115TH CONGRESS
2d Session

HOUSE OF REPRESENTATIVES

REPORT
115–723

INDIVIDUALS IN MEDICAID DESERVE CARE THAT IS APPROPRIATE AND RESPONSIBLE IN ITS EXECUTION ACT

JUNE 12, 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. 5797]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 5797) to amend title XIX of the Social Security Act to allow States to provide under Medicaid services for certain individuals with opioid use disorders in institutions for mental diseases, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

79–006

The amendment is as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Individuals in Medicaid Deserve Care that is Appropriate and Responsible in its Execution Act" or the "IMD CARE Act".

SEC. 2. MEDICAID STATE PLAN OPTION TO PROVIDE SERVICES FOR CERTAIN INDIVIDUALS WITH OPIOID USE DISORDERS IN INSTITUTIONS FOR MENTAL DISEASES.

Section 1915 of the Social Security Act (42 U.S.C. 1396n) is amended by adding at the end the following new subsection:

"(l) STATE PLAN OPTION TO PROVIDE SERVICES FOR CERTAIN INDIVIDUALS IN INSTITUTIONS FOR MENTAL DISEASES.—

"(1) IN GENERAL.—With respect to calendar quarters beginning during the period beginning January 1, 2019, and ending December 31, 2023, a State may elect, through a State plan amendment, to, notwithstanding section 1905(a), provide medical assistance for services furnished in institutions for mental diseases and for other medically necessary services furnished to eligible individuals with opioid use disorders, in accordance with the requirements of this subsection.

"(2) PAYMENTS.—

"(A) IN GENERAL.—Amounts expended under a State plan amendment under paragraph (1) for services described in such paragraph furnished, with respect to a 12-month period, to an eligible individual with an opioid use disorder who is a patient in an institution for mental diseases shall be treated as medical assistance for which payment is made under section 1903(a) but only to the extent that such services are furnished for not more than a period of 30 days (whether or not consecutive) during such 12-month period.

"(B) CLARIFICATION.—Payment made under this paragraph for expenditures under a State plan amendment under this subsection with respect to services described in paragraph (1) furnished to an eligible individual with an opioid use disorder shall not affect payment that would otherwise be made under section 1903(a) for expenditures under the State plan (or waiver of such plan) for medical assistance for such individual.

"(3) INFORMATION REQUIRED IN STATE PLAN AMENDMENT.—

"(A) IN GENERAL.—A State electing to provide medical assistance pursuant to this subsection shall include with the submission of the State plan amendment under paragraph (1) to the Secretary—

"(i) a plan on how the State will improve access to outpatient care during the period of the State plan amendment, including a description of—

"(I) the process by which eligible individuals with opioid use disorders will make the transition from receiving inpatient services in an institution for mental diseases to appropriate outpatient care; and

"(II) the process the State will undertake to ensure individuals with opioid use disorder are provided care in the most integrated setting appropriate to the needs of the individuals; and

"(ii) a description of how the State plan amendment ensures an appropriate clinical screening of eligible individuals with an opioid use disorder, including assessments to determine level of care and length of stay recommendations based upon the multidimensional assessment criteria of the American Society of Addiction Medicine.

"(B) REPORT.—Not later than the sooner of December 31, 2024, or one year after the date of the termination of a State plan amendment under this subsection, the State shall submit to the Secretary a report that includes at least—

"(i) the number of eligible individuals with opioid use disorders who received services pursuant to such State plan amendment;

"(ii) the length of the stay of each such individual in an institution for mental diseases; and

"(iii) the type of outpatient treatment, including medication-assisted treatment, each such individual received after being discharged from such institution.

"(4) DEFINITIONS.—In this subsection:

"(A) ELIGIBLE INDIVIDUAL WITH AN OPIOID USE DISORDER.—The term 'eligible individual with an opioid use disorder' means an individual who—

"(i) with respect to a State, is enrolled for medical assistance under the State plan (or a waiver of such plan);

"(ii) is at least 21 years of age;

"(iii) has not attained 65 years of age; and

"(iv) has been diagnosed with at least one opioid use disorder.

"(B) INSTITUTION FOR MENTAL DISEASES.—The term 'institution for mental diseases' has the meaning given such term in section 1905(i).

"(C) OPIOID PRESCRIPTION PAIN RELIEVER.—The term 'opioid prescription pain reliever' includes hydrocodone products, oxycodone products, tramadol products, codeine products, morphine products, fentanyl products, buprenorphine products, oxymorphone products, meperidine products, hydromorphone products, methadone, and any other prescription pain reliever identified by the Assistant Secretary for Mental Health and Substance Use.

"(D) OPIOID USE DISORDER.—The term 'opioid use disorder' means a disorder that meets the criteria of the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (or a successor edition), for heroin use disorder or pain reliever use disorder (including with respect to opioid prescription pain relievers).

"(E) OTHER MEDICALLY NECESSARY SERVICES.—The term 'other medically necessary services' means, with respect to an eligible individual with an opioid use disorder who is a patient in an institution for mental diseases, items and services that are provided to such individual outside of such institution to the extent that such items and services would be treated as medical assistance for such individual if such individual were not a patient in such institution.".

PURPOSE AND SUMMARY

H.R. 5797 was introduced on May 15, 2018, by Rep. Mimi Walters (R–CA). The bill allows state Medicaid programs to remove the Institutions for Mental Diseases (IMD) exclusion for Medicaid beneficiaries aged 21 to 64 with an opioid use disorder for fiscal years 2019 to 2023. This bill improves the continuum of care by removing a barrier to care under current law, so Medicaid would pay for up to 30 total days of care in an IMD during a 12-month period and eligible individuals can get the care they need.

BACKGROUND AND NEED FOR LEGISLATION

Deaths due to overdoses of opioids and other drugs have ravaged American communities. According to the Centers for Disease Control and Prevention (CDC), on average, 1,000 people are treated for opioid misuse in emergency departments per day, an average of 115 Americans die per day, and opioid-related overdoses have increased steadily since 1999.[1]

While the impacts to Americans' health outcomes are staggering, the opioid crisis has negatively impacted society in numerous ways. The Centers for Disease Control and Prevention note that life expectancy dropped in 2015 and 2106 and that one of the reasons was an increase in unintentional injuries, a category that includes drug overdoses.[2] The opioid crisis has also resulted in a contraction in the labor force by almost 1 million workers in the years between 1999 and 2015, which resulted in a loss of $702 billion in real out-

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[1] Centers for Disease Control and Prevention. "Drug Overdose Death Data." December 19, 2017. Available at https://www.cdc.gov/drugoverdose/data/statedeaths.html.

[2] Dowell, D., Arias E., Kochanek K. et al. "Contribution of Opioid-Involved Poisoning to the Change in Life Expectancy in the United States, 2000–2015." JAMA, September 2017. Available at https://jamanetwork.com/journals/jama/fullarticle/2654372

put.[3] In 2015, the total economic burden of the opioid epidemic was estimated to be $504 billion.[4] While all states were negatively impacted, there is geographic variation in the burden. West Virginia had the greatest loss per person ($4,378) and Nebraska had the lowest loss per person ($394).[4] One recent analysis found that the annual cost for private sector employers for treating opioid addiction and overdoses has increased more than eight-fold since 2004, and more than one in five persons aged 55 to 64 had at least one opioid prescription in 2016.[5]

Medicaid is the largest source of federal funding for behavioral health services—mental health and substance use disorder services—with nearly $71 billion in projected 2017 spending.[6] As the Medicaid and CHIP Payment and Access Commission (MACPAC) stated in 2017, "the opioid epidemic, which has reached most communities across the U.S., disproportionately affects Medicaid beneficiaries." [7] Medicaid provides care to 4 in 10 adults with opioid use disorder and compared to other insurance types, provides a significantly higher percentage of inpatient and outpatient substance use disorder treatment.[8]

MACPAC found that "Medicaid beneficiaries are prescribed pain relievers at higher rates than those with other sources of insurance. They also have a higher risk of overdose and other negative outcomes, from both prescription opioids and illegal opioids such as heroin and illicitly manufactured fentanyl." [9] Not only are the number of Medicaid beneficiaries with opioid misuse disproportionately high, so too are the number of overdoses. Studies from North Carolina and Washington indicate high rates of opioid-related deaths for the Medicaid population (33 percent and 45 percent, respectively).

For treatment, Medicaid has several pharmacy and medical benefits for treating opioid use disorders that vary by state. A primary pharmaceutical treatment offered to patients with opioid abuse and/or substance use disorder is medication-assisted treatment (MAT). The Substance Abuse and Mental Health Services Administration (SAMHSA) describes MAT as "the use of FDA-approved medications, in combination with counseling and behavioral thera-

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[3] American Action Forum. "The Labor Force and Output Consequences of the Opioid Crisis." March 27, 2018. Available at https://www.americanactionforum.org/research/labor-force-output-consequences-opioid-crisis/

[4] American Enterprise Institute. "The Geographic Variation in the Cost of the Opioid Crisis". Available at https://www.aei.org/wp-content/uploads/2018/03/Geographic—Variation—in—Cost—of—Opioid—Crisis.pdf

[5] Kaiser Family Foundation, "A Look at How the Opioid Crisis Has Affected People with Employer Coverage," April 2018. Available online at: https://www.kff.org/health-costs/press-release/analysis-cost-of-treating-opioid-addiction-rose-rapidly-for-large-employers-as-the-number-of-prescriptions-has-declined/

[6] Government Accountability Office, "Medicaid: States Fund Services for Adults in Institutions for Mental Disease Using a Variety of Strategies," GAO–17–652, August 2017. Available at https://www.gao.gov/assets/690/686456.pdf

[7] Medicaid and CHIP Payment and Access Commission, "Medicaid and the Opioid Epidemic," Chapter 2 in June *2017 Report to Congress on Medicaid and CHIP*. Available at: https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf

[8] Kaiser Family Foundation. "Medicaid's Role in Addressing the Opioid Epidemic." Available at https://www.kff.org/infographic/medicaids-role-in-addressing-opioid-epidemic/

[9] Medicaid and CHIP Payment and Access Commission, "Medicaid and the Opioid Epidemic," Chapter 2 in June *2017 Report to Congress on Medicaid and CHIP*. Available at: https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf

[10] See SAMHSA website. Available at: https://www.samhsa.gov/medication-assisted-treatment

[11] Medicaid and CHIP Payment and Access Commission, "Medicaid and the Opioid Epidemic," Chapter 2 in June *2017 Report to Congress on Medicaid and CHIP*. Available at: https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf.

pies, to provide a 'whole-patient' approach to the treatment of substance use disorders."[10]

Non-pharmaceutical treatment of opioid use disorder in Medicaid occurs in inpatient, outpatient, residential, and community-based settings. MACPAC's 2017 analysis found that "Medicaid is responding to the opioid crisis by covering treatment, innovating in the delivery of care, and working with other state agencies to reduce misuse of prescription opioids."[11] State Medicaid programs adopt strategies and design their programs to meet the needs of their Medicaid beneficiaries resulting in variations in covered treatment services and settings. It is important state Medicaid programs provide a continuum of care to serve the needs of Medicaid beneficiaries.

However, as MACPAC noted, "there are gaps in the continuum of care, and states vary in the extent to which they cover needed treatment."[12] One of the barriers to appropriate treatment consistently identified by Medicaid directors and health policy experts is a prohibition on federal Medicaid matching funds for paying for care for certain Medicaid beneficiaries in Institutions for Mental Diseases (IMD). As MACPAC has explained, "the Medicaid IMD exclusion acts a barrier for individuals with an opioid use disorder to receive residential treatment, which, depending on an individual's treatment plan, may be the most appropriate setting for care."[13] Given these and other findings, there continues to be an opportunity for Congress and state Medicaid programs to work to improve access to timely, high-quality treatment across the continuum of care. The Medicaid IMD exclusion does not allow individuals with an opioid use disorder to receive residential treatment, which, depending on an individual's treatment plan, may be the most appropriate setting for care. This includes patients in residential substance use disorder treatment facilities.[14]

Under the Medicaid statute, federal funding cannot be used to finance care for Medicaid beneficiaries aged 21 to 64 receiving mental or substance use disorder care in a residential facility that has more than 16 beds.[15] When a Medicaid-eligible individual is a patient in an IMD, he or she cannot receive Medicaid coverage for services provided inside or outside the IMD. The Medicaid IMD exclusion is one of the few instances in the Medicaid program where federal financial participation cannot be used for medically nec-

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[10] See SAMHSA website. Available at: https://www.samhsa.gov/medication-assisted-treatment

[11] Medicaid and CHIP Payment and Access Commission, "Medicaid and the Opioid Epidemic," Chapter 2 in June *2017 Report to Congress on Medicaid and CHIP*. Available at: https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf.

[12] Medicaid and CHIP Payment and Access Commission, "Medicaid and the Opioid Epidemic," Chapter 2 in June *2017 Report to Congress on Medicaid and CHIP*. Available at: https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf.

[13] Medicaid and CHIP Payment and Access Commission, "Medicaid and the Opioid Epidemic," Chapter 2 in June *2017 Report to Congress on Medicaid and CHIP*. Available at: https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf.

[14] Centers for Medicare & Medicaid Services (CMS), U.S. Department of Health and Human Services. 2015a. Letter to state Medicaid directors from Vikki Wachino regarding "New service delivery opportunities for individuals with a substance use disorder." July 27, 2015. https://www.medicaid.gov/federal-policy-guidance/downloads/ SMD15003.pdf.

[15] Social Security Act 1905(a)(B).

essary and otherwise covered services for a specific Medicaid enrollee population receiving treatment in a specific setting.[16]

The Centers for Medicare and Medicaid Services' (CMS) has allowed for some administrative flexibility to this prohibition, issuing regulatory guidance in 2016 that would allow for IMD payment for up to fifteen days in any given month. Additionally, in 2015 CMS authorized a new Section 1115 Demonstration Project pathway for SUD, allowing states to receive FFP for IMD stays so long as certain other criteria are met and as part of a full continuum of care. However, these 1115 waivers take significant time to approve as well as state resources.

COMMITTEE ACTION

On April 11, 2018, the Subcommittee on Health held a hearing on the discussion draft entitled "Limited repeal of the IMD Exclusion for adult Medicaid beneficiaries with substance use disorder." 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, Chief Executive Officer, Centerstone;
- John Kravitz, Chief Information Officer, Geisinger Health System; and,
- Sam Srivastava, Chief Executive Officer, Magellan Health.

On April 25, 2018, the Subcommittee on Health met in open markup session and forwarded the discussion draft, without amendment, to the full Committee by a record vote of 16 yeas and 10 nays. On May 17, 2018, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 5797, as amended, favorably reported to the House by a voice vote.

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. There were no record votes taken in connection with ordering H.R. 5797 reported.

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.

[16] Medicaid and CHIP Payment and Access Commission, "Medicaid and the Opioid Epidemic," Chapter 2 in June *2017 Report to Congress on Medicaid and CHIP*. Available at: https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R. 5797 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	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

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	2019–2028
Legislation Primarily Affecting the Food and Drug Administration:													
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 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 federal 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 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 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 demonstration 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 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 the 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
Net changes in fees:							
Estimated Authorization Level	0	0	0	0	0	0	0
Estimated Outlays	0	−10	−3	*	*	*	−14

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
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 periodd, 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 allow state Medicaid programs to remove the Institutions for Mental Diseases exclusion for Medicaid beneficiaries aged 21–64 with an opioid use disorder.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 5797 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. 5797 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. 5797 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 "Individuals in Medicaid Deserve Care that is Appropriate and Responsible in its Delivery Act" or the "IMD CARE Act."

Section 2. Medicaid state plan option to provide services for certain individuals with opioid use disorders in institutions for mental diseases

Section 2 amends section 1915 of the Social Security Act to allow state Medicaid programs for fiscal years 2019 through 2023 to remove the IMD exclusion for Medicaid beneficiaries aged 21 to 64 with an opioid use disorder through a state plan amendment. Opioid use disorder is defined using the Diagnostic and Statistical Manual of Mental Disorders 4th edition definition and includes heroin, fentanyl, oxycodone, tramadol, oxycodone, etc. Medicaid could pay for up to 30 total days of care in an IMD during a 12-month period year.

Section 2 requires states to include in their state plan amendment information on (1) how the state will improve access to outpatient care during the state plan amendment period, (2) the process for transitioning individuals to appropriate outpatient care, (3) a description of how individuals will receive appropriate screening and assessment. Finally, section 2 requires that within one year, states shall report on: (1) number of individuals with opioid use disorder under this plan, (2) length of stay, and (3) type of treatment received upon discharge.

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

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TITLE XIX—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

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PROVISIONS RESPECTING INAPPLICABILITY AND WAIVER OF CERTAIN REQUIREMENTS OF THIS TITLE

SEC. 1915. (a) A State shall not be deemed to be out of compliance with the requirements of paragraphs (1), (10), or (23) of section 1902(a) solely by reason of the fact that the State (or any political subdivision thereof)—

(1) has entered into—

(A) a contract with an organization which has agreed to provide care and services in addition to those offered under the State plan to individuals eligible for medical assistance who reside in the geographic area served by such organization and who elect to obtain such care and services from such organization, or by reason of the fact that the plan provides for payment for rural health clinic services only if those services are provided by a rural health clinic; or

(B) arrangements through a competitive bidding process or otherwise for the purchase of laboratory services referred to in section 1905(a)(3) or medical devices if the Secretary has found that—

(i) adequate services or devices will be available under such arrangements, and

(ii) any such laboratory services will be provided only through laboratories—

(I) which meet the applicable requirements of section 1861(e)(9) or paragraphs (16) and (17) of section 1861(s), and such additional requirements as the Secretary may require, and

(II) no more than 75 percent of whose charges for such services are for services provided to individuals who are entitled to benefits under this title or under part A or part B of title XVIII; or

(2) restricts for a reasonable period of time the provider or providers from which an individual (eligible for medical assistance for items or services under the State plan) can receive such items or services, if—

(A) the State has found, after notice and opportunity for a hearing (in accordance with procedures established by the State), that the individual has utilized such items or services at a frequency or amount not medically necessary (as determined in accordance with utilization guidelines established by the State), and

(B) under such restriction, individuals eligible for medical assistance for such services have reasonable access (taking into account geographic location and reasonable travel time) to such services of adequate quality.

(b) The Secretary, to the extent he finds it to be cost-effective and efficient and not inconsistent with the purposes of this title, may waive such requirements of section 1902 (other than subsection (s)) (other than sections 1902(a)(15), 1902(bb), and 1902(a)(10)(A) insofar as it requires provision of the care and services described in section 1905(a)(2)(C)) as may be necessary for a State—

(1) to implement a primary care case-management system or a specialty physician services arrangement which restricts the provider from (or through) whom an individual (eligible for medical assistance under this title) can obtain medical care services (other than in emergency circumstances), if such restriction does not substantially impair access to such services of adequate quality where medically necessary,

(2) to allow a locality to act as a central broker in assisting individuals (eligible for medical assistance under this title) in selecting among competing health care plans, if such restriction does not substantially impair access to services of adequate quality where medically necessary,

(3) to share (through provision of additional services) with recipients of medical assistance under the State plan cost savings resulting from use by the recipient of more cost-effective medical care, and

(4) to restrict the provider from (or through) whom an individual (eligible for medical assistance under this title) can obtain services (other than in emergency circumstances) to providers or practitioners who undertake to provide such services and who meet, accept, and comply with the reimbursement, quality, and utilization standards under the State plan, which standards shall be consistent with the requirements of section 1923 and are consistent with access, quality, and efficient and economic provision of covered care and services, if such restriction does not discriminate among classes of providers on grounds unrelated to their demonstrated effectiveness and efficiency in providing those services and if providers under such restriction are paid on a timely basis in the same manner as health care practitioners must be paid under section 1902(a)(37)(A).

No waiver under this subsection may restrict the choice of the individual in receiving services under section 1905(a)(4)(C). Subsection (h)(2) shall apply to a waiver under this subsection.

(c)(1) The Secretary may by waiver provide that a State plan approved under this title may include as "medical assistance" under such plan payment for part or all of the cost of home or community-based services (other than room and board) approved by the Secretary which are provided pursuant to a written plan of care to individuals with respect to whom there has been a determination that but for the provision of such services the individuals would require the level of care provided in a hospital or a nursing facility or intermediate care facility for the mentally retarded the cost of which could be reimbursed under the State plan. For purposes of this subsection, the term "room and board" shall not include an amount established under a method determined by the State to reflect the portion of costs of rent and food attributable to an unrelated personal caregiver who is residing in the same household with an individual who, but for the assistance of such caregiver, would require admission to a hospital, nursing facility, or intermediate care facility for the mentally retarded.

(2) A waiver shall not be granted under this subsection unless the State provides assurances satisfactory to the Secretary that—

(A) necessary safeguards (including adequate standards for provider participation) have been taken to protect the health and welfare of individuals provided services under the waiver and to assure financial accountability for funds expended with respect to such services;

(B) the State will provide, with respect to individuals who—

(i) are entitled to medical assistance for inpatient hospital services, nursing facility services, or services in an intermediate care facility for the mentally retarded under the State plan,

(ii) may require such services, and

(iii) may be eligible for such home or community-based care under such waiver,

for an evaluation of the need for inpatient hospital services, nursing facility services, or services in an intermediate care facility for the mentally retarded;

(C) such individuals who are determined to be likely to require the level of care provided in a hospital, nursing facility, or intermediate care facility for the mentally retarded are informed of the feasible alternatives, if available under the waiver, at the choice of such individuals, to the provision of inpatient hospital services, nursing facility services, or services in an intermediate care facility for the mentally retarded;

(D) under such waiver the average per capita expenditure estimated by the State in any fiscal year for medical assistance provided with respect to such individuals does not exceed 100 percent of the average per capita expenditure that the State reasonably estimates would have been made in that fiscal year for expenditures under the State plan for such individuals if the waiver had not been granted; and

(E) the State will provide to the Secretary annually, consistent with a data collection plan designed by the Secretary, information on the impact of the waiver granted under this subsection on the type and amount of medical assistance provided under the State plan and on the health and welfare of recipients.

(3) A waiver granted under this subsection may include a waiver of the requirements of section 1902(a)(1) (relating to statewideness), section 1902(a)(10)(B) (relating to comparability), and section 1902(a)(10)(C)(i)(III) (relating to income and resource rules applicable in the community). A waiver under this subsection (other than a waiver described in subsection (h)(2)) shall be for an initial term of three years and, upon the request of a State, shall be extended for additional five-year periods unless the Secretary determines that for the previous waiver period the assurances provided under paragraph (2) have not been met. A waiver may provide, with respect to post-eligibility treatment of income of all individuals receiving services under that waiver, that the maximum amount of the individual's income which may be disregarded for

any month for the maintenance needs of the individual may be an amount greater than the maximum allowed for that purpose under regulations in effect on July 1, 1985.

(4) A waiver granted under this subsection may, consistent with paragraph (2)—

(A) limit the individuals provided benefits under such waiver to individuals with respect to whom the State has determined that there is a reasonable expectation that the amount of medical assistance provided with respect to the individual under such waiver will not exceed the amount of such medical assistance provided for such individual if the waiver did not apply, and

(B) provide medical assistance to individuals (to the extent consistent with written plans of care, which are subject to the approval of the State) for case management services, homemaker/home health aide services and personal care services, adult day health services, habilitation services, respite care, and such other services requested by the State as the Secretary may approve and for day treatment or other partial hospitalization services, psychosocial rehabilitation services, and clinic services (whether or not furnished in a facility) for individuals with chronic mental illness.

Except as provided under paragraph (2)(D), the Secretary may not restrict the number of hours or days of respite care in any period which a State may provide under a waiver under this subsection.

(5) For purposes of paragraph (4)(B), the term "habilitation services"—

(A) means services designed to assist individuals in acquiring, retaining, and improving the self-help, socialization, and adaptive skills necessary to reside successfully in home and community based settings; and

(B) includes (except as provided in subparagraph (C)) prevocational, educational, and supported employment services; but

(C) does not include—

(i) special education and related services (as such terms are defined in section 602 of the Individuals with Disabilities Education Act (20 U.S.C. 1401)) which otherwise are available to the individual through a local educational agency; and

(ii) vocational rehabilitation services which otherwise are available to the individual through a program funded under section 110 of the Rehabilitation Act of 1973 (29 U.S.C. 730).

(6) The Secretary may not require, as a condition of approval of a waiver under this section under paragraph (2)(D), that the actual total expenditures for home and community-based services under the waiver (and a claim for Federal financial participation in expenditures for the services) cannot exceed the approved estimates for these services. The Secretary may not deny Federal financial payment with respect to services under such a waiver on the ground that, in order to comply with paragraph (2)(D), a State has failed to comply with such a requirement.

(7)(A) In making estimates under paragraph (2)(D) in the case of a waiver that applies only to individuals with a particular illness or condition who are inpatients in, or who would require the level of care provided in, hospitals, nursing facilities, or intermediate care facilities for the mentally retarded, the State may determine the average per capita expenditure that would have been made in a fiscal year for those individuals under the State plan separately from the expenditures for other individuals who are inpatients in, or who would require the level of care provided in, those respective facilities.

(B) In making estimates under paragraph (2)(D) in the case of a waiver that applies only to individuals with developmental disabilities who are inpatients in a nursing facility and whom the State has determined, on the basis of an evaluation under paragraph (2)(B), to need the level of services provided by an intermediate care facility for the mentally retarded, the State may determine the average per capita expenditures that would have been made in a fiscal year for those individuals under the State plan on the basis of the average per capita expenditures under the State plan for services to individuals who are inpatients in an intermediate care facility for the mentally retarded, without regard to the availability of beds for such inpatients.

(C) In making estimates under paragraph (2)(D) in the case of a waiver to the extent that it applies to individuals with mental retardation or a related condition who are resident in an intermediate care facility for the mentally retarded the participation of which under the State plan is terminated, the State may determine the average per capita expenditures that would have been made in a fiscal year for those individuals without regard to any such termination.

(8) The State agency administering the plan under this title may, whenever appropriate, enter into cooperative arrangements with the State agency responsible for administering the program for children with special health care needs under title V in order to assure improved access to coordinated services to meet the needs of such children.

(9) In the case of any waiver under this subsection which contains a limit on the number of individuals who shall receive home or community-based services, the State may substitute additional individuals to receive such services to replace any individuals who die or become ineligible for services under the State plan.

(10) The Secretary shall not limit to fewer than 200 the number of individuals in the State who may receive home and community-based services under a waiver under this subsection.

(d)(1) Subject to paragraph (2), the Secretary shall grant a waiver to provide that a State plan approved under this title shall include as "medical assistance" under such plan payment for part or all of the cost of home or community-based services (other than room and board) which are provided pursuant to a written plan of care to individuals 65 years of age or older with respect to whom there has been a determination that but for the provision of such services the individuals would be likely to require the level of care provided in a skilled nursing facility or intermediate care facility the cost of which could be reimbursed under the State plan. For purposes of this subsection, the term "room and board" shall not include an amount established under a method determined by the State to reflect the portion of costs of rent and food attributable to an unrelated personal caregiver who is residing in the same household with an individual who, but for the assistance of such caregiver, would require admission to a hospital, nursing facility, or intermediate care facility for the mentally retarded.

(2) A waiver shall not be granted under this subsection unless the State provides assurances satisfactory to the Secretary that—

(A) necessary safeguards (including adequate standards for provider participation) have been taken to protect the health and welfare of individuals provided services under the waiver and to assure financial accountability for funds expended with respect to such services;

(B) with respect to individuals 65 years of age or older who—

(i) are entitled to medical assistance for skilled nursing or intermediate care facility services under the State plan,

(ii) may require such services, and

(iii) may be eligible for such home or community-based services under such waiver,

the State will provide for an evaluation of the need for such skilled nursing facility or intermediate care facility services; and

(C) such individuals who are determined to be likely to require the level of care provided in a skilled nursing facility or intermediate care facility are informed of the feasible alternatives to the provision of skilled nursing facility or intermediate care facility services, which such individuals may choose if available under the waiver.

Each State with a waiver under this subsection shall provide to the Secretary annually, consistent with a reasonable data collection plan designed by the Secretary, information on the impact of the waiver granted under this subsection on the type and amount of medical assistance provided under the State plan and on the health and welfare of recipients.

(3) A waiver granted under this subsection may include a waiver of the requirements of section 1902(a)(1) (relating to statewideness), section 1902(a)(10)(B) (relating to comparability), and section 1902(a)(10)(C)(i)(III) (relating to income and resource rules applicable in the community). Subject to a termination by the State (with notice to the Secretary) at any time, a waiver under this subsection (other than a waiver described in subsection (h)(2)) shall be for an initial term of 3 years and, upon the request of a State, shall be extended for additional 5-year periods unless the Secretary determines that for the previous waiver period the assurances provided under paragraph (2) have not been met. A waiver may provide, with respect to post-eligibility treatment of income of all individuals receiving services under the waiver, that the maximum amount of the individual's income which may be disregarded for any month is equal to the amount that may be allowed for that purpose under a waiver under subsection (c).

(4) A waiver under this subsection may, consistent with paragraph (2), provide medical assistance to individuals for case management services, homemaker/home health aide services and personal care services, adult day health services, respite care, and other medical and social services that can contribute to the health and well-being of individuals and their ability to reside in a community-based care setting.

(5)(A) In the case of a State having a waiver approved under this subsection, notwithstanding any other provision of section 1903 to the contrary, the total amount expended by the State for medical assistance with respect to skilled nursing facility services, intermediate care facility services, and home and community-based services under the State plan for individuals 65 years of age or older during a waiver year under this subsection may not exceed the projected amount determined under subparagraph (B).

(B) For purposes of subparagraph (A), the projected amount under this subparagraph is the sum of the following:

(i) The aggregate amount of the State's medical assistance under this title for skilled nursing facility services and intermediate care facility services furnished to individuals who have attained the age of 65 for the base year increased by a percentage which is equal to the lesser of 7 percent times the number of years (rounded to the nearest quarter of a year) beginning after the base year and ending at the end of the waiver year involved or the sum of—

(I) the percentage increase (based on an appropriate market-basket index representing the costs of elements of such services) between the beginning of the base year and the beginning of the waiver year involved, plus

(II) the percentage increase between the beginning of the base year and the beginning of the waiver year involved in the number of residents in the State who have attained the age of 65, plus

(III) 2 percent for each year (rounded to the nearest quarter of a year) beginning after the base year and ending at the end of the waiver year.

(ii) The aggregate amount of the State's medical assistance under this title for home and community-based services for individuals who have attained the age of 65 for the base year increased by a percentage which is equal to the lesser of 7 percent times the number of years (rounded to the nearest quarter of a year) beginning after the base year and ending at the end of the waiver year involved or the sum of—

(I) the percentage increase (based on an appropriate market-basket index representing the costs of elements of such services) between the beginning of the base year and the beginning of the waiver year involved, plus

(II) the percentage increase between the beginning of the base year and the beginning of the waiver year involved in the number of residents in the State who have attained the age of 65, plus

(III) 2 percent for each year (rounded to the nearest quarter of a year) beginning after the base year and ending at the end of the waiver year.

(iii) The Secretary shall develop and promulgate by regulation (by not later than October 1, 1989)—

(I) a method, based on an index of appropriately weighted indicators of changes in the wages and prices of the mix of goods and services which comprise both skilled nursing facility services and intermediate care facility services (regardless of the source of payment for such services), for projecting the percentage increase for purposes of clause (i)(I);

(II) a method, based on an index of appropriately weighted indicators of changes in the wages and prices of the mix of goods and services which comprise home and community-based services (regardless of the source of payment for such services), for projecting the percentage increase for purposes of clause (ii)(I); and

(III) a method for projecting, on a State specific basis, the percentage increase in the number of residents in each State who are over 65 years of age for any period.

The Secretary shall develop (by not later than October 1, 1989) a method for projecting, on a State-specific basis, the percentage increase in the number of residents in each State who are over 65 years of age for any period. Effective on and after the date the Secretary promulgates the regulation under clause (iii), any reference in this subparagraph to the "lesser of 7 percent" shall be deemed to be a reference to the "greater of 7 percent".

(iv) If there is enacted after December 22, 1987, an Act which amends this title whose provisions become effective on or after such date and which results in an increase in the aggregate amount of medical assistance under this title for nursing facility services and home and community-based services for individuals who have attained the age of 65 years, the Secretary, at the request of a State with a waiver under this subsection for a waiver year or years and in close consultation with the State, shall adjust the projected amount computed under this subparagraph for the waiver year or years to take into account such increase.

(C) In this paragraph:

(i) The term "home and community-based services" includes services described in sections 1905(a)(7) and 1905(a)(8), services described in subsection (c)(4)(B), services described in paragraph (4), and personal care services.

(ii)(I) Subject to subclause (II), the term "base year" means the most recent year (ending before the date of the enactment of this subsection) for which actual final expenditures under this title have been reported to, and accepted by, the Secretary.

(II) For purposes of subparagraph (C), in the case of a State that does not report expenditures on the basis of the age categories described in such subparagraph for a year ending before the date of the enactment of this subsection, the term "base year" means fiscal year 1989.

(iii) The term "intermediate care facility services" does not include services furnished in an institution certified in accordance with section 1905(d).

(6)(A) A determination by the Secretary to deny a request for a waiver (or extension of waiver) under this subsection shall be subject to review to the extent provided under section 1116(b).

(B) Notwithstanding any other provision of this Act, if the Secretary denies a request of the State for an extension of a waiver under this subsection, any waiver under this subsection in effect on the date such request is made shall remain in effect for a period of not less than 90 days after the date on which the Secretary denies such request (or, if the State seeks review of such determination in accordance with subparagraph (A), the date on which a final determination is made with respect to such review).

(e)(1)(A) Subject to paragraph (2), the Secretary shall grant a waiver to provide that a State plan approved under this title shall include as "medical assistance" under such plan payment for part or all of the cost of nursing care, respite care, physicians' services, prescribed drugs, medical devices and supplies, transportation services, and such other services requested by the State as the Secretary may approve which are provided pursuant to a written plan of care to a child described in subparagraph (B) with respect to whom there has been a determination that but for the provision of such services the infants would be likely to require the level of care provided in a hospital or nursing facility the cost of which could be reimbursed under the State plan.

(B) Children described in this subparagraph are individuals under 5 years of age who—

(i) at the time of birth were infected with (or tested positively for) the etiologic agent for acquired immune deficiency syndrome (AIDS),

(ii) have such syndrome, or

(iii) at the time of birth were dependent on heroin, cocaine, or phencyclidine,

and with respect to whom adoption or foster care assistance is (or will be) made available under part E of title IV.

(2) A waiver shall not be granted under this subsection unless the State provides assurances satisfactory to the Secretary that—

(A) necessary safeguards (including adequate standards for provider participation) have been taken to protect the health and welfare of individuals provided services under the waiver and to assure financial accountability for funds expended with respect to such services;

(B) under such waiver the average per capita expenditure estimated by the State in any fiscal year for medical assistance provided with respect to such individuals does not exceed 100 percent of the average per capita expenditure that the State reasonably estimates would have been made in that fiscal year for expenditures under the State plan for such individuals if the waiver had not been granted; and

(C) the State will provide to the Secretary annually, consistent with a data collection plan designed by the Secretary, information on the impact of the waiver granted under this subsection on the type and amount of medical assistance provided under the State plan and on the health and welfare of recipients.

(3) A waiver granted under this subsection may include a waiver of the requirements of section 1902(a)(1) (relating to statewideness) and section 1902(a)(10)(B) (relating to comparability). A waiver under this subsection shall be for an initial term of 3 years and, upon the request of a State, shall be extended for additional five-year periods unless the Secretary determines that for the previous waiver period the assurances provided under paragraph (2) have not been met.

(4) The provisions of paragraph (6) of subsection (d) shall apply to this subsection in the same manner as it applies to subsection (d).

(f)(1) The Secretary shall monitor the implementation of waivers granted under this section to assure that the requirements for such waiver are being met and shall, after notice and opportunity for a hearing, terminate any such waiver where he finds noncompliance has occurred.

(2) A request to the Secretary from a State for approval of a proposed State plan or plan amendment or a waiver of a requirement of this title submitted by the State pursuant to a provision of this title shall be deemed granted unless the Secretary, within 90 days after the date of its submission to the Secretary, either denies such request in writing or informs the State agency in writing with respect to any additional information which is needed in order to make a final determination with respect to the request. After the date the Secretary receives such additional information, the request shall be deemed granted unless the Secretary, within 90 days of such date, denies such request.

(g)(1) A State may provide, as medical assistance, case management services under the plan without regard to the requirements of section 1902(a)(1) and section 1902(a)(10)(B). The provision of case management services under this subsection shall not restrict the choice of the individual to receive medical assistance in violation of section 1902(a)(23). A State may limit the provision of case management services under this subsection to individuals with acquired immune deficiency syndrome (AIDS), or with AIDS-related conditions, or with either, or to individuals described in section 1902(z)(1)(A) and a State may limit the provision of case management services under this subsection to individuals with chronic mental illness. The State may limit the case managers available with respect to case management services for eligible individuals with developmental disabilities or with chronic mental illness in order to ensure that the case managers for such individuals are capable of ensuring that such individuals receive needed services.

(2) For purposes of this subsection:

(A)(i) The term "case management services" means services which will assist individuals eligible under the plan in gaining access to needed medical, social, educational, and other services.

(ii) Such term includes the following:

(I) Assessment of an eligible individual to determine service needs, including activities that focus on needs identification, to determine the need for any medical, educational, social, or other services. Such assessment activities include the following:

(aa) Taking client history.

(bb) Identifying the needs of the individual, and completing related documentation.

(cc) Gathering information from other sources such as family members, medical providers, social workers, and educators, if necessary, to form a complete assessment of the eligible individual.

(II) Development of a specific care plan based on the information collected through an assessment, that specifies the goals and actions to address the medical, social, educational, and other services needed by the eligible individual, including activities such as ensuring the active participation of the eligible individual and working with the individual (or the individual's authorized health care decision maker) and others to develop such goals and identify a course of action to respond to the assessed needs of the eligible individual.

(III) Referral and related activities to help an individual obtain needed services, including activities that help link eligible individuals with medical, social, educational providers or other programs and services that are capable of providing needed services, such as making referrals to providers for needed services and scheduling appointments for the individual.

(IV) Monitoring and followup activities, including activities and contacts that are necessary to ensure the care plan is effectively implemented and adequately addressing the needs of the eligible individual, and which may be with the individual, family members, providers, or other entities and conducted as frequently as necessary to help determine such matters as—

(aa) whether services are being furnished in accordance with an individual's care plan;

(bb) whether the services in the care plan are adequate; and

(cc) whether there are changes in the needs or status of the eligible individual, and if so, making necessary adjustments in the care plan and service arrangements with providers.

(iii) Such term does not include the direct delivery of an underlying medical, educational, social, or other service to which an eligible individual has been referred, including, with respect to the direct delivery of foster care services, services such as (but not limited to) the following:

(I) Research gathering and completion of documentation required by the foster care program.

(II) Assessing adoption placements.

(III) Recruiting or interviewing potential foster care parents.

(IV) Serving legal papers.

(V) Home investigations.

(VI) Providing transportation.

(VII) Administering foster care subsidies.

(VIII) Making placement arrangements.

(B) The term "targeted case management services" are case management services that are furnished without regard to the requirements of section 1902(a)(1) and section 1902(a)(10)(B) to specific classes of individuals or to individuals who reside in specified areas.

(3) With respect to contacts with individuals who are not eligible for medical assistance under the State plan or, in the case of targeted case management services, individuals who are eligible for such assistance but are not part of the target population specified in the State plan, such contacts—

(A) are considered an allowable case management activity, when the purpose of the contact is directly related to the management of the eligible individual's care; and

(B) are not considered an allowable case management activity if such contacts relate directly to the identification and management of the noneligible or nontargeted individual's needs and care.

(4)(A) In accordance with section 1902(a)(25), Federal financial participation only is available under this title for case management services or targeted case management services if there are no other third parties liable to pay for such services, including as reimbursement under a medical, social, educational, or other program.

(B) A State shall allocate the costs of any part of such services which are reimbursable under another federally funded program in accordance with OMB Circular A–87 (or any related or successor guidance or regulations regarding allocation of costs among federally funded programs) under an approved cost allocation program.

(5) Nothing in this subsection shall be construed as affecting the application of rules with respect to third party liability under programs, or activities carried out under title XXVI of the Public Health Service Act or by the Indian Health Service.

(h)(1) No waiver under this section (other than a waiver under subsection (c), (d), or (e), or a waiver described in paragraph (2)) may extend over a period of longer than two years unless the State requests continuation of such waiver, and such request shall be deemed granted unless the Secretary, within 90 days after the date of its submission to the Secretary, either denies such request in writing or informs the State agency in writing with respect to any additional information which is needed in order to make a final determination with respect to the request. After the date the Secretary receives such additional information, the request shall be deemed granted unless the Secretary, within 90 days of such date, denies such request.

(2)(A) Notwithstanding subsections (c)(3) and (d) (3), any waiver under subsection (b), (c), or (d), or a waiver under section 1115, that provides medical assistance for dual eligible individuals (including any such waivers under which non dual eligible individuals may be enrolled in addition to dual eligible individuals) may be conducted for a period of 5 years and, upon the request of the State, may be extended for additional 5-year periods unless the Secretary determines that for the previous waiver period the conditions for the waiver have not been met or it would no longer be cost-effective and efficient, or consistent with the purposes of this title, to extend the waiver.

(B) In this paragraph, the term "dual eligible individual" means an individual who is entitled to, or enrolled for, benefits under part A of title XVIII, or enrolled for benefits under part B of title XVIII, and is eligible for medical assistance under the State plan under this title or under a waiver of such plan.

(i) STATE PLAN AMENDMENT OPTION TO PROVIDE HOME AND COMMUNITY-BASED SERVICES FOR ELDERLY AND DISABLED INDIVIDUALS.—

(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, a State may provide through a State plan amendment for the provision of medical assistance for home and community-based services (within the scope of services described in paragraph (4)(B) of subsection (c) for which the Secretary has the authority to approve a waiver and not including room and board) for individuals eligible for medical assistance under the State plan whose income does not exceed 150 percent of the

poverty line (as defined in section 2110(c)(5)), without determining that but for the provision of such services the individuals would require the level of care provided in a hospital or a nursing facility or intermediate care facility for the mentally retarded, but only if the State meets the following requirements:

(A) NEEDS-BASED CRITERIA FOR ELIGIBILITY FOR, AND RECEIPT OF, HOME AND COMMUNITY-BASED SERVICES.—The State establishes needs-based criteria for determining an individual's eligibility under the State plan for medical assistance for such home and community-based services, and if the individual is eligible for such services, the specific home and community-based services that the individual will receive.

(B) ESTABLISHMENT OF MORE STRINGENT NEEDS-BASED ELIGIBILITY CRITERIA FOR INSTITUTIONALIZED CARE.—The State establishes needs-based criteria for determining whether an individual requires the level of care provided in a hospital, a nursing facility, or an intermediate care facility for the mentally retarded under the State plan or under any waiver of such plan that are more stringent than the needs-based criteria established under subparagraph (A) for determining eligibility for home and community-based services.

(C) PROJECTION OF NUMBER OF INDIVIDUALS TO BE PROVIDED HOME AND COMMUNITY-BASED SERVICES.—The State submits to the Secretary, in such form and manner, and upon such frequency as the Secretary shall specify, the projected number of individuals to be provided home and community-based services.

(D) CRITERIA BASED ON INDIVIDUAL ASSESSMENT.—

(i) IN GENERAL.—The criteria established by the State for purposes of subparagraphs (A) and (B) requires an assessment of an individual's support needs and capabilities, and may take into account the inability of the individual to perform 2 or more activities of daily living (as defined in section 7702B(c)(2)(B) of the Internal Revenue Code of 1986) or the need for significant assistance to perform such activities, and such other risk factors as the State determines to be appropriate.

(ii) ADJUSTMENT AUTHORITY.—The State plan amendment provides the State with the option to modify the criteria established under subparagraph (A) (without having to obtain prior approval from the Secretary) in the event that the enrollment of individuals eligible for home and community-based services exceeds the projected enrollment submitted for purposes of subparagraph (C), but only if—

(I) the State provides at least 60 days notice to the Secretary and the public of the proposed modification;

(II) the State deems an individual receiving home and community-based services on the basis of the most recent version of the criteria in effect prior to the effective date of the modification to continue to be eligible for such services after the effective date of the modification and until such time as the individual no longer meets the standard for receipt of such services under such premodified criteria; and

(III) after the effective date of such modification, the State, at a minimum, applies the criteria for determining whether an individual requires the level of care provided in a hospital, a nursing facility, or an intermediate care facility for the mentally retarded under the State plan or under any waiver of such plan which applied prior to the application of the more stringent criteria developed under subparagraph (B).

(E) INDEPENDENT EVALUATION AND ASSESSMENT.—

(i) ELIGIBILITY DETERMINATION.—The State uses an independent evaluation for making the determinations described in subparagraphs (A) and (B).

(ii) ASSESSMENT.—In the case of an individual who is determined to be eligible for home and community-based services, the State uses an independent assessment, based on the needs of the individual to—

(I) determine a necessary level of services and supports to be provided, consistent with an individual's physical and mental capacity;

(II) prevent the provision of unnecessary or inappropriate care; and

(III) establish an individualized care plan for the individual in accordance with subparagraph (G).

(F) ASSESSMENT.—The independent assessment required under subparagraph (E)(ii) shall include the following:

(i) An objective evaluation of an individual's inability to perform 2 or more activities of daily living (as defined in section 7702B(c)(2)(B) of the Internal Revenue Code of 1986) or the need for significant assistance to perform such activities.

(ii) A face-to-face evaluation of the individual by an individual trained in the assessment and evaluation of individuals whose physical or mental conditions trigger a potential need for home and community-based services.

(iii) Where appropriate, consultation with the individual's family, spouse, guardian, or other responsible individual.

(iv) Consultation with appropriate treating and consulting health and support professionals caring for the individual.

(v) An examination of the individual's relevant history, medical records, and care and support needs, guided by best practices and research on effective strategies that result in improved health and quality of life outcomes.

(vi) If the State offers individuals the option to self-direct the purchase of, or control the receipt of, home and community-based service, an evaluation of the ability of the individual or the individual's representative to self-direct the purchase of, or control the receipt of, such services if the individual so elects.

(G) INDIVIDUALIZED CARE PLAN.—

(i) IN GENERAL.—In the case of an individual who is determined to be eligible for home and community-based services, the State uses the independent assessment required under subparagraph (E)(ii) to establish a written individualized care plan for the individual.

(ii) PLAN REQUIREMENTS.—The State ensures that the individualized care plan for an individual—

(I) is developed—

(aa) in consultation with the individual, the individual's treating physician, health care or support professional, or other appropriate individuals, as defined by the State, and, where appropriate the individual's family, caregiver, or representative; and

(bb) taking into account the extent of, and need for, any family or other supports for the individual;

(II) identifies the necessary home and community-based services to be furnished to the individual (or, if the individual elects to self-direct the purchase of, or control the receipt of, such services, funded for the individual); and

(III) is reviewed at least annually and as needed when there is a significant change in the individual's circumstances.

(iii) STATE OPTION TO OFFER ELECTION FOR SELF-DIRECTED SERVICES.—

(I) INDIVIDUAL CHOICE.—At the option of the State, the State may allow an individual or the individual's representative to elect to receive self-directed home and community-based services in a manner which gives them the most control over such services consistent with the individual's abilities and the requirements of subclauses (II) and (III).

(II) SELF-DIRECTED SERVICES.—The term "self-directed" means, with respect to the home and community-based services offered under the State plan amendment, such services for the individual which are planned and purchased under the direction and control of such individual or the individual's authorized representative, including the amount, duration, scope, provider, and location of such services, under the State plan consistent with the following requirements:

(aa) ASSESSMENT.—There is an assessment of the needs, capabilities, and preferences of the individual with respect to such services.

(bb) SERVICE PLAN.—Based on such assessment, there is developed jointly with such individual or the individual's authorized representative a plan for such services for such individual that is approved by the State and that satisfies the requirements of subclause (III).

(III) PLAN REQUIREMENTS.—For purposes of subclause (II)(bb), the requirements of this subclause are that the plan—

(aa) specifies those services which the individual or the individual's authorized representative would be responsible for directing;

(bb) identifies the methods by which the individual or the individual's authorized representative will select, manage, and dismiss providers of such services;

(cc) specifies the role of family members and others whose participation is sought by the individual or the individual's authorized representative with respect to such services;

(dd) is developed through a person-centered process that is directed by the individual or the individual's authorized representative, builds upon the individual's capacity to engage in activities that promote community life and that respects the individual's preferences, choices, and abilities, and involves families, friends, and professionals as desired or required by the individual or the individual's authorized representative;

(ee) includes appropriate risk management techniques that recognize the roles and sharing of responsibilities in obtaining services in a self-directed manner and assure the appropriateness of such plan based upon the resources and capabilities of the individual or the individual's authorized representative; and

(ff) may include an individualized budget which identifies the dollar value of the services and supports under the control and direction of the individual or the individual's authorized representative.

(IV) BUDGET PROCESS.—With respect to individualized budgets described in subclause (III)(ff), the State plan amendment—

(aa) describes the method for calculating the dollar values in such budgets based on reliable costs and service utilization;

(bb) defines a process for making adjustments in such dollar values to reflect changes in individual assessments and service plans; and (cc) provides a procedure to evaluate expenditures under such budgets.

(H) QUALITY ASSURANCE; CONFLICT OF INTEREST STANDARDS.—

(i) QUALITY ASSURANCE.—The State ensures that the provision of home and community-based services meets Federal and State guidelines for quality assurance.

(ii) CONFLICT OF INTEREST STANDARDS.—The State establishes standards for the conduct of the independent evaluation and the independent assessment to safeguard against conflicts of interest.

(I) REDETERMINATIONS AND APPEALS.—The State allows for at least annual redeterminations of eligibility, and appeals in accordance with the frequency of, and manner in which, redeterminations and appeals of eligibility are made under the State plan.

(J) PRESUMPTIVE ELIGIBILITY FOR ASSESSMENT.—The State, at its option, elects to provide for a period of presumptive eligibility (not to exceed a period of 60 days) only for those individuals that the State has reason to believe may be eligible for home and community-based services. Such presumptive eligibility shall be limited to medical assistance for carrying out the independent evaluation and assessment under subparagraph (E) to determine an individual's eligibility for such services and if the individual is so eligible, the specific home and community-based services that the individual will receive.

(2) DEFINITION OF INDIVIDUAL'S REPRESENTATIVE.—In this section, the term "individual's representative" means, with respect to an individual, a parent, a family member, or a guardian of the individual, an advocate for the individual, or any other individual who is authorized to represent the individual.

(3) NONAPPLICATION.—A State may elect in the State plan amendment approved under this section to not comply with the requirements of section 1902(a)(10)(B) (relating to comparability) and section 1902(a)(10)(C)(i)(III) (relating to income and resource rules applicable in the community), but only for purposes of provided home and community-based services in accordance with such amendment. Any such election shall not be construed to apply to the provision of services to an individual receiving medical assistance in an institutionalized setting as a result of a determination that the individual requires the level of care provided in a hospital or a nursing facility or intermediate care facility for the mentally retarded.

(4) NO EFFECT ON OTHER WAIVER AUTHORITY.—Nothing in this subsection shall be construed as affecting the option of a State to offer home and community-based services under a waiver under subsections (c) or (d) of this section or under section 1115.

(5) CONTINUATION OF FEDERAL FINANCIAL PARTICIPATION FOR MEDICAL ASSISTANCE PROVIDED TO INDIVIDUALS AS OF EFFECTIVE DATE OF STATE PLAN AMENDMENT.—Notwithstanding paragraph (1)(B), Federal financial participation shall continue to be available for an individual who is receiving medical assist-

ance in an institutionalized setting, or home and community-based services provided under a waiver under this section or section 1115 that is in effect as of the effective date of the State plan amendment submitted under this subsection, as a result of a determination that the individual requires the level of care provided in a hospital or a nursing facility or intermediate care facility for the mentally retarded, without regard to whether such individuals satisfy the more stringent eligibility criteria established under that paragraph, until such time as the individual is discharged from the institution or waiver program or no longer requires such level of care.

(6) STATE OPTION TO PROVIDE HOME AND COMMUNITY-BASED SERVICES TO INDIVIDUALS ELIGIBLE FOR SERVICES UNDER A WAIVER.—

(A) IN GENERAL.—A State that provides home and community-based services in accordance with this subsection to individuals who satisfy the needs-based criteria for the receipt of such services established under paragraph (1)(A) may, in addition to continuing to provide such services to such individuals, elect to provide home and community-based services in accordance with the requirements of this paragraph to individuals who are eligible for home and community-based services under a waiver approved for the State under subsection (c), (d), or (e) or under section 1115 to provide such services, but only for those individuals whose income does not exceed 300 percent of the supplemental security income benefit rate established by section 1611(b)(1).

(B) APPLICATION OF SAME REQUIREMENTS FOR INDIVIDUALS SATISFYING NEEDS-BASED CRITERIA.—Subject to subparagraph (C), a State shall provide home and community-based services to individuals under this paragraph in the same manner and subject to the same requirements as apply under the other paragraphs of this subsection to the provision of home and community-based services to individuals who satisfy the needs-based criteria established under paragraph (1)(A).

(C) AUTHORITY TO OFFER DIFFERENT TYPE, AMOUNT, DURATION, OR SCOPE OF HOME AND COMMUNITY-BASED SERVICES.—A State may offer home and community-based services to individuals under this paragraph that differ in type, amount, duration, or scope from the home and community-based services offered for individuals who satisfy the needs-based criteria established under paragraph (1)(A), so long as such services are within the scope of services described in paragraph (4)(B) of subsection (c) for which the Secretary has the authority to approve a waiver and do not include room or board.

(7) STATE OPTION TO OFFER HOME AND COMMUNITY-BASED SERVICES TO SPECIFIC, TARGETED POPULATIONS.—

(A) IN GENERAL.—A State may elect in a State plan amendment under this subsection to target the provision of home and community-based services under this subsection to specific populations and to differ the type, amount, duration, or scope of such services to such specific populations.

(B) 5-YEAR TERM.—

(i) IN GENERAL.—An election by a State under this paragraph shall be for a period of 5 years.

(ii) PHASE-IN OF SERVICES AND ELIGIBILITY PERMITTED DURING INITIAL 5-YEAR PERIOD.—A State making an election under this paragraph may, during the first 5-year period for which the election is made, phase-in the enrollment of eligible individuals, or the provision of services to such individuals, or both, so long as all eligible individuals in the State for such services are enrolled, and all such services are provided, before the end of the initial 5-year period.

(C) RENEWAL.—An election by a State under this paragraph may be renewed for additional 5-year terms if the Secretary determines, prior to beginning of each such renewal period, that the State has—

(i) adhered to the requirements of this subsection and paragraph in providing services under such an election; and

(ii) met the State's objectives with respect to quality improvement and beneficiary outcomes.

(j)(1) A State may provide, as "medical assistance", payment for part or all of the cost of self-directed personal assistance services (other than room and board) under the plan which are provided pursuant to a written plan of care to individuals with respect to whom there has been a determination that, but for the provision of such services, the individuals would require and receive personal care services under the plan, or home and community-based services provided pursuant to a waiver under subsection (c). Self-directed personal assistance services may not be provided under this subsection to individuals who reside in a home or property that is owned, operated, or controlled by a provider of services, not related by blood or marriage.

(2) The Secretary shall not grant approval for a State self-directed personal assistance services program under this section unless the State provides assurances satisfactory to the Secretary of the following:

(A) Necessary safeguards have been taken to protect the health and welfare of individuals provided services under the program, and to assure financial accountability for funds expended with respect to such services.

(B) The State will provide, with respect to individuals who—

(i) are entitled to medical assistance for personal care services under the plan, or receive home and community-based services under a waiver granted under subsection (c);

(ii) may require self-directed personal assistance services; and

(iii) may be eligible for self-directed personal assistance services,

an evaluation of the need for personal care under the plan, or personal services under a waiver granted under subsection (c).

(C) Such individuals who are determined to be likely to require personal care under the plan, or home and community-based services under a waiver granted under subsection (c) are informed of the feasible alternatives, if available under the State's self-directed personal assistance services program, at the choice of such individuals, to the provision of personal care services under the plan, or personal assistance services under a waiver granted under subsection (c).

(D) The State will provide for a support system that ensures participants in the self-directed personal assistance services program are appropriately assessed and counseled prior to enrollment and are able to manage their budgets. Additional counseling and management support may be provided at the request of the participant.

(E) The State will provide to the Secretary an annual report on the number of individuals served and total expenditures on their behalf in the aggregate. The State shall also provide an evaluation of overall impact on the health and welfare of participating individuals compared to non-participants every three years.

(3) A State may provide self-directed personal assistance services under the State plan without regard to the requirements of section 1902(a)(1) and may limit the population eligible to receive these services and limit the number of persons served without regard to section 1902(a)(10)(B).

(4)(A) For purposes of this subsection, the term "self-directed personal assistance services" means personal care and related services, or home and community-based services otherwise available under the plan under this title or subsection (c), that are provided to an eligible participant under a self-directed personal assistance services program under this section, under which individuals, within an approved self-directed services plan and budget, purchase personal assistance and related services, and permits participants to hire, fire, supervise, and manage the individuals providing such services.

(B) At the election of the State—

(i) a participant may choose to use any individual capable of providing the assigned tasks including legally liable relatives as paid providers of the services; and

(ii) the individual may use the individual's budget to acquire items that increase independence or substitute (such as a microwave oven or an accessibility ramp) for human assistance, to the extent that expenditures would otherwise be made for the human assistance.

(5) For purpose of this section, the term "approved self-directed services plan and budget" means, with respect to a participant, the establishment of a plan and budget for the provision of self-directed personal assistance services, consistent with the following requirements:

(A) SELF-DIRECTION.—The participant (or in the case of a participant who is a minor child, the participant's parent or guardian, or in the case of an incapacitated adult, another individual recognized by State law to act on behalf of the participant) exercises choice and control over the budget, planning, and purchase of self-directed personal assistance services, including the amount, duration, scope, provider, and location of service provision.

(B) ASSESSMENT OF NEEDS.—There is an assessment of the needs, strengths, and preferences of the participants for such services.

(C) SERVICE PLAN.—A plan for such services (and supports for such services) for the participant has been developed and approved by the State based on such assessment through a person-centered process that—

(i) builds upon the participant's capacity to engage in activities that promote community life and that respects the participant's preferences, choices, and abilities; and

(ii) involves families, friends, and professionals in the planning or delivery of services or supports as desired or required by the participant.

(D) SERVICE BUDGET.—A budget for such services and supports for the participant has been developed and approved by the State based on such assessment and plan and on a methodology that uses valid, reliable cost data, is open to public inspection, and includes a calculation of the expected cost of such services if those services were not self-directed. The budget may not restrict access to other medically necessary care and services furnished under the plan and approved by the State but not included in the budget.

(E) APPLICATION OF QUALITY ASSURANCE AND RISK MANAGEMENT.—There are appropriate quality assurance and risk management techniques used in establishing and implementing such plan and budget that recognize the roles and responsibilities in obtaining services in a self-directed manner and assure the appropriateness of such plan and budget based upon the participant's resources and capabilities.

(6) A State may employ a financial management entity to make payments to providers, track costs, and make reports under the program. Payment for the activities of the financial management entity shall be at the administrative rate established in section 1903(a).

(k) STATE PLAN OPTION TO PROVIDE HOME AND COMMUNITY-BASED ATTENDANT SERVICES AND SUPPORTS.—

(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, beginning October 1, 2011, a State may provide through a State plan amendment for the provision of medical assistance for home and community-based attendant services and supports for individuals who are eligible for medical assistance under the State plan whose income does not exceed 150 percent of the poverty line (as defined in section 2110(c)(5)) or, if greater, the income level applicable for an individual who has been determined to require an institutional level of care to be eligible for nursing facility services under the State plan and with respect to whom there has been a determination that, but for the provision of such services, the individuals would require the level of care provided in a hospital, a nursing facility, an intermediate care facility for the mentally retarded, or an institution for mental diseases, the cost of which could be reimbursed under the State plan, but only if the individual chooses to receive such home and community-based attendant services

and supports, and only if the State meets the following requirements:

(A) AVAILABILITY.—The State shall make available home and community-based attendant services and supports to eligible individuals, as needed, to assist in accomplishing activities of daily living, instrumental activities of daily living, and health-related tasks through hands-on assistance, supervision, or cueing—

(i) under a person-centered plan of services and supports that is based on an assessment of functional need and that is agreed to in writing by the individual or, as appropriate, the individual's representative;

(ii) in a home or community setting, which does not include a nursing facility, institution for mental diseases, or an intermediate care facility for the mentally retarded;

(iii) under an agency-provider model or other model (as defined in paragraph (6)(C)); and

(iv) the furnishing of which—

(I) is selected, managed, and dismissed by the individual, or, as appropriate, with assistance from the individual's representative;

(II) is controlled, to the maximum extent possible, by the individual or where appropriate, the individual's representative, regardless of who may act as the employer of record; and

(III) provided by an individual who is qualified to provide such services, including family members (as defined by the Secretary).

(B) INCLUDED SERVICES AND SUPPORTS.—In addition to assistance in accomplishing activities of daily living, instrumental activities of daily living, and health related tasks, the home and community-based attendant services and supports made available include—

(i) the acquisition, maintenance, and enhancement of skills necessary for the individual to accomplish activities of daily living, instrumental activities of daily living, and health related tasks;

(ii) back-up systems or mechanisms (such as the use of beepers or other electronic devices) to ensure continuity of services and supports; and

(iii) voluntary training on how to select, manage, and dismiss attendants.

(C) EXCLUDED SERVICES AND SUPPORTS.—Subject to subparagraph (D), the home and community-based attendant services and supports made available do not include—

(i) room and board costs for the individual;

(ii) special education and related services provided under the Individuals with Disabilities Education Act and vocational rehabilitation services provided under the Rehabilitation Act of 1973;

(iii) assistive technology devices and assistive technology services other than those under (1)(B)(ii);

(iv) medical supplies and equipment; or

(v) home modifications.

(D) PERMISSIBLE SERVICES AND SUPPORTS.—The home and community-based attendant services and supports may include—

(i) expenditures for transition costs such as rent and utility deposits, first month's rent and utilities, bedding, basic kitchen supplies, and other necessities required for an individual to make the transition from a nursing facility, institution for mental diseases, or intermediate care facility for the mentally retarded to a community-based home setting where the individual resides; and

(ii) expenditures relating to a need identified in an individual's person-centered plan of services that increase independence or substitute for human assistance, to the extent that expenditures would otherwise be made for the human assistance.

(2) INCREASED FEDERAL FINANCIAL PARTICIPATION.—For purposes of payments to a State under section 1903(a)(1), with respect to amounts expended by the State to provide medical assistance under the State plan for home and community-based attendant services and supports to eligible individuals in accordance with this subsection during a fiscal year quarter occurring during the period described in paragraph (1), the Federal medical assistance percentage applicable to the State (as determined under section 1905(b)) shall be increased by 6 percentage points.

(3) STATE REQUIREMENTS.—In order for a State plan amendment to be approved under this subsection, the State shall—

(A) develop and implement such amendment in collaboration with a Development and Implementation Council established by the State that includes a majority of members with disabilities, elderly individuals, and their representatives and consults and collaborates with such individuals;

(B) provide consumer controlled home and community-based attendant services and supports to individuals on a statewide basis, in a manner that provides such services and supports in the most integrated setting appropriate to the individual's needs, and without regard to the individual's age, type or nature of disability, severity of disability, or the form of home and community-based attendant services and supports that the individual requires in order to lead an independent life;

(C) with respect to expenditures during the first full fiscal year in which the State plan amendment is implemented, maintain or exceed the level of State expenditures for medical assistance that is provided under section 1905(a), section 1915, section 1115, or otherwise to individuals with disabilities or elderly individuals attributable to the preceding fiscal year;

(D) establish and maintain a comprehensive, continuous quality assurance system with respect to community-based attendant services and supports that—

(i) includes standards for agency-based and other delivery models with respect to training, appeals for denials and reconsideration procedures of an individual plan, and other factors as determined by the Secretary;

(ii) incorporates feedback from consumers and their representatives, disability organizations, providers, families of disabled or elderly individuals, members of the community, and others and maximizes consumer independence and consumer control;

(iii) monitors the health and well-being of each individual who receives home and community-based attendant services and supports, including a process for the mandatory reporting, investigation, and resolution of allegations of neglect, abuse, or exploitation in connection with the provision of such services and supports; and

(iv) provides information about the provisions of the quality assurance required under clauses (i) through (iii) to each individual receiving such services; and

(E) collect and report information, as determined necessary by the Secretary, for the purposes of approving the State plan amendment, providing Federal oversight, and conducting an evaluation under paragraph (5)(A), including data regarding how the State provides home and community-based attendant services and supports and other home and community-based services, the cost of such services and supports, and how the State provides individuals with disabilities who otherwise qualify for institutional care under the State plan or under a waiver the choice to instead receive home and community-based services in lieu of institutional care.

(4) COMPLIANCE WITH CERTAIN LAWS.—A State shall ensure that, regardless of whether the State uses an agency-provider model or other models to provide home and community-based attendant services and supports under a State plan amendment under this subsection, such services and supports are provided in accordance with the requirements of the Fair Labor Standards Act of 1938 and applicable Federal and State laws regarding—

(A) withholding and payment of Federal and State income and payroll taxes;

(B) the provision of unemployment and workers compensation insurance;

(C) maintenance of general liability insurance; and

(D) occupational health and safety.

(5) EVALUATION, DATA COLLECTION, AND REPORT TO CONGRESS.—

(A) EVALUATION.—The Secretary shall conduct an evaluation of the provision of home and community-based attendant services and supports under this subsection in order to determine the effectiveness of the provision of such services and supports in allowing the individuals receiving such services and supports to lead an independent life to the maximum extent possible; the impact on the physical and emotional health of the individuals who receive such services; and an comparative analysis of the costs of services provided under the State plan amendment under this subsection and those provided under institutional care in a nursing facility, institution for mental diseases, or an intermediate care facility for the mentally retarded.

(B) DATA COLLECTION.—The State shall provide the Secretary with the following information regarding the provision of home and community-based attendant services and supports under this subsection for each fiscal year for which such services and supports are provided:

(i) The number of individuals who are estimated to receive home and community-based attendant services and supports under this subsection during the fiscal year.

(ii) The number of individuals that received such services and supports during the preceding fiscal year.

(iii) The specific number of individuals served by type of disability, age, gender, education level, and employment status.

(iv) Whether the specific individuals have been previously served under any other home and community based services program under the State plan or under a waiver.

(C) REPORTS.—Not later than—

(i) December 31, 2013, the Secretary shall submit to Congress and make available to the public an interim report on the findings of the evaluation under subparagraph (A); and

(ii) December 31, 2015, the Secretary shall submit to Congress and make available to the public a final report on the findings of the evaluation under subparagraph (A).

(6) DEFINITIONS.—In this subsection:

(A) ACTIVITIES OF DAILY LIVING.—The term "activities of daily living" includes tasks such as eating, toileting, grooming, dressing, bathing, and transferring.

(B) CONSUMER CONTROLLED.—The term "consumer controlled" means a method of selecting and providing services and supports that allow the individual, or where appropriate, the individual's representative, maximum control of the home and community-based attendant services and supports, regardless of who acts as the employer of record.

(C) DELIVERY MODELS.—

(i) AGENCY-PROVIDER MODEL.—The term "agency-provider model" means, with respect to the provision of home and community-based attendant services and supports for an individual, subject to paragraph (4), a method of providing consumer controlled services and supports under which entities contract for the provision of such services and supports.

(ii) OTHER MODELS.—The term "other models" means, subject to paragraph (4), methods, other than an agency-provider model, for the provision of consumer controlled services and supports. Such models may include the provision of vouchers, direct cash payments, or use of a fiscal agent to assist in obtaining services.

(D) HEALTH-RELATED TASKS.—The term "health-related tasks" means specific tasks related to the needs of an individual, which can be delegated or assigned by licensed health-care professionals under State law to be performed by an attendant.

(E) INDIVIDUAL'S REPRESENTATIVE.—The term "individual's representative" means a parent, family member, guardian, advocate, or other authorized representative of an individual

(F) INSTRUMENTAL ACTIVITIES OF DAILY LIVING.—The term "instrumental activities of daily living" includes (but is not limited to) meal planning and preparation, managing finances, shopping for food, clothing, and other essential items, performing essential household chores, communicating by phone or other media, and traveling around and participating in the community.

(l) STATE PLAN OPTION TO PROVIDE SERVICES FOR CERTAIN INDIVIDUALS IN INSTITUTIONS FOR MENTAL DISEASES.—

(1) IN GENERAL.—With respect to calendar quarters beginning during the period beginning January 1, 2019, and ending December 31, 2023, a State may elect, through a State plan amendment, to, notwithstanding section 1905(a), provide medical assistance for services furnished in institutions for mental diseases and for other medically necessary services furnished to eligible individuals with opioid use disorders, in accordance with the requirements of this subsection.

(2) PAYMENTS.—

(A) IN GENERAL.—Amounts expended under a State plan amendment under paragraph (1) for services described in such paragraph furnished, with respect to a 12-month period, to an eligible individual with an opioid use disorder who is a patient in an institution for mental diseases shall be treated as medical assistance for which payment is made under section 1903(a) but only to the extent that such services are furnished for not more than a period of 30 days (whether or not consecutive) during such 12-month period.

(B) CLARIFICATION.—Payment made under this paragraph for expenditures under a State plan amendment under this subsection with respect to services described in paragraph (1) furnished to an eligible individual with an opioid use disorder shall not affect payment that would otherwise be made under section 1903(a) for expenditures under the State plan (or waiver of such plan) for medical assistance for such individual.

(3) INFORMATION REQUIRED IN STATE PLAN AMENDMENT.—

(A) IN GENERAL.—A State electing to provide medical assistance pursuant to this subsection shall include with the submission of the State plan amendment under paragraph (1) to the Secretary—

(i) a plan on how the State will improve access to outpatient care during the period of the State plan amendment, including a description of—

(I) the process by which eligible individuals with opioid use disorders will make the transition from receiving inpatient services in an institution for mental diseases to appropriate outpatient care; and

(II) the process the State will undertake to ensure individuals with opioid use disorder are provided care in the most integrated setting appropriate to the needs of the individuals; and

(ii) a description of how the State plan amendment ensures an appropriate clinical screening of eligible individuals with an opioid use disorder, including assessments to determine level of care and length of stay recommendations based upon the multidimensional assessment criteria of the American Society of Addiction Medicine.

(B) REPORT.—Not later than the sooner of December 31, 2024, or one year after the date of the termination of a State plan amendment under this subsection, the State shall submit to the Secretary a report that includes at least—

(i) the number of eligible individuals with opioid use disorders who received services pursuant to such State plan amendment;

(ii) the length of the stay of each such individual in an institution for mental diseases; and

(iii) the type of outpatient treatment, including medication-assisted treatment, each such individual received after being discharged from such institution.

(4) DEFINITIONS.—In this subsection:

(A) ELIGIBLE INDIVIDUAL WITH AN OPIOID USE DISORDER.—The term "eligible individual with an opioid use disorder" means an individual who—

(i) with respect to a State, is enrolled for medical assistance under the State plan (or a waiver of such plan);

(ii) is at least 21 years of age;

(iii) has not attained 65 years of age; and

(iv) has been diagnosed with at least one opioid use disorder.

(B) INSTITUTION FOR MENTAL DISEASES.—The term "institution for mental diseases" has the meaning given such term in section 1905(i).

(C) OPIOID PRESCRIPTION PAIN RELIEVER.—The term "opioid prescription pain reliever" includes hydrocodone products, oxycodone products, tramadol products, codeine products, morphine products, fentanyl products, buprenorphine products, oxymorphone products, meperidine products, hydromorphone products, methadone, and any other prescription pain reliever identified by the Assistant Secretary for Mental Health and Substance Use.

(D) OPIOID USE DISORDER.—The term "opioid use disorder" means a disorder that meets the criteria of the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (or a successor edition), for heroin use disorder or

pain reliever use disorder (including with respect to opioid prescription pain relievers).

(E) OTHER MEDICALLY NECESSARY SERVICES.—The term "other medically necessary services" means, with respect to an eligible individual with an opioid use disorder who is a patient in an institution for mental diseases, items and services that are provided to such individual outside of such institution to the extent that such items and services would be treated as medical assistance for such individual if such individual were not a patient in such institution.

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DISSENTING VIEWS

In recognition of states' traditional roles in treating individuals with mental disorders, there is a long-standing prohibition on using federal Medicaid matching funds to support inpatient facilities with more than 16 beds that treat "mental diseases."[1] This provision, known as the "IMD exclusion," applies equally to small facilities and to large state mental hospitals. The IMD exclusion has been identified as a barrier to building state capacity to treat individuals with Substance Use Disorders. At the same time, the IMD exclusion often is credited with helping to accomplish a shift away from institutional care and segregation of people with mental illness and Substance Use Disorder (SUD). For the past 54 years the United States has been engaged in an effort to effectively bring people with mental illness and SUD into the mainstream of American society and its medical care arrangements.

However, when integrated into a full continuum of care, IMD treatment for SUD can provide an important option for treatment for some individuals. Importantly, the Centers for Medicare and Medicaid Services (CMS) have exercised significant administrative flexibility already with respects to the statutory IMD exclusion, prioritizing IMDs for SUD as one part of the continuum of care. States can receive approval to waive the IMD exclusion through Section 1115 demonstrations (also known as "waivers") when pursuing "broad and deep system transformations" in the area of SUD. More than 20 state Medicaid programs have approved SUD waivers or pending SUD waivers before CMS that allow for IMD reimbursement. More broadly, states are providing IMD services for both mental health and SUD needs through capitated payments to managed care organizations[2], and lump-sum payments from Disproportionate Share Hospital (DSH) funding.[3]

Unfortunately, the legislation reported by the Committee is less flexible than the administrative options currently available to states; allowing for a five-year state option that would lift the IMD exclusion for Opioid Use Disorder (OUD) only for a 30-day period in a calendar year.

Studies have demonstrated a high rate of co-occurring substance-related disorders. Studies have demonstrated up to 80 percent of those being treated for OUD had another substance use disorder.[4,5]

[1] The regulatory definition of an institution for mental diseases is found at 42 CFR 435.1010.

[2] Centers for Medicare and Medicaid Services, *Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability, Final Rule* (Mar. 6, 2016) (https://www.federalregister.gov/documents/2016/05/06/2016–09581/medicaid-and-childrens-health-insurance-program-chip-programs-medicaid-managed-care-chip-delivered).

[3] Kelsey C. Priest, et al., *Medicaid Coverage For Residential Substance Use Disorder Treatment: Addressing The Institution For Mental Disease Exclusion Policy*, Health Affairs Blog (Aug. 31, 2017) (https://www.healthaffairs.org/do/10.1377/hblog20170831.061745/full/).

[4] American Society of Addiction Medicine. National Practice Guideline For the Use of Medications in the Treatment of Addiction Involving Opioid Use. (Jun 1, 2015) (https://www.asam.org/

During the initial assessment for substance abuse therapy, any factors that may influence a patient's use of opioids, such as dependence or abuse of other substances, must be taken into consideration. Then, management of withdrawal symptoms from and treatment for all substances should be addressed as part of the treatment plan.[6]

The correlation between OUD and abuse of other depressants is high.[7] In those with OUD, 65–75 percent also have a benzodiazepine abuse disorder and 12–25 percent have alcohol abuse.[8,9,10] Treatment for any substance use disorder (SUD) includes a comprehensive approach that addresses the entirety of a patient's medical and psychosocial conditions. Those with OUD frequently suffer from other SUDs, such as alcohol, cocaine, methamphetamine, or benzodiazepine abuse.

Given the high overlap of OUD with other forms of substance abuse, it is vital that treatment options exist not only for OUD, but for all substance use disorders. For those with any SUD, a no wrong door approach allows patients desiring to be treated for any SUD to receive comprehensive consideration of all medical and psychiatric conditions, including other substance use disorders.

Therefore, repeal of the IMD Exclusion for OUD exclusively, as this legislation does, creates additional barriers and may further limit treatment options for patients that require treatment for other substances. Additionally, fewer resources and less access to treatment for individuals that initially seek treatment for substances other than OUD would mean missed opportunities to engage patients in SUD treatment.

Conversely, creating an option whereby states would put in place two different benefit packages for SUD based on the substance an individual is addicted to could create a perverse incentive towards opioids or reported opioid abuse in the hopes of gaining access to treatment. At the very least, such an option would create the practical effect of a two-tiered system for substance use disorder in states that chose to take the option created by the legislation, leaving some beneficiaries worse off than others and without access to the same level of treatment.

Given these concerns, Democratic members of the Committee do not support a repeal of the IMD exclusion in this form.

FRANK PALLONE, Jr.
Ranking Member.

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docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf)

[5] Wu, Li-Tzy., Zhu, He, Swartz, Marvin S. Treatment Utilization among persons with opioid use disorder in the United States. Drug and Alcohol Dependence. (Oct 19, 2016).

[6] American Psychiatric Assocation. Practice Guideline for the Treatment of Patients with Substance Use Disorders, 2nd Edition. (2010) (https://psychiatryonline.org/pb/assets/raw/sitewide/practice guidelines/guidelines/substanceuse.pdf)

[7] *See* note 3.

[8] *See* note 4.

[9] Jones, Jermaine D., Mogali, Shanthi, and Corner, Sandra D. Polydrug abuse: A review of opioid and benzodiazepine combination use. Drug and Alcohol Dependence. (Aug 2, 2012)

[10] McCabe, S.E., et al. Simultaneous and concurrent polydrug use of alcohol and prescription drugs: Prevalence, correlates, and consequences. Journal of Studies on Alcohol (2006).