

(A) FEE SCHEDULE ADJUSTMENTS.—The medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service or group and year is adjusted for relative differences in the cost of labor and other factors determined by the Secretary, as computed under paragraphs (2)(D) and (2)(E).

(B) SUBTRACT APPLICABLE DEDUCTIBLE.—Reduce the adjusted amount determined under subparagraph (A) by the amount of the deductible under section 1833(b), to the extent applicable.

(C) APPLY PAYMENT PROPORTION TO REMAINDER.—The amount of payment is the amount so determined under subparagraph (B) multiplied by the pre-deductible payment percentage (as determined under paragraph (3)(E)) for the service or group and year involved, plus the amount of any reduction in the copayment amount attributable to paragraph (8)(C).

(5) OUTLIER ADJUSTMENT.—

(A) IN GENERAL.—Subject to subparagraph (D), the Secretary shall provide for an additional payment for each covered OPD service (or group of services) for which a hospital's charges, adjusted to cost, exceed—

(i) a fixed multiple of the sum of—

(I) the applicable medicare OPD fee schedule amount determined under paragraph (3)(D), as adjusted under paragraph (4)(A) (other than for adjustments under this paragraph or paragraph (6)); and

(II) any transitional pass-through payment under paragraph (6); and

(ii) at the option of the Secretary, such fixed dollar amount as the Secretary may establish.

(B) AMOUNT OF ADJUSTMENT.—The amount of the additional payment under subparagraph (A) shall be determined by the Secretary and shall approximate the marginal cost of care beyond the applicable cutoff point under such subparagraph.

(C) LIMIT ON AGGREGATE OUTLIER ADJUSTMENTS.—

(i) IN GENERAL.—The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year.

(ii) APPLICABLE PERCENTAGE.—For purposes of clause (i), the term “applicable percentage” means a percentage specified by the Secretary up to (but not to exceed)—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, 3.0 percent.

(D) TRANSITIONAL AUTHORITY.—In applying subparagraph (A) for covered OPD services furnished before January 1, 2002, the Secretary may—

(i) apply such subparagraph to a bill for such services related to an outpatient encounter (rather than for a specific service or group of services) using OPD fee schedule amounts and transitional pass-through payments covered under the bill; and

(ii) use an appropriate cost-to-charge ratio for the hospital involved (as determined by the Secretary), rather than for specific departments within the hospital.

(E) EXCLUSION OF SEPARATE DRUG AND BIOLOGICAL APCs FROM OUTLIER PAYMENTS.—No additional payment shall be made under subparagraph (A) in the case of ambulatory payment classification groups established separately for drugs or biologicals.

(6) TRANSITIONAL PASS-THROUGH FOR ADDITIONAL COSTS OF INNOVATIVE MEDICAL DEVICES, DRUGS, AND BIOLOGICALS.—

(A) IN GENERAL.—The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services):

(i) CURRENT ORPHAN DRUGS.—A drug or biological that is used for a rare disease or condition with respect to which the drug or biological has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act if payment for the drug or biological as an outpatient hospital service under this part was being made on the first date that the system under this subsection is implemented.

(ii) CURRENT CANCER THERAPY DRUGS AND BIOLOGICALS AND BRACHYTHERAPY.—A drug or biological that is used in cancer therapy, including (but not limited to) a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and a device of brachytherapy or temperature monitored cryoablation, if payment for such drug, biological, or device as an outpatient hospital service under this part was being made on such first date.

(iii) CURRENT RADIOPHARMACEUTICAL DRUGS AND BIOLOGICAL PRODUCTS.—A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine procedures if payment for the drug or biological as an outpatient hospital service under this part was being made on such first date.

(iv) NEW MEDICAL DEVICES, DRUGS, AND BIOLOGICALS.—A medical device, drug, or biological not described in clause (i), (ii), or (iii) if—

(I) payment for the device, drug, or biological as an outpatient hospital service under this part was not being made as of December 31, 1996; and

(II) the cost of the drug or biological or the average cost of the category of devices is not insignificant in relation to the OPD fee schedule amount (as calculated under paragraph (3)(D)) payable for the service (or group of services) involved.

(B) USE OF CATEGORIES IN DETERMINING ELIGIBILITY OF A DEVICE FOR PASS-THROUGH PAYMENTS.—The following provisions apply for purposes of determining whether a medical device qualifies for additional payments under clause (ii) or (iv) of subparagraph (A):

(i) ESTABLISHMENT OF INITIAL CATEGORIES.—

(I) IN GENERAL.—The Secretary shall initially establish under this clause categories of medical devices based on type of device by April 1, 2001. Such categories shall be established in a manner such that each medical device that meets the requirements of clause (ii) or (iv) of subparagraph (A) as of January 1, 2001, is included in such a category and no such device is included in more than one category. For purposes of the preceding sentence, whether a medical device meets such requirements as of such date shall be determined on the basis of the program memoranda issued before such date.

(II) AUTHORIZATION OF IMPLEMENTATION OTHER THAN THROUGH REGULATIONS.—The categories may be established under this clause by program memorandum or otherwise, after consultation with groups representing hospitals, manufacturers of medical devices, and other affected parties.

(ii) ESTABLISHING CRITERIA FOR ADDITIONAL CATEGORIES.—

(I) IN GENERAL.—The Secretary shall establish criteria that will be used for creation of additional categories (other than those established under clause (i)) through rulemaking (which may include use of an interim final rule with comment period).

(II) STANDARD.—Such categories shall be established under this clause in a manner such that no medical device is described by more than one category. Such criteria shall include a test of whether the average cost of devices that would be included in a category and are in use at the time the category is established is not insignificant, as described in subparagraph (A)(iv)(II).

(III) DEADLINE.—Criteria shall first be established under this clause by July 1, 2001. The Secretary may establish in compelling circumstances categories under this clause before the date such criteria are established.

(IV) ADDING CATEGORIES.—The Secretary shall promptly establish a new category of medical devices under this clause for any medical device that meets the requirements of subparagraph (A)(iv) and for which none of the categories in effect (or that were previously in effect) is appropriate.

(iii) PERIOD FOR WHICH CATEGORY IS IN EFFECT.—A category of medical devices established under clause (i) or (ii) shall be in effect for a period of at least 2 years, but not more than 3 years, that begins—

(I) in the case of a category established under clause (i), on the first date on which payment was made under this paragraph for any device described by such category (including payments made during the period before April 1, 2001); and

(II) in the case of any other category, on the first date on which payment is made under this paragraph for any medical device that is described by such category.

(iv) REQUIREMENTS TREATED AS MET.—A medical device shall be treated as meeting the requirements of subparagraph (A)(iv), regardless of whether the device meets the requirement of subclause (I) of such subparagraph, if—

(I) the device is described by a category established and in effect under clause (i); or

(II) the device is described by a category established and in effect under clause (ii) and an application under section 515 of the Federal Food, Drug, and Cosmetic Act has been approved with respect to the device, or the device has been cleared for market under section 510(k) of such Act, or the device is exempt from the requirements of section 510(k) of such Act pursuant to subsection (l) or (m) of section 510 of such Act or section 520(g) of such Act.

Nothing in this clause shall be construed as requiring an application or prior approval (other than that described in subclause (II)) in order for a covered device described by a category to qualify for payment under this paragraph.

(C) LIMITED PERIOD OF PAYMENT.—

(i) DRUGS AND BIOLOGICALS.—Subject to subparagraph (G), the payment under this paragraph with respect to a drug or biological shall only apply during a period of at least 2 years, but not more than 3 years, *or, in the case of an eligible non-opioid analgesic (as defined in subparagraph (J)), during a period of 5 years*, that begins—

(I) on the first date this subsection is implemented in the case of a drug or biological described in clause (i), (ii), or (iii) of subparagraph (A) and in the case of a drug or biological described in subparagraph (A)(iv) and for which payment under this part is made as an outpatient hospital service before such first date; or

(II) in the case of a drug or biological described in subparagraph (A)(iv) not described in subclause (I), on the first date on which payment is made under this part for the drug or biological as an outpatient hospital service.

(ii) MEDICAL DEVICES.—Payment shall be made under this paragraph with respect to a medical device only if such device—

(I) is described by a category of medical devices established and in effect under subparagraph (B); and

(II) is provided as part of a service (or group of services) paid for under this subsection and provided during the period for which such category is in effect under such subparagraph.

(D) AMOUNT OF ADDITIONAL PAYMENT.—Subject to subparagraph (E)(iii), the amount of the payment under this paragraph with respect to a device, drug, or biological provided as part of a covered OPD service is—

(i) subject to subparagraph (H), in the case of a drug or biological, the amount by which the amount determined under section 1842(o) (or if the drug or biological is covered under a competitive acquisition contract under section 1847B, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary for purposes of this paragraph) for the drug or biological exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the drug or biological; or

(ii) in the case of a medical device, the amount by which the hospital's charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable

medicare OPD fee schedule that the Secretary determines is associated with the device.

(E) LIMIT ON AGGREGATE ANNUAL ADJUSTMENT.—

(i) IN GENERAL.—The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year. This clause shall not apply for 2018.

(ii) APPLICABLE PERCENTAGE.—For purposes of clause (i), the term “applicable percentage” means—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, a percentage specified by the Secretary up to (but not to exceed) 2.0 percent.

(iii) UNIFORM PROSPECTIVE REDUCTION IF AGGREGATE LIMIT PROJECTED TO BE EXCEEDED.—If the Secretary estimates before the beginning of a year that the amount of the additional payments under this paragraph for the year (or portion thereof) as determined under clause (i) without regard to this clause will exceed the limit established under such clause, the Secretary shall reduce pro rata the amount of each of the additional payments under this paragraph for that year (or portion thereof) in order to ensure that the aggregate additional payments under this paragraph (as so estimated) do not exceed such limit.

(F) LIMITATION OF APPLICATION OF FUNCTIONAL EQUIVALENCE STANDARD.—

(i) IN GENERAL.—The Secretary may not publish regulations that apply a functional equivalence standard to a drug or biological under this paragraph.

(ii) APPLICATION.—Clause (i) shall apply to the application of a functional equivalence standard to a drug or biological on or after the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 unless—

(I) such application was being made to such drug or biological prior to such date of enactment; and

(II) the Secretary applies such standard to such drug or biological only for the purpose of determining eligibility of such drug or biological for additional payments under this paragraph and not for the purpose of any other payments under this title.

(iii) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed to effect the Secretary’s authority to deem a particular drug to be identical to

another drug if the 2 products are pharmaceutically equivalent and bioequivalent, as determined by the Commissioner of Food and Drugs.

(G) PASS-THROUGH EXTENSION FOR CERTAIN DRUGS AND BIOLOGICALS.—In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2018, such pass-through status shall be extended for a 2-year period beginning on October 1, 2018.

(H) TEMPORARY PAYMENT RULE FOR CERTAIN DRUGS AND BIOLOGICALS.—In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2018, the payment amount for such drug or biological under this subsection that is furnished during the period beginning on October 1, 2018, and ending on March 31, 2019, shall be the greater of—

- (i) the payment amount that would otherwise apply under subparagraph (D)(i) for such drug or biological during such period; or
- (ii) the payment amount that applied under such subparagraph (D)(i) for such drug or biological on December 31, 2017.

(I) SPECIAL PAYMENT ADJUSTMENT RULES FOR LAST QUARTER OF 2018.—In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment amount for a covered OPD service (or group of services) beginning January 1, 2018, the following rules shall apply with respect to payment amounts under this subsection for covered a OPD service (or group of services) furnished during the period beginning on October 1, 2018, and ending on December 31, 2018:

- (i) The Secretary shall remove the packaged costs of such drug or biological (as determined by the Secretary) from the payment amount under this subsection for the covered OPD service (or group of services) with which it is packaged.
- (ii) The Secretary shall not make any adjustments to payment amounts under this subsection for a covered OPD service (or group of services) for which no costs were removed under clause (i).

(J) *ELIGIBLE NON-OPIOID ANALGESIC DEFINED.*—*In this paragraph, the term “eligible non-opioid analgesic” means a drug or biological—*

- (i) that is an analgesic that is not an opioid;*
- (ii) that demonstrated substantial clinical improvement; and*
- (iii) for which payment—*

(I) as an outpatient hospital service under this part was not being made as of the date of the enactment of this subparagraph; or

(II) was being made under this paragraph as of such date.

(7) TRANSITIONAL ADJUSTMENT TO LIMIT DECLINE IN PAYMENT.—

(A) BEFORE 2002.—Subject to subparagraph (D), for covered OPD services furnished before January 1, 2002, for which the PPS amount (as defined in subparagraph (E)) is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount (as defined in subparagraph (F)), the amount of payment under this subsection shall be increased by 80 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.71 and the pre-BBA amount, exceeds (II) the product of 0.70 and the PPS amount;

(iii) at least 70 percent, but less than 80 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.63 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iv) less than 70 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 21 percent of the pre-BBA amount.

(B) 2002.—Subject to subparagraph (D), for covered OPD services furnished during 2002, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 70 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.61 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iii) less than 80 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 13 percent of the pre-BBA amount.

(C) 2003.—Subject to subparagraph (D), for covered OPD services furnished during 2003, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 60 percent of the amount of such difference; or

(ii) less than 90 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 6 percent of the pre-BBA amount.

(D) HOLD HARMLESS PROVISIONS.—

(i) TEMPORARY TREATMENT FOR CERTAIN RURAL HOSPITALS.—(I) In the case of a hospital located in a rural area and that has not more than 100 beds or a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) located in a rural area, for covered OPD services furnished before January 1, 2006, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(II) In the case of a hospital located in a rural area and that has not more than 100 beds and that is not a sole community hospital (as defined in section 1886(d)(5)(D)(iii)), for covered OPD services furnished on or after January 1, 2006, and before January 1, 2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the applicable percentage of the amount of such difference. For purposes of the preceding sentence, the applicable percentage shall be 95 percent with respect to covered OPD services furnished in 2006, 90 percent with respect to such services furnished in 2007, and 85 percent with respect to such services furnished in 2008, 2009, 2010, 2011, or 2012.

(III) In the case of a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) that has not more than 100 beds, for covered OPD services furnished on or after January 1, 2009, and before January 1, 2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by 85 percent of the amount of such difference. In the case of covered OPD services furnished on or after January 1, 2010, and before March 1, 2012, the preceding sentence shall be applied without regard to the 100-bed limitation.

(ii) PERMANENT TREATMENT FOR CANCER HOSPITALS AND CHILDREN'S HOSPITALS.—In the case of a hospital described in clause (iii) or (v) of section 1886(d)(1)(B), for covered OPD services for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(E) PPS AMOUNT DEFINED.—In this paragraph, the term “PPS amount” means, with respect to covered OPD services, the amount payable under this title for such services (determined without regard to this paragraph), including amounts payable as copayment under paragraph (8), coinsurance under section 1866(a)(2)(A)(ii), and the deductible under section 1833(b).

(F) PRE-BBA AMOUNT DEFINED.—

(i) IN GENERAL.—In this paragraph, the “pre-BBA amount” means, with respect to covered OPD services furnished by a hospital in a year, an amount equal to the product of the reasonable cost of the hospital for such services for the portions of the hospital’s cost reporting period (or periods) occurring in the year and the base OPD payment-to-cost ratio for the hospital (as defined in clause (ii)).

(ii) BASE PAYMENT-TO-COST-RATIO DEFINED.—For purposes of this subparagraph, the “base payment-to-cost ratio” for a hospital means the ratio of—

(I) the hospital’s reimbursement under this part for covered OPD services furnished during the cost reporting period ending in 1996 (or in the case of a hospital that did not submit a cost report for such period, during the first subsequent cost reporting period ending before 2001 for which the hospital submitted a cost report), including any reimbursement for such services through cost-sharing described in subparagraph (E), to

(II) the reasonable cost of such services for such period.

The Secretary shall determine such ratios as if the amendments made by section 4521 of the Balanced Budget Act of 1997 were in effect in 1996.

(G) INTERIM PAYMENTS.—The Secretary shall make payments under this paragraph to hospitals on an interim basis, subject to retrospective adjustments based on settled cost reports.

(H) NO EFFECT ON COPAYMENTS.—Nothing in this paragraph shall be construed to affect the unadjusted copayment amount described in paragraph (3)(B) or the copayment amount under paragraph (8).

(I) APPLICATION WITHOUT REGARD TO BUDGET NEUTRALITY.—The additional payments made under this paragraph—

(i) shall not be considered an adjustment under paragraph (2)(E); and

(ii) shall not be implemented in a budget neutral manner.

(8) COPAYMENT AMOUNT.—

(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), the copayment amount under this subsection is the amount by which the amount described in paragraph (4)(B) exceeds the amount of payment determined under paragraph (4)(C).

(B) ELECTION TO OFFER REDUCED COPAYMENT AMOUNT.—The Secretary shall establish a procedure under which a hospital, before the beginning of a year (beginning with 1999), may elect to reduce the copayment amount otherwise established under subparagraph (A) for some or all covered OPD services to an amount that is not less than 20 percent of the medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service involved. Under such procedures, such reduced copayment amount

may not be further reduced or increased during the year involved and the hospital may disseminate information on the reduction of copayment amount effected under this subparagraph.

(C) LIMITATION ON COPAYMENT AMOUNT.—

(i) TO INPATIENT HOSPITAL DEDUCTIBLE AMOUNT.—In no case shall the copayment amount for a procedure performed in a year exceed the amount of the inpatient hospital deductible established under section 1813(b) for that year.

(ii) TO SPECIFIED PERCENTAGE.—The Secretary shall reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed the following percentage:

(I) For procedures performed in 2001, on or after April 1, 2001, 57 percent.

(II) For procedures performed in 2002 or 2003, 55 percent.

(III) For procedures performed in 2004, 50 percent.

(IV) For procedures performed in 2005, 45 percent.

(V) For procedures performed in 2006 and thereafter, 40 percent.

(D) NO IMPACT ON DEDUCTIBLES.—Nothing in this paragraph shall be construed as affecting a hospital's authority to waive the charging of a deductible under section 1833(b).

(E) COMPUTATION IGNORING OUTLIER AND PASS-THROUGH ADJUSTMENTS.—The copayment amount shall be computed under subparagraph (A) as if the adjustments under paragraphs (5) and (6) (and any adjustment made under paragraph (2)(E) in relation to such adjustments) had not occurred.

(9) PERIODIC REVIEW AND ADJUSTMENTS COMPONENTS OF PROSPECTIVE PAYMENT SYSTEM.—

(A) PERIODIC REVIEW.—The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.

(B) BUDGET NEUTRALITY ADJUSTMENT.—If the Secretary makes adjustments under subparagraph (A), then the ad-

justments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made. In determining adjustments under the preceding sentence for 2004 and 2005, the Secretary shall not take into account under this subparagraph or paragraph (2)(E) any expenditures that would not have been made but for the application of paragraph (14).

(C) UPDATE FACTOR.—If the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year.

(10) SPECIAL RULE FOR AMBULANCE SERVICES.—The Secretary shall pay for hospital outpatient services that are ambulance services on the basis described in section 1861(v)(1)(U), or, if applicable, the fee schedule established under section 1834(l).

(11) SPECIAL RULES FOR CERTAIN HOSPITALS.—In the case of hospitals described in clause (iii) or (v) of section 1886(d)(1)(B)—

(A) the system under this subsection shall not apply to covered OPD services furnished before January 1, 2000; and

(B) the Secretary may establish a separate conversion factor for such services in a manner that specifically takes into account the unique costs incurred by such hospitals by virtue of their patient population and service intensity.

(12) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise of—

(A) the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F);

(B) the calculation of base amounts under paragraph (3);

(C) periodic adjustments made under paragraph (6);

(D) the establishment of a separate conversion factor under paragraph (8)(B); and

(E) the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under paragraph (6).

(13) AUTHORIZATION OF ADJUSTMENT FOR RURAL HOSPITALS.—

(A) STUDY.—The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals located in rural areas by ambulatory payment classification groups (APCs) exceed those costs incurred by hospitals located in urban areas.

(B) AUTHORIZATION OF ADJUSTMENT.—Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals located in rural areas exceed those costs incurred by hospitals located in urban areas, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs by January 1, 2006.

(14) DRUG APC PAYMENT RATES.—

(A) IN GENERAL.—The amount of payment under this subsection for a specified covered outpatient drug (defined in subparagraph (B)) that is furnished as part of a covered OPD service (or group of services)—

(i) in 2004, in the case of—

(I) a sole source drug shall in no case be less than 88 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug;

(ii) in 2005, in the case of—

(I) a sole source drug shall in no case be less than 83 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug; or

(iii) in a subsequent year, shall be equal, subject to subparagraph (E)—

(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or

(II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

(B) SPECIFIED COVERED OUTPATIENT DRUG DEFINED.—

(i) IN GENERAL.—In this paragraph, the term “specified covered outpatient drug” means, subject to clause (ii), a covered outpatient drug (as defined in section 1927(k)(2)) for which a separate ambulatory payment classification group (APC) has been established and that is—

(I) a radiopharmaceutical; or

(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

(ii) EXCEPTION.—Such term does not include—

(I) a drug or biological for which payment is first made on or after January 1, 2003, under paragraph (6);

(II) a drug or biological for which a temporary HCPCS code has not been assigned; or

(III) during 2004 and 2005, an orphan drug (as designated by the Secretary).

(C) PAYMENT FOR DESIGNATED ORPHAN DRUGS DURING 2004 AND 2005.—The amount of payment under this subsection for an orphan drug designated by the Secretary under subparagraph (B)(ii)(III) that is furnished as part of a covered OPD service (or group of services) during 2004 and 2005 shall equal such amount as the Secretary may specify.

(D) ACQUISITION COST SURVEY FOR HOSPITAL OUTPATIENT DRUGS.—

(i) ANNUAL GAO SURVEYS IN 2004 AND 2005.—

(I) IN GENERAL.—The Comptroller General of the United States shall conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each specified covered outpatient drug. Not later than April 1, 2005, the Comptroller General shall furnish data from such surveys to the Secretary for use in setting the payment rates under subparagraph (A) for 2006.

(II) RECOMMENDATIONS.—Upon the completion of such surveys, the Comptroller General shall recommend to the Secretary the frequency and methodology of subsequent surveys to be conducted by the Secretary under clause (ii).

(ii) SUBSEQUENT SECRETARIAL SURVEYS.—The Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates under subparagraph (A).

(iii) SURVEY REQUIREMENTS.—The surveys conducted under clauses (i) and (ii) shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug. With respect to the surveys conducted under clause (i), the Comptroller General shall report to Congress on the

justification for the size of the sample used in order to assure the validity of such estimates.

(iv) DIFFERENTIATION IN COST.—In conducting surveys under clause (i), the Comptroller General shall determine and report to Congress if there is (and the extent of any) variation in hospital acquisition costs for drugs among hospitals based on the volume of covered OPD services performed by such hospitals or other relevant characteristics of such hospitals (as defined by the Comptroller General).

(v) COMMENT ON PROPOSED RATES.—Not later than 30 days after the date the Secretary promulgated proposed rules setting forth the payment rates under subparagraph (A) for 2006, the Comptroller General shall evaluate such proposed rates and submit to Congress a report regarding the appropriateness of such rates based on the surveys the Comptroller General has conducted under clause (i).

(E) ADJUSTMENT IN PAYMENT RATES FOR OVERHEAD COSTS.—

(i) MEDPAC REPORT ON DRUG APC DESIGN.—The Medicare Payment Advisory Commission shall submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Such report shall include—

(I) a description and analysis of the data available with regard to such expenses;

(II) a recommendation as to whether such a payment adjustment should be made; and

(III) if such adjustment should be made, a recommendation regarding the methodology for making such an adjustment.

(ii) ADJUSTMENT AUTHORIZED.—The Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account the recommendations contained in the report submitted under clause (i).

(F) CLASSES OF DRUGS.—For purposes of this paragraph:

(i) SOLE SOURCE DRUGS.—The term “sole source drug” means—

(I) a biological product (as defined under section 1861(t)(1)); or

(II) a single source drug (as defined in section 1927(k)(7)(A)(iv)).

(ii) INNOVATOR MULTIPLE SOURCE DRUGS.—The term “innovator multiple source drug” has the meaning given such term in section 1927(k)(7)(A)(ii).

(iii) NONINNOVATOR MULTIPLE SOURCE DRUGS.—The term “noninnovator multiple source drug” has the meaning given such term in section 1927(k)(7)(A)(iii).

(G) REFERENCE AVERAGE WHOLESALE PRICE.—The term “reference average wholesale price” means, with respect to

a specified covered outpatient drug, the average wholesale price for the drug as determined under section 1842(o) as of May 1, 2003.

(H) INAPPLICABILITY OF EXPENDITURES IN DETERMINING CONVERSION, WEIGHTING, AND OTHER ADJUSTMENT FACTORS.—Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.

(15) PAYMENT FOR NEW DRUGS AND BIOLOGICALS UNTIL HCPCS CODE ASSIGNED.—With respect to payment under this part for an outpatient drug or biological that is covered under this part and is furnished as part of covered OPD services for which a HCPCS code has not been assigned, the amount provided for payment for such drug or biological under this part shall be equal to 95 percent of the average wholesale price for the drug or biological.

(16) MISCELLANEOUS PROVISIONS.—

(A) APPLICATION OF RECLASSIFICATION OF CERTAIN HOSPITALS.—If a hospital is being treated as being located in a rural area under section 1886(d)(8)(E), that hospital shall be treated under this subsection as being located in that rural area.

(B) THRESHOLD FOR ESTABLISHMENT OF SEPARATE APCs FOR DRUGS.—The Secretary shall reduce the threshold for the establishment of separate ambulatory payment classification groups (APCs) with respect to drugs or biologicals to \$50 per administration for drugs and biologicals furnished in 2005 and 2006.

(C) PAYMENT FOR DEVICES OF BRACHYTHERAPY AND THERAPEUTIC RADIOPHARMACEUTICALS AT CHARGES ADJUSTED TO COST.—Notwithstanding the preceding provisions of this subsection, for a device of brachytherapy consisting of a seed or seeds (or radioactive source) furnished on or after January 1, 2004, and before January 1, 2010, and for therapeutic radiopharmaceuticals furnished on or after January 1, 2008, and before January 1, 2010, the payment basis for the device or therapeutic radiopharmaceutical under this subsection shall be equal to the hospital's charges for each device or therapeutic radiopharmaceutical furnished, adjusted to cost. Charges for such devices or therapeutic radiopharmaceuticals shall not be included in determining any outlier payment under this subsection.

(D) SPECIAL PAYMENT RULE.—

(i) IN GENERAL.—In the case of covered OPD services furnished on or after April 1, 2013, in a hospital described in clause (ii), if—

(I) the payment rate that would otherwise apply under this subsection for stereotactic radiosurgery, complete course of treatment of cranial lesion(s) consisting of 1 session that is multi-source Cobalt 60 based (identified as of January 1, 2013, by HCPCS code 77371 (and any succeeding

code) and reimbursed as of such date under APC 0127 (and any succeeding classification group)); exceeds

(II) the payment rate that would otherwise apply under this subsection for linear accelerator based stereotactic radiosurgery, complete course of therapy in one session (identified as of January 1, 2013, by HCPCS code G0173 (and any succeeding code) and reimbursed as of such date under APC 0067 (and any succeeding classification group)), the payment rate for the service described in subclause (I) shall be reduced to an amount equal to the payment rate for the service described in subclause (II).

(ii) HOSPITAL DESCRIBED.—A hospital described in this clause is a hospital that is not—

(I) located in a rural area (as defined in section 1886(d)(2)(D));

(II) classified as a rural referral center under section 1886(d)(5)(C); or

(III) a sole community hospital (as defined in section 1886(d)(5)(D)(iii)).

(iii) NOT BUDGET NEUTRAL.—In making any budget neutrality adjustments under this subsection for 2013 (with respect to covered OPD services furnished on or after April 1, 2013, and before January 1, 2014) or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

(E) APPLICATION OF APPROPRIATE USE CRITERIA FOR CERTAIN IMAGING SERVICES.—For provisions relating to the application of appropriate use criteria for certain imaging services, see section 1834(q).

(F) PAYMENT INCENTIVE FOR THE TRANSITION FROM TRADITIONAL X-RAY IMAGING TO DIGITAL RADIOGRAPHY.—Notwithstanding the previous provisions of this subsection:

(i) LIMITATION ON PAYMENT FOR FILM X-RAY IMAGING SERVICES.—In the case of an imaging service that is an X-ray taken using film and that is furnished during 2017 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 20 percent.

(ii) PHASED-IN LIMITATION ON PAYMENT FOR COMPUTED RADIOGRAPHY IMAGING SERVICES.—In the case of an imaging service that is an X-ray taken using computed radiography technology (as defined in section 1848(b)(9)(C))—

(I) in the case of such a service furnished during 2018, 2019, 2020, 2021, or 2022, the payment amount for such service (including the X-ray component of a packaged service) that would other-

wise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 7 percent; and

(II) in the case of such a service furnished during 2023 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 10 percent.

(iii) APPLICATION WITHOUT REGARD TO BUDGET NEUTRALITY.—The reductions made under this subparagraph—

(I) shall not be considered an adjustment under paragraph (2)(E); and

(II) shall not be implemented in a budget neutral manner.

(iv) IMPLEMENTATION.—In order to implement this subparagraph, the Secretary shall adopt appropriate mechanisms which may include use of modifiers.

(17) QUALITY REPORTING.—

(A) REDUCTION IN UPDATE FOR FAILURE TO REPORT.—

(i) IN GENERAL.—For purposes of paragraph (3)(C)(iv) for 2009 and each subsequent year, in the case of a subsection (d) hospital (as defined in section 1886(d)(1)(B)) that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to such a year, the OPD fee schedule increase factor under paragraph (3)(C)(iv) for such year shall be reduced by 2.0 percentage points.

(ii) NON-CUMULATIVE APPLICATION.—A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take into account such reduction in computing the OPD fee schedule increase factor for a subsequent year.

(B) FORM AND MANNER OF SUBMISSION.—Each subsection (d) hospital shall submit data on measures selected under this paragraph to the Secretary in a form and manner, and at a time, specified by the Secretary for purposes of this paragraph.

(C) DEVELOPMENT OF OUTPATIENT MEASURES.—

(i) IN GENERAL.—The Secretary shall develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

(ii) CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing the Secretary from selecting measures that are the same as (or a subset of) the measures for which data are required to be submitted under section 1886(b)(3)(B)(viii).

(D) REPLACEMENT OF MEASURES.—For purposes of this paragraph, the Secretary may replace any measures or indicators in appropriate cases, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown not to represent the best clinical practice.

(E) AVAILABILITY OF DATA.—The Secretary shall establish procedures for making data submitted under this paragraph available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in outpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(18) AUTHORIZATION OF ADJUSTMENT FOR CANCER HOSPITALS.—

(A) STUDY.—The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals described in section 1886(d)(1)(B)(v) with respect to ambulatory payment classification groups exceed those costs incurred by other hospitals furnishing services under this subsection (as determined appropriate by the Secretary). In conducting the study under this subparagraph, the Secretary shall take into consideration the cost of drugs and biologicals incurred by such hospitals.

(B) AUTHORIZATION OF ADJUSTMENT.—Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals described in section 1886(d)(1)(B)(v) exceed those costs incurred by other hospitals furnishing services under this subsection, the Secretary shall, subject to subparagraph (C), provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs effective for services furnished on or after January 1, 2011.

(C) TARGET PCR ADJUSTMENT.—In applying section 419.43(i) of title 42 of the Code of Federal Regulations to implement the appropriate adjustment under this paragraph for services furnished on or after January 1, 2018, the Secretary shall use a target PCR that is 1.0 percentage points less than the target PCR that would otherwise apply. In addition to the percentage point reduction under the previous sentence, the Secretary may consider making an additional percentage point reduction to such target PCR that takes into account payment rates for applicable items and services described in paragraph (21)(C) other than for services furnished by hospitals described in section 1886(d)(1)(B)(v). In making any budget neutrality adjustments under this subsection for 2018 or a subsequent

year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

(19) FLOOR ON AREA WAGE ADJUSTMENT FACTOR FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES IN FRONTIER STATES.—

(A) IN GENERAL.—Subject to subparagraph (B), with respect to covered OPD services furnished on or after January 1, 2011, the area wage adjustment factor applicable under the payment system established under this subsection to any hospital outpatient department which is located in a frontier State (as defined in section 1886(d)(3)(E)(iii)(II)) may not be less than 1.00. The preceding sentence shall not be applied in a budget neutral manner.

(B) LIMITATION.—This paragraph shall not apply to any hospital outpatient department located in a State that receives a non-labor related share adjustment under section 1886(d)(5)(H).

(20) NOT BUDGET NEUTRAL APPLICATION OF REDUCED EXPENDITURES RESULTING FROM QUALITY INCENTIVES FOR COMPUTED TOMOGRAPHY.—The Secretary shall not take into account the reduced expenditures that result from the application of section 1834(p) in making any budget neutrality adjustments this subsection.

(21) SERVICES FURNISHED BY AN OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.—

(A) APPLICABLE ITEMS AND SERVICES.—For purposes of paragraph (1)(B)(v) and this paragraph, the term “applicable items and services” means items and services other than items and services furnished by a dedicated emergency department (as defined in section 489.24(b) of title 42 of the Code of Federal Regulations).

(B) OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.—

(i) IN GENERAL.—For purposes of paragraph (1)(B)(v) and this paragraph, subject to the subsequent provisions of this subparagraph, the term “off-campus outpatient department of a provider” means a department of a provider (as defined in section 413.65(a)(2) of title 42 of the Code of Federal Regulations, as in effect as of the date of the enactment of this paragraph) that is not located—

(I) on the campus (as defined in such section 413.65(a)(2)) of such provider; or

(II) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section 413.65(a)(2)).

(ii) EXCEPTION.—For purposes of paragraph (1)(B)(v) and this paragraph, the term “off-campus outpatient department of a provider” shall not include a department of a provider (as so defined) that was billing under this subsection with respect to covered OPD

services furnished prior to the date of the enactment of this paragraph.

(iii) **DEEMED TREATMENT FOR 2017.**—For purposes of applying clause (ii) with respect to applicable items and services furnished during 2017, a department of a provider (as so defined) not described in such clause is deemed to be billing under this subsection with respect to covered OPD services furnished prior to November 2, 2015, if the Secretary received from the provider prior to December 2, 2015, an attestation (pursuant to section 413.65(b)(3) of title 42 of the Code of Federal Regulations) that such department was a department of a provider (as so defined).

(iv) **ALTERNATIVE EXCEPTION BEGINNING WITH 2018.**—For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2018 or a subsequent year, the term “off-campus outpatient department of a provider” also shall not include a department of a provider (as so defined) that is not described in clause (ii) if—

(I) the Secretary receives from the provider an attestation (pursuant to such section 413.65(b)(3)) not later than December 31, 2016 (or, if later, 60 days after the date of the enactment of this clause), that such department met the requirements of a department of a provider specified in section 413.65 of title 42 of the Code of Federal Regulations;

(II) the provider includes such department as part of the provider on its enrollment form in accordance with the enrollment process under section 1866(j); and

(III) the department met the mid-build requirement of clause (v) and the Secretary receives, not later than 60 days after the date of the enactment of this clause, from the chief executive officer or chief operating officer of the provider a written certification that the department met such requirement.

(v) **MID-BUILD REQUIREMENT DESCRIBED.**—The mid-build requirement of this clause is, with respect to a department of a provider, that before November 2, 2015, the provider had a binding written agreement with an outside unrelated party for the actual construction of such department.

(vi) **EXCLUSION FOR CERTAIN CANCER HOSPITALS.**—For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2017 or a subsequent year, the term “off-campus outpatient department of a provider” also shall not include a department of a provider (as so defined) that is not described in clause (ii) if the provider is a hospital described in section 1886(d)(1)(B)(v) and—

(I) in the case of a department that met the requirements of section 413.65 of title 42 of the Code of Federal Regulations after November 1, 2015, and before the date of the enactment of this clause, the Secretary receives from the provider an attestation that such department met such requirements not later than 60 days after such date of enactment; or

(II) in the case of a department that meets such requirements after such date of enactment, the Secretary receives from the provider an attestation that such department meets such requirements not later than 60 days after the date such requirements are first met with respect to such department.

(vii) AUDIT.—Not later than December 31, 2018, the Secretary shall audit the compliance with requirements of clause (iv) with respect to each department of a provider to which such clause applies. Not later than 2 years after the date the Secretary receives an attestation under clause (vi) relating to compliance of a department of a provider with requirements referred to in such clause, the Secretary shall audit the compliance with such requirements with respect to the department. If the Secretary finds as a result of an audit under this clause that the applicable requirements were not met with respect to such department, the department shall not be excluded from the term “off-campus outpatient department of a provider” under such clause.

(viii) IMPLEMENTATION.—For purposes of implementing clauses (iii) through (vii):

(I) Notwithstanding any other provision of law, the Secretary may implement such clauses by program instruction or otherwise.

(II) Subchapter I of chapter 35 of title 44, United States Code, shall not apply.

(III) For purposes of carrying out this subparagraph with respect to clauses (iii) and (iv) (and clause (vii) insofar as it relates to clause (iv)), \$10,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841, to remain available until December 31, 2018. For purposes of carrying out this subparagraph with respect to clause (vi) (and clause (vii) insofar as it relates to such clause), \$2,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841, to remain available until expended.

(C) AVAILABILITY OF PAYMENT UNDER OTHER PAYMENT SYSTEMS.—Payments for applicable items and services furnished by an off-campus outpatient department of a provider that are described in paragraph (1)(B)(v) shall be made under the applicable payment system under this

part (other than under this subsection) if the requirements for such payment are otherwise met.

(D) INFORMATION NEEDED FOR IMPLEMENTATION.—Each hospital shall provide to the Secretary such information as the Secretary determines appropriate to implement this paragraph and paragraph (1)(B)(v) (which may include reporting of information on a hospital claim using a code or modifier and reporting information about off-campus outpatient departments of a provider on the enrollment form described in section 1866(j)).

(E) LIMITATIONS.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

(i) The determination of the applicable items and services under subparagraph (A) and applicable payment systems under subparagraph (C).

(ii) The determination of whether a department of a provider meets the term described in subparagraph (B).

(iii) Any information that hospitals are required to report pursuant to subparagraph (D).

(iv) The determination of an audit under subparagraph (B)(vii).

(u) INCENTIVE PAYMENTS FOR PHYSICIAN SCARCITY AREAS.—

(1) IN GENERAL.—In the case of physicians' services furnished on or after January 1, 2005, and before July 1, 2008—

(A) by a primary care physician in a primary care scarcity county (identified under paragraph (4)); or

(B) by a physician who is not a primary care physician in a specialist care scarcity county (as so identified),

in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid an amount equal to 5 percent of the payment amount for the service under this part.

(2) DETERMINATION OF RATIOS OF PHYSICIANS TO MEDICARE BENEFICIARIES IN AREA.—Based upon available data, the Secretary shall establish for each county or equivalent area in the United States, the following:

(A) NUMBER OF PHYSICIANS PRACTICING IN THE AREA.—

The number of physicians who furnish physicians' services in the active practice of medicine or osteopathy in that county or area, other than physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services. Of such number, the number of such physicians who are—

(i) primary care physicians; or

(ii) physicians who are not primary care physicians.

(B) NUMBER OF MEDICARE BENEFICIARIES RESIDING IN THE AREA.—The number of individuals who are residing in the county and are entitled to benefits under part A or enrolled under this part, or both (in this subsection referred to as "individuals").

(C) DETERMINATION OF RATIOS.—

(i) PRIMARY CARE RATIO.—The ratio (in this paragraph referred to as the “primary care ratio”) of the number of primary care physicians (determined under subparagraph (A)(i)), to the number of individuals determined under subparagraph (B).

(ii) SPECIALIST CARE RATIO.—The ratio (in this paragraph referred to as the “specialist care ratio”) of the number of other physicians (determined under subparagraph (A)(ii)), to the number of individuals determined under subparagraph (B).

(3) RANKING OF COUNTIES.—The Secretary shall rank each such county or area based separately on its primary care ratio and its specialist care ratio.

(4) IDENTIFICATION OF COUNTIES.—

(A) IN GENERAL.—The Secretary shall identify—

(i) those counties and areas (in this paragraph referred to as “primary care scarcity counties”) with the lowest primary care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph; and

(ii) those counties and areas (in this subsection referred to as “specialist care scarcity counties”) with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph.

(B) PERIODIC REVISIONS.—The Secretary shall periodically revise the counties or areas identified in subparagraph (A) (but not less often than once every three years) unless the Secretary determines that there is no new data available on the number of physicians practicing in the county or area or the number of individuals residing in the county or area, as identified in paragraph (2).

(C) IDENTIFICATION OF COUNTIES WHERE SERVICE IS FURNISHED.—For purposes of paying the additional amount specified in paragraph (1), if the Secretary uses the 5-digit postal ZIP Code where the service is furnished, the dominant county of the postal ZIP Code (as determined by the United States Postal Service, or otherwise) shall be used to determine whether the postal ZIP Code is in a scarcity county identified in subparagraph (A) or revised in subparagraph (B).

(D) SPECIAL RULE.—With respect to physicians’ services furnished on or after January 1, 2008, and before July 1, 2008, for purposes of this subsection, the Secretary shall use the primary care scarcity counties and the specialty care scarcity counties (as identified under the preceding provisions of this paragraph) that the Secretary was using under this subsection with respect to physicians’ services furnished on December 31, 2007.

(E) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting—

- 116.(i) the identification of a county or area;
- (ii) the assignment of a specialty of any physician under this paragraph;
- (iii) the assignment of a physician to a county under paragraph (2); or
- (iv) the assignment of a postal ZIP Code to a county or other area under this subsection.

(5) RURAL CENSUS TRACTS.—To the extent feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)), as an equivalent area for purposes of qualifying as a primary care scarcity county or specialist care scarcity county under this subsection.

(6) PHYSICIAN DEFINED.—For purposes of this paragraph, the term “physician” means a physician described in section 1861(r)(1) and the term “primary care physician” means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

(7) PUBLICATION OF LIST OF COUNTIES; POSTING ON WEBSITE.—With respect to a year for which a county or area is identified or revised under paragraph (4), the Secretary shall identify such counties or areas as part of the proposed and final rule to implement the physician fee schedule under section 1848 for the applicable year. The Secretary shall post the list of counties identified or revised under paragraph (4) on the Internet website of the Centers for Medicare & Medicaid Services.

(v) INCREASE OF FQHC PAYMENT LIMITS.—In the case of services furnished by Federally qualified health centers (as defined in section 1861(aa)(4)), the Secretary shall establish payment limits with respect to such services under this part for services furnished—

- (1) in 2010, at the limits otherwise established under this part for such year increased by \$5; and
- (2) in a subsequent year, at the limits established under this subsection for the previous year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year.

(w) METHODS OF PAYMENT.—The Secretary may develop alternative methods of payment for items and services provided under clinical trials and comparative effectiveness studies sponsored or supported by an agency of the Department of Health and Human Services, as determined by the Secretary, to those that would otherwise apply under this section, to the extent such alternative methods are necessary to preserve the scientific validity of such trials or studies, such as in the case where masking the identity of interventions from patients and investigators is necessary to comply with the particular trial or study design.

(x) INCENTIVE PAYMENTS FOR PRIMARY CARE SERVICES.—

(1) IN GENERAL.—In the case of primary care services furnished on or after January 1, 2011, and before January 1, 2016, by a primary care practitioner, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

(2) DEFINITIONS.—In this subsection:

(A) PRIMARY CARE PRACTITIONER.—The term “primary care practitioner” means an individual—

(i) who—

(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or

(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5)); and

(ii) for whom primary care services accounted for at least 60 percent of the allowed charges under this part for such physician or practitioner in a prior period as determined appropriate by the Secretary.

(B) PRIMARY CARE SERVICES.—The term “primary care services” means services identified, as of January 1, 2009, by the following HCPCS codes (and as subsequently modified by the Secretary):

(i) 99201 through 99215.

(ii) 99304 through 99340.

(iii) 99341 through 99350.

(3) COORDINATION WITH OTHER PAYMENTS.—The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively. The amount of the additional payment for a service under this subsection and subsection (z) shall be determined without regard to any additional payment for the service under subsection (z) and this subsection, respectively.

(4) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting the identification of primary care practitioners under this subsection.

(y) INCENTIVE PAYMENTS FOR MAJOR SURGICAL PROCEDURES FURNISHED IN HEALTH PROFESSIONAL SHORTAGE AREAS.—

(1) IN GENERAL.—In the case of major surgical procedures furnished on or after January 1, 2011, and before January 1, 2016, by a general surgeon in an area that is designated (under section 332(a)(1)(A) of the Public Health Service Act) as a health professional shortage area as identified by the Secretary prior to the beginning of the year involved, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

(2) DEFINITIONS.—In this subsection:

(A) GENERAL SURGEON.—In this subsection, the term “general surgeon” means a physician (as described in section 1861(r)(1)) who has designated CMS specialty code 02—General Surgery as their primary specialty code in the physician’s enrollment under section 1866(j).

(B) MAJOR SURGICAL PROCEDURES.—The term “major surgical procedures” means physicians’ services which are surgical procedures for which a 10-day or 90-day global period is used for payment under the fee schedule under section 1848(b).

(3) COORDINATION WITH OTHER PAYMENTS.—The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively. The amount of the additional payment for a service under this subsection and subsection (z) shall be determined without regard to any additional payment for the service under subsection (z) and this subsection, respectively.

(4) APPLICATION.—The provisions of paragraph (2) and (4) of subsection (m) shall apply to the determination of additional payments under this subsection in the same manner as such provisions apply to the determination of additional payments under subsection (m).

(z) INCENTIVE PAYMENTS FOR PARTICIPATION IN ELIGIBLE ALTERNATIVE PAYMENT MODELS.—

(1) PAYMENT INCENTIVE.—

(A) IN GENERAL.—In the case of covered professional services furnished by an eligible professional during a year that is in the period beginning with 2019 and ending with 2024 and for which the professional is a qualifying APM participant with respect to such year, in addition to the amount of payment that would otherwise be made for such covered professional services under this part for such year, there also shall be paid to such professional an amount equal to 5 percent of the estimated aggregate payment amounts for such covered professional services under this part for the preceding year. For purposes of the previous sentence, the payment amount for the preceding year may be an estimation for the full preceding year based on a period of such preceding year that is less than the full year. The Secretary shall establish policies to implement this subparagraph in cases in which payment for covered professional services furnished by a qualifying APM participant in an alternative payment model—

(i) is made to an eligible alternative payment entity rather than directly to the qualifying APM participant; or

(ii) is made on a basis other than a fee-for-service basis (such as payment on a capitated basis).

(B) FORM OF PAYMENT.—Payments under this subsection shall be made in a lump sum, on an annual basis, as soon as practicable.

(C) TREATMENT OF PAYMENT INCENTIVE.—Payments under this subsection shall not be taken into account for purposes of determining actual expenditures under an al-

ternative payment model and for purposes of determining or rebasing any benchmarks used under the alternative payment model.

(D) COORDINATION.—The amount of the additional payment under this subsection or subsection (m) shall be determined without regard to any additional payment under subsection (m) and this subsection, respectively. The amount of the additional payment under this subsection or subsection (x) shall be determined without regard to any additional payment under subsection (x) and this subsection, respectively. The amount of the additional payment under this subsection or subsection (y) shall be determined without regard to any additional payment under subsection (y) and this subsection, respectively.

(2) QUALIFYING APM PARTICIPANT.—For purposes of this subsection, the term “qualifying APM participant” means the following:

(A) 2019 AND 2020.—With respect to 2019 and 2020, an eligible professional for whom the Secretary determines that at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(B) 2021 AND 2022.—With respect to 2021 and 2022, an eligible professional described in either of the following clauses:

(i) MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional for whom the Secretary determines that at least 50 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(ii) COMBINATION ALL-PAYER AND MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional—

(I) for whom the Secretary determines, with respect to items and services furnished by such professional during the most recent period for which data are available (which may be less than a year), that at least 50 percent of the sum of—

(aa) payments described in clause (i); and

(bb) all other payments, regardless of payer (other than payments made by the Secretary of Defense or the Secretary of Veterans Affairs and other than payments made under title XIX in a State in which no medical home or alternative payment model is available under the State program under that title),

meet the requirement described in clause (iii)(I) with respect to payments described in item (aa) and meet the requirement described in clause

(iii)(II) with respect to payments described in item (bb);

(II) for whom the Secretary determines at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity; and

(III) who provides to the Secretary such information as is necessary for the Secretary to make a determination under subclause (I), with respect to such professional.

(iii) REQUIREMENT.—For purposes of clause (ii)(I)—

(I) the requirement described in this subclause, with respect to payments described in item (aa) of such clause, is that such payments are made to an eligible alternative payment entity; and

(II) the requirement described in this subclause, with respect to payments described in item (bb) of such clause, is that such payments are made under arrangements in which—

(aa) quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i) apply;

(bb) certified EHR technology is used; and

(cc) the eligible professional participates in an entity that—

(AA) bears more than nominal financial risk if actual aggregate expenditures exceeds expected aggregate expenditures; or

(BB) with respect to beneficiaries under title XIX, is a medical home that meets criteria comparable to medical homes expanded under section 1115A(c).

(C) BEGINNING IN 2023.—With respect to 2023 and each subsequent year, an eligible professional described in either of the following clauses:

(i) MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional for whom the Secretary determines that at least 75 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(ii) COMBINATION ALL-PAYER AND MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional—

(I) for whom the Secretary determines, with respect to items and services furnished by such professional during the most recent period for which data are available (which may be less than a year), that at least 75 percent of the sum of—

(aa) payments described in clause (i); and

(bb) all other payments, regardless of payer (other than payments made by the Secretary of Defense or the Secretary of Veterans Affairs and other than payments made under title XIX in a State in which no medical home or alternative payment model is available under the State program under that title), meet the requirement described in clause (iii)(I) with respect to payments described in item (aa) and meet the requirement described in clause (iii)(II) with respect to payments described in item (bb);

(II) for whom the Secretary determines at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity; and

(III) who provides to the Secretary such information as is necessary for the Secretary to make a determination under subclause (I), with respect to such professional.

(iii) REQUIREMENT.—For purposes of clause (ii)(I)—

(I) the requirement described in this subclause, with respect to payments described in item (aa) of such clause, is that such payments are made to an eligible alternative payment entity; and

(II) the requirement described in this subclause, with respect to payments described in item (bb) of such clause, is that such payments are made under arrangements in which—

(aa) quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i) apply;

(bb) certified EHR technology is used; and

(cc) the eligible professional participates in an entity that—

(AA) bears more than nominal financial risk if actual aggregate expenditures exceeds expected aggregate expenditures; or

(BB) with respect to beneficiaries under title XIX, is a medical home that meets criteria comparable to medical homes expanded under section 1115A(c).

(D) USE OF PATIENT APPROACH.—The Secretary may base the determination of whether an eligible professional is a qualifying APM participant under this subsection and the determination of whether an eligible professional is a partial qualifying APM participant under section 1848(q)(1)(C)(iii) by using counts of patients in lieu of using payments and using the same or similar percentage criteria (as specified in this subsection and such section, respectively), as the Secretary determines appropriate.

(3) ADDITIONAL DEFINITIONS.—In this subsection:

(A) COVERED PROFESSIONAL SERVICES.—The term “covered professional services” has the meaning given that term in section 1848(k)(3)(A).

(B) ELIGIBLE PROFESSIONAL.—The term “eligible professional” has the meaning given that term in section 1848(k)(3)(B) and includes a group that includes such professionals.

(C) ALTERNATIVE PAYMENT MODEL (APM).—The term “alternative payment model” means, other than for purposes of subparagraphs (B)(ii)(I)(bb) and (C)(ii)(I)(bb) of paragraph (2), any of the following:

(i) A model under section 1115A (other than a health care innovation award).

(ii) The shared savings program under section 1899.

(iii) A demonstration under section 1866C.

(iv) A demonstration required by Federal law.

(D) ELIGIBLE ALTERNATIVE PAYMENT ENTITY.—The term “eligible alternative payment entity” means, with respect to a year, an entity that—

(i) participates in an alternative payment model that—

(I) requires participants in such model to use certified EHR technology (as defined in subsection (o)(4)); and

(II) provides for payment for covered professional services based on quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i); and

(ii)(I) bears financial risk for monetary losses under such alternative payment model that are in excess of a nominal amount; or

(II) is a medical home expanded under section 1115A(c).

(4) LIMITATION.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, of the following:

(A) The determination that an eligible professional is a qualifying APM participant under paragraph (2) and the determination that an entity is an eligible alternative payment entity under paragraph (3)(D).

(B) The determination of the amount of the 5 percent payment incentive under paragraph (1)(A), including any estimation as part of such determination.

(z) MEDICAL REVIEW OF SPINAL SUBLUXATION SERVICES.—

(1) IN GENERAL.—The Secretary shall implement a process for the medical review (as described in paragraph (2)) of treatment by a chiropractor described in section 1861(r)(5) by means of manual manipulation of the spine to correct a subluxation (as described in such section) of an individual who is enrolled under this part and apply such process to such services furnished on or after January 1, 2017, focusing on services such as—

(A) services furnished by a such a chiropractor whose pattern of billing is aberrant compared to peers; and

(B) services furnished by such a chiropractor who, in a prior period, has a services denial percentage in the 85th percentile or greater, taking into consideration the extent that service denials are overturned on appeal.

(2) MEDICAL REVIEW.—

(A) PRIOR AUTHORIZATION MEDICAL REVIEW.—

(i) IN GENERAL.—Subject to clause (ii), the Secretary shall use prior authorization medical review for services described in paragraph (1) that are furnished to an individual by a chiropractor described in section 1861(r)(5) that are part of an episode of treatment that includes more than 12 services. For purposes of the preceding sentence, an episode of treatment shall be determined by the underlying cause that justifies the need for services, such as a diagnosis code.

(ii) ENDING APPLICATION OF PRIOR AUTHORIZATION MEDICAL REVIEW.—The Secretary shall end the application of prior authorization medical review under clause (i) to services described in paragraph (1) by such a chiropractor if the Secretary determines that the chiropractor has a low denial rate under such prior authorization medical review. The Secretary may subsequently reapply prior authorization medical review to such chiropractor if the Secretary determines it to be appropriate and the chiropractor has, in the time period subsequent to the determination by the Secretary of a low denial rate with respect to the chiropractor, furnished such services described in paragraph (1).

(iii) EARLY REQUEST FOR PRIOR AUTHORIZATION REVIEW PERMITTED.—Nothing in this subsection shall be construed to prevent such a chiropractor from requesting prior authorization for services described in paragraph (1) that are to be furnished to an individual before the chiropractor furnishes the twelfth such service to such individual for an episode of treatment.

(B) TYPE OF REVIEW.—The Secretary may use pre-payment review or post-payment review of services described in section 1861(r)(5) that are not subject to prior authorization medical review under subparagraph (A).

(C) RELATIONSHIP TO LAW ENFORCEMENT ACTIVITIES.—The Secretary may determine that medical review under this subsection does not apply in the case where potential fraud may be involved.

(3) NO PAYMENT WITHOUT PRIOR AUTHORIZATION.—With respect to a service described in paragraph (1) for which prior authorization medical review under this subsection applies, the following shall apply:

(A) PRIOR AUTHORIZATION DETERMINATION.—The Secretary shall make a determination, prior to the service being furnished, of whether the service would or would not meet the applicable requirements of section 1862(a)(1)(A).

(B) DENIAL OF PAYMENT.—Subject to paragraph (5), no payment may be made under this part for the service unless the Secretary determines pursuant to subparagraph

(A) that the service would meet the applicable requirements of such section 1862(a)(1)(A).

(4) SUBMISSION OF INFORMATION.—A chiropractor described in section 1861(r)(5) may submit the information necessary for medical review by fax, by mail, or by electronic means. The Secretary shall make available the electronic means described in the preceding sentence as soon as practicable.

(5) TIMELINESS.—If the Secretary does not make a prior authorization determination under paragraph (3)(A) within 14 business days of the date of the receipt of medical documentation needed to make such determination, paragraph (3)(B) shall not apply.

(6) APPLICATION OF LIMITATION ON BENEFICIARY LIABILITY.—Where payment may not be made as a result of the application of paragraph (2)(B), section 1879 shall apply in the same manner as such section applies to a denial that is made by reason of section 1862(a)(1).

(7) REVIEW BY CONTRACTORS.—The medical review described in paragraph (2) may be conducted by medicare administrative contractors pursuant to section 1874A(a)(4)(G) or by any other contractor determined appropriate by the Secretary that is not a recovery audit contractor.

(8) MULTIPLE SERVICES.—The Secretary shall, where practicable, apply the medical review under this subsection in a manner so as to allow an individual described in paragraph (1) to obtain, at a single time rather than on a service-by-service basis, an authorization in accordance with paragraph (3)(A) for multiple services.

(9) CONSTRUCTION.—With respect to a service described in paragraph (1) that has been affirmed by medical review under this subsection, nothing in this subsection shall be construed to preclude the subsequent denial of a claim for such service that does not meet other applicable requirements under this Act.

(10) IMPLEMENTATION.—

(A) AUTHORITY.—The Secretary may implement the provisions of this subsection by interim final rule with comment period.

(B) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to medical review under this subsection.

* * * * *

DISSENTING VIEWS

H.R. 5809 would extend a temporary pass-through payment for non-opioid analgesics for post-surgical pain management from three to five years in the Medicare Outpatient Prospective Payment System (OPPS). This bill is not an effective or efficient use of taxpayer dollars, and would increase out-of-pocket costs for Medicare beneficiaries. Additionally, there is no evidence that this bill would have any positive impact on the opioid crisis.

Under current law, new drugs maintain pass-through status in the OPPS for three years, and are separately reimbursed. After pass-through status expires, drugs that are deemed part of an outpatient procedure or service are bundled into the cost of the procedure. This encourages efficient use of hospital resources. The bill would extend pass-through status for new non-opioid analgesics for post-surgical pain from three to five years, thereby allowing the manufacturers of these drugs to obtain higher reimbursement for a longer period of time.

Supporters of H.R. 5809 state that extending pass-through status would incentivize the development of more nonopioid analgesics and thereby reduce opioid prescribing. However, there is no evidence that this bill will have any impact on reducing opioid prescribing. There are already many low cost non-opioid analgesics for postoperative pain on the market.¹ Yet the availability of these non-opioid alternatives does not appear to have had any meaningful impact on the opioid crisis.

Additionally, new drugs already get three years of pass through status in the OPPS. There is no evidence to establish that an additional two years of pass-through status is necessary to incentivize the development of new non-opioid analgesics.

Moreover, this bill is setting a troubling precedent of Congress picking winners in the OPPS. The recent Balanced Budget Act also extended pass-through status for two years for a particular drug.² Other drug companies will likely also request extensions of pass-through status for their drugs. Ultimately, more requests for extended pass-through status will increase federal drug spending and out-of-pocket costs for beneficiaries, who will now have to pay 20 percent coinsurance on both the cost of the procedure and on the separately reimbursed drug.

Supporters of H.R. 5809 have argued that we need to do more to incentivize non-opioid alternatives for pain management. While

¹American Pain Society, *Guidelines on the Management of Postoperative Pain: A Clinical Practice Guideline From the American Pain Society, the American Society of Regional Anesthesia and Pain Medicine, and the American Society of Anesthesiologists' Committee on Regional Anesthesia, Executive Committee, and Administrative Council*, *The Journal of Pain* (Feb. 2016).

²*Buried in spending package: a big win for a small drug company*, STAT (Mar. 21, 2018) (www.statnews.com/2018/03/21/omeros-pass-through). *Eye drug company scores gift in spending bill*, Axios (Mar. 22, 2018) (www.axios.com/omeros-eye-drug-gift-1521729513-453a5b4f-7c86-44d0-b966-f463c4bca05d.html).

this is an important goal, but there are better ways to address these concerns. At the Full Committee mark-up, Representative Debbie Dingell offered an alternative to H.R. 5809, which would require the Centers for Medicare & Medicaid Services (CMS) to conduct a comprehensive review of the Outpatient Prospective Payment System (OPPS) and examine whether there are financial disincentives to use non-opioid alternatives for pain management, vis-à-vis opioid therapies. The agency would be required to do this systematically, and examine all the evidence-based non-opioid alternatives for pain management that are currently on the market. The agency would then be empowered to revise the OPPS to reduce any payment incentives to use opioids instead of non-opioid alternatives. CMS would do this on a budget neutral basis, rather than costing taxpayers hundreds of millions of dollars. This is how we should address the potential problem that the bill's sponsors have raised, rather than Congress picking and choosing winners. Unfortunately, the amendment failed on a roll call vote.

H.R. 5809 is not a judicious use of taxpayer dollars, will have no meaningful impact on the opioid crisis, and will set a troubling precedent that likely increase federal spending on drugs.

FRANK PALLONE, Jr.,
Ranking Member.

EXCHANGE OF LETTERS WITH ADDITIONAL COMMITTEES OF
REFERRAL

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

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Minority (202) 225-3641

June 7, 2018

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

Dear Chairman Brady:

On May 9 and 17, 2018, the Committee on Energy and Commerce ordered favorably reported over 50 bills to address the opioid epidemic facing communities across our nation. Several of the bills were also referred to the Committee on Ways and Means.

I ask that the Committee on Ways and Means not insist on its referral of the following bills so that they may be scheduled for consideration by the Majority Leader:

- **H.R. 1925**, At-Risk Youth Medicaid Protection Act of 2017;
- **H.R. 3331**, To amend title XI of the Social Security Act to promote testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology;
- **H.R. 3528**, Every Prescription Conveyed Securely Act;
- **H.R. 4841**, Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018;
- **H.R. 5582**, Abuse Deterrent Access Act of 2018;
- **H.R. 5590**, Opioid Addiction Action Plan Act;
- **H.R. 5603**, Access to Telehealth Services for Opioid Use Disorder;

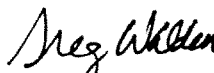
The Honorable Kevin Brady
Page 2

- **H.R. 5605**, Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act;
- **H.R. 5675**, To amend title XVIII of the Social Security Act to require prescription drug plan sponsors under the Medicare program to establish drug management programs for at-risk beneficiaries;
- **H.R. 5684**, Protecting Seniors from Opioid Abuse Act;
- **H.R. 5685**, Medicare Opioid Safety Education Act;
- **H.R. 5686**, Medicare Clear Health Options in Care for Enrollees (CHOICE) Act;
- **H.R. 5715**, Strengthening Partnerships to Prevent Opioid Abuse Act;
- **H.R. 5716**, Commit to Opioid Medical Prescriber Accountability and Safety for Seniors (COMPASS) Act;
- **H.R. 5796**, Responsible Education Achieves Care and Healthy Outcomes for Users' Treatment (REACH OUT) Act of 2018;
- **H.R. 5798**, Opioid Screening and Chronic Pain Management Alternatives for Seniors Act;
- **H.R. 5804**, Post-Surgical Injections as an Opioid Alternative Act; and
- **H.R. 5809**, Postoperative Opioid Prevention Act of 2018.

This concession in no way affects your jurisdiction over the subject matter of these bills, and it will not serve as precedent for future referrals. In addition, should a conference on the bills be necessary, I would support your request to have the Committee on Ways and Means on the conference committee. Finally, I would be pleased to include this letter and your response in the bill reports and the Congressional Record.

Thank you for your consideration of my request and for the extraordinary cooperation shown by you and your staff over matters of shared jurisdiction. I look forward to further opportunities to work with you this Congress.

Sincerely,


Greg Walden
Chairman

KEVIN BRADY, TEXAS
CHAIRMAN

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DEVIN NUÑEZ, CALIFORNIA
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GARY J. ANDRES,
STAFF DIRECTOR

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BRANDON CASEY,
MINORITY CHIEF OF STAFF

June 8, 2018

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

Dear Chairman Walden,

Thank you for your letter concerning several bills favorably reported out of the Committee on Energy and Commerce to address the opioid epidemic and which the Committee on Ways and Means was granted an additional referral.

As a result of your having consulted with us on provisions within these bills that fall within the Rule X jurisdiction of the Committee on Ways and Means, I agree to waive formal consideration of the following bills so that they may move expeditiously to the floor:

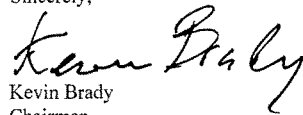
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- **H.R. 5603**, Access to Telehealth Services for Opioid Use Disorder;
- **H.R. 5605**, Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act;

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- **H.R. 5796**, Responsible Education Achieves Care and Healthy Outcomes for Users' Treatment (REACH OUT) Act of 2018;
- **H.R. 5798**, Opioid Screening and Chronic Pain Management Alternatives for Seniors Act;
- **H.R. 5804**, Post-Surgical Injections as an Opioid Alternative Act; and
- **H.R. 5809**, Postoperative Opioid Prevention Act of 2018.

The Committee on Ways and Means takes this action with the mutual understanding that we do not waive any jurisdiction over the subject matter contained in this or similar legislation, and the Committee will be appropriately consulted and involved as the bill or similar legislation moves forward so that we may address any remaining issues that fall within our jurisdiction. The Committee also reserves the right to seek appointment of an appropriate number of conferees to any House-Senate conference involving this or similar legislation and requests your support for such a request.

Finally, I would appreciate your commitment to include this exchange of letters in the bill reports and the Congressional Record.

Sincerely,



Kevin Brady
Chairman

cc: The Honorable Paul Ryan, Speaker
The Honorable Richard E. Neal
The Honorable Frank Pallone
Thomas J. Wickham, Jr., Parliamentarian