

RURAL DEVELOPMENT OF OPIOID CAPACITY SERVICES  
 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

[To accompany H.R. 5477]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 5477) to amend title XIX of the Social Security Act to provide for a demonstration project to increase substance use provider capacity under the Medicaid program, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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

**SECTION 1. SHORT TITLE.**

This Act may be cited as the “Rural Development of Opioid Capacity Services Act” or the “Rural DOCS Act”.

**SEC. 2. DEMONSTRATION PROJECT TO INCREASE SUBSTANCE USE PROVIDER CAPACITY UNDER THE MEDICAID PROGRAM.**

Section 1903 of the Social Security Act (42 U.S.C. 1396b) is amended by adding at the end the following new subsection:

“(aa) DEMONSTRATION PROJECT TO INCREASE SUBSTANCE USE PROVIDER CAPACITY.—

“(1) IN GENERAL.—Not later than the date that is 180 days after the date of the enactment of this section, the Secretary shall, in consultation, as appropriate, with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, conduct a 5-year demonstration project for the purpose described in paragraph (2) under which the Secretary shall—

“(A) for the first 18-month period of such project, award planning grants described in paragraph (3); and

“(B) for the remaining 42-month period of such project, provide to each State selected under paragraph (4) payments in accordance with paragraph (5).

“(2) PURPOSE.—The purpose described in this paragraph is for each State selected under paragraph (4) to increase the treatment capacity of providers participating under the State plan (or a waiver of such plan) to provide substance use disorder treatment or recovery services under such plan (or waiver) through the following activities:

“(A) For the purpose described in paragraph (3)(C)(i), activities that support an ongoing assessment of the behavioral health treatment needs of the State, taking into account the matters described in subclauses (I) through (IV) of such paragraph.

“(B) Activities that, taking into account the results of the assessment described in subparagraph (A), support the recruitment, training, and provision of technical assistance for providers participating under the State plan (or a waiver of such plan) that offer substance use disorder treatment or recovery services.

“(C) Improved reimbursement for and expansion of, through the provision of education, training, and technical assistance, the number or treatment capacity of providers participating under the State plan (or waiver) that—

“(i) are authorized to dispense drugs approved by the Food and Drug Administration for individuals with a substance use disorder who need withdrawal management or maintenance treatment for such disorder;

“(ii) have in effect a registration or waiver under section 303(g) of the Controlled Substances Act for purposes of dispensing narcotic drugs to individuals for maintenance treatment or detoxification treatment and are in compliance with any regulation promulgated by the Assistant Secretary for Mental Health and Substance Use for purposes of carrying out the requirements of such section 303(g); and

“(iii) are qualified under applicable State law to provide substance use disorder treatment or recovery services.

“(D) Improved reimbursement for and expansion of, through the provision of education, training, and technical assistance, the number or treatment capacity of providers participating under the State plan (or waiver) that have the qualifications to address the treatment or recovery needs of—

“(i) individuals enrolled under the State plan (or a waiver of such plan) who have neonatal abstinence syndrome, in accordance with guidelines issued by the American Academy of Pediatrics and American College of Obstetricians and Gynecologists relating to maternal care and infant care with respect to neonatal abstinence syndrome;

“(ii) pregnant women, postpartum women, and infants, particularly the concurrent treatment, as appropriate, and comprehensive case management of pregnant women, postpartum women and infants, enrolled under the State plan (or a waiver of such plan);

“(iii) adolescents and young adults between the ages of 12 and 21 enrolled under the State plan (or a waiver of such plan); or

“(iv) American Indian and Alaska Native individuals enrolled under the State plan (or a waiver of such plan).

“(3) PLANNING GRANTS.—

“(A) IN GENERAL.—The Secretary shall, with respect to the first 18-month period of the demonstration project conducted under paragraph (1), award planning grants to at least 10 States selected in accordance with subpara-

graph (B) for purposes of preparing an application described in paragraph (4)(C) and carrying out the activities described in subparagraph (C).

“(B) SELECTION.—In selecting States for purposes of this paragraph, the Secretary shall—

“(i) select States that have a State plan (or waiver of the State plan) approved under this title;

“(ii) select States in a manner that ensures geographic diversity; and

“(iii) give preference to States with a prevalence of substance use disorders (in particular opioid use disorders) that is comparable to or higher than the national average prevalence, as measured by aggregate per capita drug overdoses, or any other measure that the Secretary deems appropriate.

“(C) ACTIVITIES DESCRIBED.—Activities described in this subparagraph are, with respect to a State, each of the following:

“(i) Activities that support the development of an initial assessment of the behavioral health treatment needs of the State to determine the extent to which providers are needed (including the types of such providers and geographic area of need) to improve the network of providers that treat substance use disorders under the State plan (or waiver), including the following:

“(I) An estimate of the number of individuals enrolled under the State plan (or a waiver of such plan) who have a substance use disorder.

“(II) Information on the capacity of providers to provide substance use disorder treatment or recovery services to individuals enrolled under the State plan (or waiver), including information on providers who provide such services and their participation under the State plan (or waiver).

“(III) Information on the gap in substance use disorder treatment or recovery services under the State plan (or waiver) based on the information described in subclauses (I) and (II).

“(IV) Projections regarding the extent to which the State participating under the demonstration project would increase the number of providers offering substance use disorder treatment or recovery services under the State plan (or waiver) during the period of the demonstration project.

“(ii) Activities that, taking into account the results of the assessment described in clause (i), support the development of State infrastructure to, with respect to the provision of substance use disorder treatment or recovery services under the State plan (or a waiver of such plan), recruit prospective providers and provide training and technical assistance to such providers.

“(D) FUNDING.—For purposes of subparagraph (A), there is appropriated, out of any funds in the Treasury not otherwise appropriated, \$50,000,000, to remain available until expended.

“(4) POST-PLANNING STATES.—

“(A) IN GENERAL.—The Secretary shall, with respect to the remaining 42-month period of the demonstration project conducted under paragraph (1), select not more than 5 States in accordance with subparagraph (B) for purposes of carrying out the activities described in paragraph (2) and receiving payments in accordance with paragraph (5).

“(B) SELECTION.—In selecting States for purposes of this paragraph, the Secretary shall—

“(i) select States that received a planning grant under paragraph (3);

“(ii) select States that submit to the Secretary an application in accordance with the requirements in subparagraph (C), taking into consideration the quality of each such application;

“(iii) select States in a manner that ensures geographic diversity; and

“(iv) give preference to States with a prevalence of substance use disorders (in particular opioid use disorders) that is comparable to or higher than the national average prevalence, as measured by aggregate per capita drug overdoses, or any other measure that the Secretary deems appropriate.

“(C) APPLICATIONS.—

“(i) IN GENERAL.—A State seeking to be selected for purposes of this paragraph shall submit to the Secretary, at such time and in such form and manner as the Secretary requires, an application that includes such information, provisions, and assurances, as the Secretary may require, in addition to the following:

“(I) A proposed process for carrying out the ongoing assessment described in paragraph (2)(A), taking into account the results of the initial assessment described in paragraph (3)(C)(i).

“(II) A review of reimbursement methodologies and other policies related to substance use disorder treatment or recovery services under the State plan (or waiver) that may create barriers to increasing the number of providers delivering such services.

“(III) The development of a plan, taking into account activities carried out under paragraph (3)(C)(ii), that will result in long-term and sustainable provider networks under the State plan (or waiver) that will offer a continuum of care for substance use disorders. Such plan shall include the following:

“(aa) Specific activities to increase the number of providers (including providers that specialize in providing substance use disorder treatment or recovery services, hospitals, health care systems, Federally qualified health centers, and, as applicable, certified community behavioral health clinics) that offer substance use disorder treatment, recovery, or support services, including short-term detoxification services, outpatient substance use disorder services, and evidence-based peer recovery services.

“(bb) Strategies that will incentivize providers described in subparagraphs (C) and (D) of paragraph (2) to obtain the necessary training, education, and support to deliver substance use disorder treatment or recovery services in the State.

“(cc) Milestones and timeliness for implementing activities set forth in the plan.

“(dd) Specific measurable targets for increasing the substance use disorder treatment and recovery provider network under the State plan (or a waiver of such plan).

“(IV) A proposed process for reporting the information required under paragraph (6)(A), including information to assess the effectiveness of the efforts of the State to expand the capacity of providers to deliver substance use disorder treatment or recovery services during the period of the demonstration project under this subsection.

“(V) The expected financial impact of the demonstration project under this subsection on the State.

“(VI) A description of all funding sources available to the State to provide substance use disorder treatment or recovery services in the State.

“(VII) A preliminary plan for how the State will sustain any increase in the capacity of providers to deliver substance use disorder treatment or recovery services resulting from the demonstration project under this subsection after the termination of such demonstration project.

“(VIII) A description of how the State will coordinate the goals of the demonstration project with any waiver received pursuant to section 1115 for the delivery of substance use services under the State plan, as applicable.

“(ii) CONSULTATION.—In completing an application under clause (i), a State shall consult with relevant stakeholders, including Medicaid managed care plans, health care providers, and Medicaid beneficiary advocates, and include in such application a description of such consultation.

“(5) PAYMENT.—

“(A) IN GENERAL.—For each quarter occurring during the period for which the demonstration project is conducted (after the first 18 months of such period), the Secretary shall pay under this subsection, subject to subparagraphs (C) and (D), to each State selected under paragraph (4) an amount equal to 80 percent of so much of the qualified sums expended during such quarter.

“(B) QUALIFIED SUMS DEFINED.—For purposes of subparagraph (A), the term ‘qualified sums’ means, with respect to a State and a quarter, the amount equal to the amount (if any) by which the sums expended by the State during such quarter attributable to substance use treatment or recovery services furnished by providers participating under the State plan (or a waiver of such plan) exceeds 1/4 of such sums expended by the State dur-

ing fiscal year 2018 attributable to substance use treatment or recovery services.

“(C) NON-DUPLICATION OF PAYMENT.—In the case that payment is made under subparagraph (A) with respect to expenditures for substance use treatment or recovery services furnished by providers participating under the State plan (or a waiver of such plan), payment may not also be made under subsection (a) with respect to expenditures for the same services so furnished.

“(D) CONDITIONS.—In the case of a State selected under paragraph (4) that provides substance use disorder treatment and recovery services under a waiver under section 1115, such State shall, as a condition of receiving payments under subparagraph (A)—

“(i) coordinate such services under such waiver with substance use disorder treatment and recovery services provided under the demonstration project under this subsection; and

“(ii) take such actions as appropriate under the demonstration project to expand such services under such waiver.

“(6) REPORTS.—

“(A) STATE REPORTS.—A State receiving payments under paragraph (5) shall, for the period of the demonstration project under this subsection, submit to the Secretary a quarterly report, with respect to expenditures for substance use treatment or recovery services for which payment is made to the State under this subsection, on the following:

“(i) The specific activities with respect to which payment under this subsection was provided.

“(ii) The number of providers that delivered substance use disorder treatment or recovery services in the State under the demonstration project compared to the estimated number of providers that would have otherwise delivered such services in the absence of such demonstration project.

“(iii) The number of individuals enrolled under the State plan (or a waiver of such plan) who received substance use disorder treatment or recovery services under the demonstration project compared to the estimated number of such individuals who would have otherwise received such services in the absence of such demonstration project.

“(iv) Other matters as determined by the Secretary.

“(B) CMS REPORTS.—

“(i) INITIAL REPORT.—Not later than October 1, 2020, the Administrator of the Centers for Medicare & Medicaid Services shall, in consultation with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, submit to Congress an initial report on—

“(I) the States awarded planning grants under paragraph (3);

“(II) the criteria used in such selection; and

“(III) the activities carried out by such States under such planning grants.

“(ii) INTERIM REPORT.—Not later than October 1, 2022, the Administrator of the Centers for Medicare & Medicaid Services shall, in consultation with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, submit to Congress an interim report—

“(I) on activities carried out under the demonstration project under this subsection;

“(II) on the extent to which States selected under paragraph (4) have achieved the stated goals submitted in their applications under subparagraph (C) of such paragraph;

“(III) with a description of the strengths and limitations of such demonstration project; and

“(IV) with a plan for the sustainability of such project.

“(iii) FINAL REPORT.—Not later than October 1, 2024, the Administrator of the Centers for Medicare & Medicaid Services shall, in consultation with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, submit to Congress a final report—

“(I) providing updates on the matters reported in the interim report under clause (ii);

“(II) including a description of any changes made with respect to the demonstration project under this subsection after the submission of such interim report; and

“(III) evaluating such demonstration project.

“(C) AHRQ REPORT.—Not later than three years after the date of the enactment of this subsection, the Director of the Agency for Healthcare Research and Quality shall submit to Congress a summary on the experiences of States awarded planning grants under paragraph (3) and States selected under paragraph (4).

“(7) DATA SHARING AND BEST PRACTICES.—During the period of the demonstration project under this subsection, the Secretary shall, in collaboration with States selected under paragraph (4), facilitate data sharing and the development of best practices between such States and States that were not so selected.

“(8) CMS FUNDING.—There is appropriated, out of any funds in the Treasury not otherwise appropriated, \$5,000,000 to the Centers for Medicare & Medicaid Services for purposes of implementing this subsection. Such amount shall remain available until expended.”

#### PURPOSE AND SUMMARY

H.R. 5477 was introduced on April 11, 2018, by Rep. Tom O’Halloran (D-AZ). The bill requires the Centers for Medicare and Medicaid Services (CMS) to carry out a demonstration project to provide an enhanced federal matching rate for state Medicaid expenditures related to the expansion of substance-use treatment and recovery services.

#### 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.<sup>1</sup>

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.<sup>2</sup> 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 output.<sup>3</sup> In 2015, the total economic burden of the opioid epidemic was estimated to be \$504 billion.<sup>4</sup> 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).<sup>4</sup> 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.<sup>5</sup>

<sup>1</sup>Centers for Disease Control and Prevention. “Drug Overdose Death Data.” December 19, 2017. Available at <https://www.cdc.gov/drugoverdose/data/statedeaths.html>.

<sup>2</sup>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>.

<sup>3</sup>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/>.

<sup>4</sup>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](https://www.aei.org/wp-content/uploads/2018/03/Geographic_Variation_in_Cost_of_Opioid_Crisis.pdf).

<sup>5</sup>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/>

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.<sup>6</sup> 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.”<sup>7</sup> Of the two million non-elderly Americans with opioid addiction, Medicaid provides health coverage for an estimated 38 percent of this population, which is the largest percentage of any insurer type.<sup>8</sup> 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.<sup>9</sup>

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.”<sup>10</sup> 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 disorder 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 therapies, to provide a “whole-patient” approach to the treatment of substance use disorders.”<sup>11</sup>

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.” 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.

analysis-cost-of-treating-opioid-addiction-rose-rapidly-for-large-employers-as-the-number-of-prescriptions-has-declined/.

<sup>6</sup>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>.

<sup>7</sup>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>.

<sup>8</sup>Kaiser Family Foundation. “Medicaid’s Role in Addressing the Opioid Epidemic.” Available at <https://www.kff.org/infographic/medicaids-role-in-addressing-opioid-epidemic/>.

<sup>9</sup>Kaiser Family Foundation. “Medicaid’s Role in Addressing the Opioid Epidemic.” Available at <https://www.kff.org/infographic/medicaids-role-in-addressing-opioid-epidemic/>.

<sup>10</sup>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>.

<sup>11</sup>See SAMHSA website. Available at: <https://www.samhsa.gov/medication-assisted-treatment>.

However, as MACPAC noted, “there are gaps in the continuum of care, and states vary in the extent to which they cover needed treatment.” One of the barriers to appropriate treatment consistently identified by Medicaid directors and health policy experts is a statutory 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.” 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.

One of the barriers to appropriate substance use disorder treatment consistently identified by Medicaid directors and health policy experts is a shortage of providers. A shortage of providers creates barriers for Medicaid beneficiaries to access treatment. Approximately 40 percent of U.S. counties lack a single outpatient addiction treatment program that accepts any Medicaid enrollees.<sup>12</sup> In 2012, 96 percent of states, including the District of Columbia, had opioid abuse or dependence rates higher than their current buprenorphine treatment capacity rates.<sup>13</sup> In addition to the shortage of providers, most opioid treatment programs are located in urban areas, which causes significant regional disparities within and among states.<sup>14</sup>

#### COMMITTEE ACTION

On April 11 and 12, 2018, the Subcommittee on Health held a hearing on H.R. 5477. 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 May 17, 2018, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 5477, as amended, favorably reported to the House by a voice vote.

<sup>12</sup>Cummings, J.R., Wen, H., Ko, M. & Druss, B.G., “Race/Ethnicity and Geographic Access to Medicaid Substance Use Disorder Treatment facilities in the United States,” *Journal of the American Medical Association, Psychiatry*, February 2014, 71(2), 190–196.

<sup>13</sup>Jones, C.M., Campopiano, M., Baldwin, G. & McCance-Katz, E. “National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment,” *American Journal of Public Health*, August 2015, 105(8), 55–63.

<sup>14</sup>Abraham, A.J., Andrews, C.M., Yingling, M.E. & Shannon, J. “Geographic Disparities in Availability of Opioid Use Disorder Treatment for Medicaid Enrollees,” *Health Services Research*, February 2018, 53(1), 389–404.

## 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. 5477 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.

## NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R. 5477 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
<b>INCREASES OR DECREASES (–) IN DIRECT SPENDING</b>													
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 <sup>a</sup> .....	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 <sup>a</sup> .....	0	*	*	*	*	*	*	*	*	*	*	*	*
H.R. 5808, Medicaid Pharmaceutical Home Act of 2018 <sup>a</sup> .....	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 <sup>a</sup> .....	0	0	0	25	30	25	10	5	0	0	0	100	115
H.R. 5809, Postoperative Opioid Prevention Act of 2018 .....	0	0	0	0	10	15	20	25	30	35	45	25	180
Legislation Primarily Affecting the Food and Drug Administration:													



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

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

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

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

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

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

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

*H.R. 5799, the Medicaid DRUG Improvement Act*, would require state Medicaid programs to implement additional reviews of opioid prescriptions, monitor concurrent prescribing of opioids and certain other drugs, and monitor use of antipsychotic drugs by children. CBO estimates that the bill would increase direct spending by \$5 million over 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 filed because they are not converted to an electronic format. Therefore, CBO expects that enacting H.R. 3528 would reduce the number of prescriptions filed and estimates that Medicare spending would be reduced by \$250 million over the 2019–2028 period.

*H.R. 4841, the Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018*, would require health care professionals to submit prior authorization requests electronically, starting on January 1, 2021, for drugs covered under Medicare Part D. Taking into account that many prescribers already use electronic methods to submit such requests, CBO estimates that enacting H.R. 4841 would not significantly affect direct spending for Part D.

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

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

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

*H.R. 5675, a bill to amend title XVIII of the Social Security Act to require prescription drug plan sponsors under the Medicare program to establish drug management programs for at-risk beneficiaries*, would require Part D prescription drug plans to provide drug management programs for Medicare beneficiaries who are at risk for prescription drug abuse. (Under current law, Part D plans are permitted but not required to establish such programs as of 2019.) Based on an analysis of the number of plans currently providing those programs, CBO estimates that enacting H.R. 5675 would lower federal spending by \$64 million over the 2019–2028 period by reducing the number of prescriptions filled and Medicare's payments for controlled substances.

*H.R. 5684, the Protecting Seniors From Opioid Abuse Act*, would expand medication therapy management programs under Medicare Part D to include beneficiaries who are at risk for prescription drug abuse. Because relatively few beneficiaries would be affected by this bill, CBO estimates that its enactment would not significantly affect direct spending for Part D.

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

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

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

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

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

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

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

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

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

#### *Spending subject to appropriation*

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

- Bills that would have no budgetary effect,

- Bills with provisions that would authorize specified amounts to be appropriated (see Table 2),
- Bills with provisions for which CBO has estimated an authorization of appropriations (see Table 3), and
- Bills with provisions that would affect spending subject to appropriation for which CBO has not yet completed an estimate.

No Budgetary Effect. CBO estimates that 6 of the 59 bills would have no effect on direct spending, revenues, or spending subject to appropriation.

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

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

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

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

*H.R. 5686, the Medicare Clear Health Options in Care for Enrollees Act of 2018*, would require prescription drug plans that provide coverage under Medicare Part D to furnish information to beneficiaries about the risks of opioid use and the availability of alternative treatments for pain. CBO estimates that enacting the bill would not affect direct spending because the required activities would not impose significant administrative costs.

*H.R. 5716, the Commit to Opioid Medical Prescriber Accountability and Safety for Seniors Act*, would require the Secretary of HHS on an annual basis to identify high prescribers of opioids and furnish them with information about proper prescribing methods. Because HHS already has the capacity to meet those requirements,

CBO estimates that enacting that provision would not impose additional administrative costs on the agency.

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

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

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

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

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

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

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

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

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

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

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

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

*H.R. 5353, the Eliminating Opioid Related Infectious Diseases Act of 2018*, would amend the Public Health Service Act by broadening the focus of surveillance and education programs from preventing and treating hepatitis C virus to preventing and treating infections associated with injection drug use. It would authorize \$40 million

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

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

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

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

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

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

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

TABLE 3.—ESTIMATED SPENDING SUBJECT TO APPROPRIATION FOR BILLS WITH ESTIMATED AUTHORIZATIONS

	By fiscal year, in millions of dollars—						
	2018	2019	2020	2021	2022	2023	2019–2023
<b>INCREASES IN SPENDING SUBJECT TO APPROPRIATION</b>							
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: <sup>a</sup>							
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	*	*
<b>Total, H.R. 5333:</b>							
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	–40	–50	–51	–53	–55	–257
Spending of fees:							
Animal drug fees .....	0	30	31	32	33	34	159
Generic animal drug fees .....	0	18	19	19	20	21	97
Total, Estimated Authorization Level .....	0	49	50	51	53	55	257
Total, Estimated Outlays .....	0	39	47	51	52	54	243

TABLE 3.—ESTIMATED SPENDING SUBJECT TO APPROPRIATION FOR BILLS WITH ESTIMATED AUTHORIZATIONS—Continued

	By fiscal year, in millions of dollars—						
	2018	2019	2020	2021	2022	2023	2019–2023
Net changes in fees:							
Estimated Authorization Level .....	0	0	0	0	0	0	0
Estimated Outlays .....	0	–10	–3	*	*	*	–14
Other effects:							
Estimated Authorization Level .....	0	3	1	1	1	1	6
Estimated Outlays .....	0	2	1	1	1	1	6
<b>Total, H.R. 5554:</b>							
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: <sup>a</sup>							
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.

<sup>a</sup>This bill also would affect mandatory spending (see Table 1).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*H.R. 5715, the Strengthening Partnerships to Prevent Opioid Abuse Act*, would require the Secretary of HHS to establish a secure Internet portal to allow HHS, Medicare Advantage plans, and Medicare Part D plans to exchange information about fraud, waste, and abuse among providers and suppliers no later than two years after enactment. H.R. 5715 also would require organizations with Medicare Advantage contracts to submit information on investigations related to providers suspected of prescribing large volumes of opioids through a process established by the Secretary no later than January 2021. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5715 would cost approximately \$9 million over the 2019–2023 period.

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

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

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

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

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

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

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

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

**Pay-As-You-Go considerations:** The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. Twenty-two of the bills discussed in this document contain direct spending or revenues and are subject to pay-as-you-go procedures. Details about the amount of direct spending and revenues in those bills can be found in Table 1.

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

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

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

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

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

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

#### *Mandates Affecting Public and Private Entities*

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

#### *Mandates Affecting Private Entities*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### FEDERAL MANDATES STATEMENT

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

#### STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to authorize a demonstration project to expand treatment capacity of current and new Medicaid providers.

#### DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 5477 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. 5477 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. 5477 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 “Rural Development of Opioid Capacity Services Act” or the “Rural DOCS Act.”

*Section 2. Demonstration project to increase substance use provider capacity under the Medicaid Program*

Section 2 amends section 1903 of the Social Security Act. Section 2 authorizes a demonstration project to expand treatment capacity of current and new Medicaid providers through expanding technical assistance to Medicaid providers for Medicaid billing and substance use disorder education and allowing states to receive enhanced matching dollars to raise reimbursement rates for providers delivering SUD services. Section 2 includes planning grants for at least ten states to develop applications for the demonstration project and recruit prospective Medicaid providers.

Section 2 allows for five states to participate in the demonstration and receive an enhanced FMAP. These five states would be eligible to receive an 80 percent match for new spending on activities in the demonstration.

Finally, section 2 requires the states and CMS to conduct robust evaluations of the demonstrations and requires a report detailing best practices.

## CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

**SOCIAL SECURITY ACT**

\*        \*        \*        \*        \*        \*        \*

TITLE XIX—GRANTS TO STATES FOR MEDICAL ASSISTANCE  
PROGRAMS

\*        \*        \*        \*        \*        \*        \*

PAYMENT TO STATES

SEC. 1903. (a) From the sums appropriated therefor, the Secretary (except as otherwise provided in this section) shall pay to each State which has a plan approved under this title, for each quarter, beginning with the quarter commencing January 1, 1966—

(1) an amount equal to the Federal medical assistance percentage (as defined in section 1905(b), subject to subsections (g) and (j) of this section and subsection 1923(f)) of the total amount expended during such quarter as medical assistance under the State plan; plus

(2)(A) an amount equal to 75 per centum of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to compensation or training of skilled professional medical personnel, and staff directly supporting such personnel, of the State agency or any other public agency; plus

(B) notwithstanding paragraph (1) or subparagraph (A), with respect to amounts expended for nursing aide training and competency evaluation programs, and competency evaluation programs, described in section 1919(e)(1) (including the costs for nurse aides to complete such competency evaluation programs), regardless of whether the programs are provided in or outside nursing facilities or of the skill of the personnel involved in such programs, an amount equal to 50 percent (or, for calendar quarters beginning on or after July 1, 1988, and before October 1, 1990, the lesser of 90 percent or the Federal medical assistance percentage plus 25 percentage points) of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to such programs; plus

(C) an amount equal to 75 percent of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to preadmission screening and resident review activities conducted by the State under section 1919(e)(7); plus

(D) for each calendar quarter during—

(i) fiscal year 1991, an amount equal to 90 percent,

(ii) fiscal year 1992, an amount equal to 85 percent,

(iii) fiscal year 1993, an amount equal to 80 percent, and

(iv) fiscal year 1994 and thereafter, an amount equal to 75 percent,

of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient

administration of the State plan) as are attributable to State activities under section 1919(g); plus

(E) an amount equal to 75 percent of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to translation or interpretation services in connection with the enrollment of, retention of, and use of services under this title by, children of families for whom English is not the primary language; plus

(3) an amount equal to—

(A)(i) 90 per centum of so much of the sums expended during such quarter as are attributable to the design, development, or installation of such mechanized claims processing and information retrieval systems as the Secretary determines are likely to provide more efficient, economical, and effective administration of the plan and to be compatible with the claims processing and information retrieval systems utilized in the administration of title XVIII, including the State's share of the cost of installing such a system to be used jointly in the administration of such State's plan and the plan of any other State approved under this title,

(ii) 90 per centum of so much of the sums expended during any such quarter in the fiscal year ending June 30, 1972, or the fiscal year ending June 30, 1973, as are attributable to the design, development, or installation of cost determination systems for State-owned general hospitals (except that the total amount paid to all States under this clause for either such fiscal year shall not exceed \$150,000), and

(iii) an amount equal to the Federal medical assistance percentage (as defined in section 1905(b)) of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to such developments or modifications of systems of the type described in clause (i) as are necessary for the efficient collection and reporting on child health measures; and

(B) 75 per centum of so much of the sums expended during such quarter as are attributable to the operation of systems (whether such systems are operated directly by the State or by another person under a contract with the State) of the type described in subparagraph (A)(i) (whether or not designed, developed, or installed with assistance under such subparagraph) which are approved by the Secretary and which include provision for prompt written notice to each individual who is furnished services covered by the plan, or to each individual in a sample group of individuals who are furnished such services, of the specific services (other than confidential services) so covered, the name of the person or persons furnishing the services, the date or dates on which the services were furnished, and the amount of the payment or payments made under the plan on account of the services; and

(C)(i) 75 per centum of the sums expended with respect to costs incurred during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to the performance of medical and utilization review by a utilization and quality control peer review organization or by an entity which meets the requirements of section 1152, as determined by the Secretary, under a contract entered into under section 1902(d); and

(ii) 75 percent of the sums expended with respect to costs incurred during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to the performance of independent external reviews conducted under section 1932(c)(2); and

(D) 75 percent of so much of the sums expended by the State plan during a quarter in 1991, 1992, or 1993, as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of section 1927(g);

(E) 50 percent of the sums expended with respect to costs incurred during such quarter as are attributable to providing—

(i) services to identify and educate individuals who are likely to be eligible for medical assistance under this title and who have Sickle Cell Disease or who are carriers of the sickle cell gene, including education regarding how to identify such individuals; or

(ii) education regarding the risks of stroke and other complications, as well as the prevention of stroke and other complications, in individuals who are likely to be eligible for medical assistance under this title and who have Sickle Cell Disease; and

(F)(i) 100 percent of so much of the sums expended during such quarter as are attributable to payments to Medicaid providers described in subsection (t)(1) to encourage the adoption and use of certified EHR technology; and

(ii) 90 percent of so much of the sums expended during such quarter as are attributable to payments for reasonable administrative expenses related to the administration of payments described in clause (i) if the State meets the condition described in subsection (t)(9); plus

(H)(i) 90 percent of the sums expended during the quarter as are attributable to the design, development, or installation of such mechanized verification and information retrieval systems as the Secretary determines are necessary to implement section 1902(ee) (including a system described in paragraph (2)(B) thereof), and

(ii) 75 percent of the sums expended during the quarter as are attributable to the operation of systems to which clause (i) applies, plus

(4) an amount equal to 100 percent of the sums expended during the quarter which are attributable to the costs of the implementation and operation of the immigration status verification system described in section 1137(d); plus

(5) an amount equal to 90 per centum of the sums expended during such quarter which are attributable to the offering, arranging, and furnishing (directly or on a contract basis) of family planning services and supplies;

(6) subject to subsection (b)(3), an amount equal to—

(A) 90 per centum of the sums expended during such a quarter within the twelve-quarter period beginning with the first quarter in which a payment is made to the State pursuant to this paragraph, and

(B) 75 per centum of the sums expended during each succeeding calendar quarter, with respect to costs incurred during such quarter (as found necessary by the Secretary for the elimination of fraud in the provision and administration of medical assistance provided under the State plan) which are attributable to the establishment and operation of (including the training of personnel employed by) a State medicaid fraud control unit (described in subsection (q)); plus

(7) subject to section 1919(g)(3)(B), an amount equal to 50 per centum of the remainder of the amounts expended during such quarter as found necessary by the Secretary for the proper and efficient administration of the State plan.

(b)(1) Notwithstanding the preceding provisions of this section, the amount determined under subsection (a)(1) for any State for any quarter beginning after December 31, 1969, shall not take into account any amounts expended as medical assistance with respect to individuals aged 65 or over and disabled individuals entitled to hospital insurance benefits under title XVIII which would not have been so expended if the individuals involved had been enrolled in the insurance program established by part B of title XVIII, other than amounts expended under provisions of the plan of such State required by section 1902(a)(34).

(2) For limitation on Federal participation for capital expenditures which are out of conformity with a comprehensive plan of a State or areawide planning agency, see section 1122.

(3) The amount of funds which the Secretary is otherwise obligated to pay a State during a quarter under subsection (a)(6) may not exceed the higher of—

(A) \$125,000, or

(B) one-quarter of 1 per centum of the sums expended by the Federal, State, and local governments during the previous quarter in carrying out the State's plan under this title.

(4) Amounts expended by a State for the use of an enrollment broker in marketing medicaid managed care organizations and other managed care entities to eligible individuals under this title shall be considered, for purposes of subsection (a)(7), to be necessary for the proper and efficient administration of the State plan but only if the following conditions are met with respect to the broker:

(A) The broker is independent of any such entity and of any health care providers (whether or not any such provider participates in the State plan under this title) that provide coverage of services in the same State in which the broker is conducting enrollment activities.

(B) No person who is an owner, employee, consultant, or has a contract with the broker either has any direct or indirect financial interest with such an entity or health care provider or has been excluded from participation in the program under this title or title XVIII or debarred by any Federal agency, or subject to a civil money penalty under this Act.

(5) Notwithstanding the preceding provisions of this section, the amount determined under subsection (a)(1) for any State shall be decreased in a quarter by the amount of any health care related taxes (described in section 1902(w)(3)(A)) that are imposed on a hospital described in subsection (w)(3)(F) in that quarter.

(c) Nothing in this title shall be construed as prohibiting or restricting, or authorizing the Secretary to prohibit or restrict, payment under subsection (a) for medical assistance for covered services furnished to a child with a disability because such services are included in the child's individualized education program established pursuant to part B of the Individuals with Disabilities Education Act or furnished to an infant or toddler with a disability because such services are included in the child's individualized family service plan adopted pursuant to part C of such Act.

(d)(1) Prior to the beginning of each quarter, the Secretary shall estimate the amount to which a State will be entitled under subsections (a) and (b) for such quarter, such estimates to be based on (A) a report filed by the State containing its estimate of the total sum to be expended in such quarter in accordance with the provisions of such subsections, and stating the amount appropriated or made available by the State and its political subdivisions for such expenditures in such quarter, and if such amount is less than the State's proportionate share of the total sum of such estimated expenditures, the source or sources from which the difference is expected to be derived, and (B) such other investigation as the Secretary may find necessary.

(2)(A) The Secretary shall then pay to the State, in such installments as he may determine, the amount so estimated, reduced or increased to the extent of any overpayment or underpayment which the Secretary determines was made under this section to such State for any prior quarter and with respect to which adjustment has not already been made under this subsection.

(B) Expenditures for which payments were made to the State under subsection (a) shall be treated as an overpayment to the extent that the State or local agency administering such plan has been reimbursed for such expenditures by a third party pursuant to the provisions of its plan in compliance with section 1902(a)(25).

(C) For purposes of this subsection, when an overpayment is discovered, which was made by a State to a person or other entity, the State shall have a period of 1 year in which to recover or attempt to recover such overpayment before adjustment is made in the Federal payment to such State on account of such overpayment. Except as otherwise provided in subparagraph (D), the adjustment in the Federal payment shall be made at the end of the 1-year period, whether or not recovery was made.

(D)(i) In any case where the State is unable to recover a debt which represents an overpayment (or any portion thereof) made to a person or other entity on account of such debt having been discharged in bankruptcy or otherwise being uncollectable, no adjust-

ment shall be made in the Federal payment to such State on account of such overpayment (or portion thereof).

(ii) In any case where the State is unable to recover a debt which represents an overpayment (or any portion thereof) made to a person or other entity due to fraud within 1 year of discovery because there is not a final determination of the amount of the overpayment under an administrative or judicial process (as applicable), including as a result of a judgment being under appeal, no adjustment shall be made in the Federal payment to such State on account of such overpayment (or portion thereof) before the date that is 30 days after the date on which a final judgment (including, if applicable, a final determination on an appeal) is made.

(3)(A) The pro rata share to which the United States is equitably entitled, as determined by the Secretary, of the net amount recovered during any quarter by the State or any political subdivision thereof with respect to medical assistance furnished under the State plan shall be considered an overpayment to be adjusted under this subsection.

(B)(i) Subparagraph (A) and paragraph (2)(B) shall not apply to any amount recovered or paid to a State as part of the comprehensive settlement of November 1998 between manufacturers of tobacco products, as defined in section 5702(d) of the Internal Revenue Code of 1986, and State Attorneys General, or as part of any individual State settlement or judgment reached in litigation initiated or pursued by a State against one or more such manufacturers.

(ii) Except as provided in subsection (i)(19), a State may use amounts recovered or paid to the State as part of a comprehensive or individual settlement, or a judgment, described in clause (i) for any expenditures determined appropriate by the State.

(4) Upon the making of any estimate by the Secretary under this subsection, any appropriations available for payments under this section shall be deemed obligated.

(5) In any case in which the Secretary estimates that there has been an overpayment under this section to a State on the basis of a claim by such State that has been disallowed by the Secretary under section 1116(d), and such State disputes such disallowance, the amount of the Federal payment in controversy shall, at the option of the State, be retained by such State or recovered by the Secretary pending a final determination with respect to such payment amount. If such final determination is to the effect that any amount was properly disallowed, and the State chose to retain payment of the amount in controversy, the Secretary shall offset, from any subsequent payments made to such State under this title, an amount equal to the proper amount of the disallowance plus interest on such amount disallowed for the period beginning on the date such amount was disallowed and ending on the date of such final determination at a rate (determined by the Secretary) based on the average of the bond equivalent of the weekly 90-day treasury bill auction rates during such period.

(6)(A) Each State (as defined in subsection (w)(7)(D)) shall include, in the first report submitted under paragraph (1) after the end of each fiscal year, information related to—

(i) provider-related donations made to the State or units of local government during such fiscal year, and

(ii) health care related taxes collected by the State or such units during such fiscal year.

(B) Each State shall include, in the first report submitted under paragraph (1) after the end of each fiscal year, information related to the total amount of payment adjustments made, and the amount of payment adjustments made to individual providers (by provider), under section 1923(c) during such fiscal year.

(e) A State plan approved under this title may include, as a cost with respect to hospital services under the plan under this title, periodic expenditures made to reflect transitional allowances established with respect to a hospital closure or conversion under section 1884.

(f)(1)(A) Except as provided in paragraph (4), payment under the preceding provisions of this section shall not be made with respect to any amount expended as medical assistance in a calendar quarter, in any State, for any member of a family the annual income of which exceeds the applicable income limitation determined under this paragraph.

(B)(i) Except as provided in clause (ii) of this subparagraph, the applicable income limitation with respect to any family is the amount determined, in accordance with standards prescribed by the Secretary, to be equivalent to 133 $\frac{1}{3}$  percent of the highest amount which would ordinarily be paid to a family of the same size without any income or resources, in the form of money payments, under the plan of the State approved under part A of title IV of this Act.

(ii) If the Secretary finds that the operation of a uniform maximum limits payments to families of more than one size, he may adjust the amount otherwise determined under clause (i) to take account of families of different sizes.

(C) The total amount of any applicable income limitation determined under subparagraph (B) shall, if it is not a multiple of \$100 or such other amount as the Secretary may prescribe, be rounded to the next higher multiple of \$100 or such other amount, as the case may be.

(2)(A) In computing a family's income for purposes of paragraph (1), there shall be excluded any costs (whether in the form of insurance premiums or otherwise and regardless of whether such costs are reimbursed under another public program of the State or political subdivision thereof) incurred by such family for medical care or for any other type of remedial care recognized under State law or, (B) notwithstanding section 1916 at State option, an amount paid by such family, at the family's option, to the State, provided that the amount, when combined with costs incurred in prior months, is sufficient when excluded from the family's income to reduce such family's income below the applicable income limitation described in paragraph (1). The amount of State expenditures for which medical assistance is available under subsection (a)(1) will be reduced by amounts paid to the State pursuant to this subparagraph.

(3) For purposes of paragraph (1)(B), in the case of a family consisting of only one individual, the "highest amount which would ordinarily be paid" to such family under the State's plan approved under part A of title IV of this Act shall be the amount determined by the State agency (on the basis of reasonable relationship to the

amounts payable under such plan to families consisting of two or more persons) to be the amount of the aid which would ordinarily be payable under such plan to a family (without any income or resources) consisting of one person if such plan provided for aid to such a family.

(4) The limitations on payment imposed by the preceding provisions of this subsection shall not apply with respect to any amount expended by a State as medical assistance for any individual described in section 1902(a)(10)(A)(i)(III), 1902(a)(10)(A)(i)(IV), 1902(a)(10)(A)(i)(V), 1902(a)(10)(A)(i)(VI), 1902(a)(10)(A)(i)(VII), 1902(a)(10)(A)(i)(VIII), 1902(a)(10)(A)(i)(IX), 1902(a)(10)(A)(ii)(IX), 1902(a)(10)(A)(ii)(X), 1902(a)(10)(A)(ii)(XIII), 1902(a)(10)(A)(ii)(XIV), or 1902(a)(10)(A)(ii)(XV), 1902(a)(10)(A)(ii)(XVI), 1902(a)(10)(A)(ii)(XVII), 1902(a)(10)(A)(ii)(XVIII), 1902(a)(10)(A)(ii)(XIX), 1902(a)(10)(A)(ii)(XX), 1902(a)(10)(A)(ii)(XXI), 1902(a)(10)(A)(ii)(XXII), 1905(p)(1) or for any individual—

(A) who is receiving aid or assistance under any plan of the State approved under title I, X, XIV or XVI, or part A of title IV, or with respect to whom supplemental security income benefits are being paid under title XVI, or

(B) who is not receiving such aid or assistance, and with respect to whom such benefits are not being paid, but (i) is eligible to receive such aid or assistance, or to have such benefits paid with respect to him, or (ii) would be eligible to receive such aid or assistance, or to have such benefits paid with respect to him if he were not in a medical institution, or

(C) with respect to whom there is being paid, or who is eligible, or would be eligible if he were not in a medical institution, to have paid with respect to him, a State supplementary payment and is eligible for medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in section 1902(a)(10)(A), or who is a PACE program eligible individual enrolled in a PACE program under section 1934, but only if the income of such individual (as determined under section 1612, but without regard to subsection (b) thereof) does not exceed 300 percent of the supplemental security income benefit rate established by section 1611(b)(1),

at the time of the provision of the medical assistance giving rise to such expenditure.

(g)(1) Subject to paragraph (3), with respect to amounts paid for the following services furnished under the State plan after June 30, 1973 (other than services furnished pursuant to a contract with a health maintenance organization as defined in section 1876 or which is a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Service Act)), the Federal medical assistance percentage shall be decreased as follows: After an individual has received inpatient hospital services or services in an intermediate care facility for the mentally retarded for 60 days or inpatient mental hospital services for 90 days (whether or not such days are consecutive), during any fiscal year, the Federal medical assistance percentage with respect to amounts paid for any such care furnished thereafter to such individual shall be decreased by a per centum thereof (determined under paragraph (5)) unless the

State agency responsible for the administration of the plan makes a showing satisfactory to the Secretary that, with respect to each calendar quarter for which the State submits a request for payment at the full Federal medical assistance percentage for amounts paid for inpatient hospital services or services in an intermediate care facility for the mentally retarded furnished beyond 60 days (or inpatient mental hospital services furnished beyond 90 days), such State has an effective program of medical review of the care of patients in mental hospitals and intermediate care facilities for the mentally retarded pursuant to paragraphs (26) and (31) of section 1902(a) whereby the professional management of each case is reviewed and evaluated at least annually by independent professional review teams. In determining the number of days on which an individual has received services described in this subsection, there shall not be counted any days with respect to which such individual is entitled to have payments made (in whole or in part) on his behalf under section 1812.

(2) The Secretary shall, as part of his validation procedures under this subsection, conduct timely sample onsite surveys of private and public institutions in which recipients of medical assistance may receive care and services under a State plan approved under this title, and his findings with respect to such surveys (as well as the showings of the State agency required under this subsection) shall be made available for public inspection.

(3)(A) No reduction in the Federal medical assistance percentage of a State otherwise required to be imposed under this subsection shall take effect—

(i) if such reduction is due to the State's unsatisfactory or invalid showing made with respect to a calendar quarter beginning before January 1, 1977;

(ii) before January 1, 1978;

(iii) unless a notice of such reduction has been provided to the State at least 30 days before the date such reduction takes effect; or

(iv) due to the State's unsatisfactory or invalid showing made with respect to a calendar quarter beginning after September 30, 1977, unless notice of such reduction has been provided to the State no later than the first day of the fourth calendar quarter following the calendar quarter with respect to which such showing was made.

(B) The Secretary shall waive application of any reduction in the Federal medical assistance percentage of a State otherwise required to be imposed under paragraph (1) because a showing by the State, made under such paragraph with respect to a calendar quarter ending after January 1, 1977, and before January 1, 1978, is determined to be either unsatisfactory under such paragraph or invalid under paragraph (2), if the Secretary determines that the State's showing made under paragraph (1) with respect to any calendar quarter ending on or before December 31, 1978, is satisfactory under such paragraph and is valid under paragraph (2).

(4)(A) The Secretary may not find the showing of a State, with respect to a calendar quarter under paragraph (1), to be satisfactory if the showing is submitted to the Secretary later than the 30th day after the last day of the calendar quarter, unless the

State demonstrates to the satisfaction of the Secretary good cause for not meeting such deadline.

(B) The Secretary shall find a showing of a State, with respect to a calendar quarter under paragraph (1), to be satisfactory under such paragraph with respect to the requirement that the State conduct annual onsite inspections in mental hospitals and intermediate care facilities for the mentally retarded under paragraphs (26) and (31) of section 1902(a), if the showing demonstrates that the State has conducted such an onsite inspection during the 12-month period ending on the last date of the calendar quarter—

- (i) in each of not less than 98 per centum of the number of such hospitals and facilities requiring such inspection, and
- (ii) in every such hospital or facility which has 200 or more beds,

and that, with respect to such hospitals and facilities not inspected within such period, the State has exercised good faith and due diligence in attempting to conduct such inspection, or if the State demonstrates to the satisfaction of the Secretary that it would have made such a showing but for failings of a technical nature only.

(5) In the case of a State's unsatisfactory or invalid showing made with respect to a type of facility or institutional services in a calendar quarter, the per centum amount of the reduction of the State's Federal medical assistance percentage for that type of services under paragraph (1) is equal to  $33\frac{1}{3}$  per centum multiplied by a fraction, the denominator of which is equal to the total number of patients receiving that type of services in that quarter under the State plan in facilities or institutions for which a showing was required to be made under this subsection, and the numerator of which is equal to the number of such patients receiving such type of services in that quarter in those facilities or institutions for which a satisfactory and valid showing was not made for that calendar quarter.

(6)(A) Recertifications required under section 1902(a)(44) shall be conducted at least every 60 days in the case of inpatient hospital services.

(B) Such recertifications in the case of services in an intermediate care facility for the mentally retarded shall be conducted at least—

- (i) 60 days after the date of the initial certification,
- (ii) 180 days after the date of the initial certification,
- (iii) 12 months after the date of the initial certification,
- (iv) 18 months after the date of the initial certification,
- (v) 24 months after the date of the initial certification, and
- (vi) every 12 months thereafter.

(C) For purposes of determining compliance with the schedule established by this paragraph, a recertification shall be considered to have been done on a timely basis if it was performed not later than 10 days after the date the recertification was otherwise required and the State establishes good cause why the physician or other person making such recertification did not meet such schedule.

(i) Payment under the preceding provisions of this section shall not be made—

- (1) for organ transplant procedures unless the State plan provides for written standards respecting the coverage of such procedures and unless such standards provide that—

- (A) similarly situated individuals are treated alike; and
- (B) any restriction, on the facilities or practitioners which may provide such procedures, is consistent with the accessibility of high quality care to individuals eligible for the procedures under the State plan; or
- (2) with respect to any amount expended for an item or service (other than an emergency item or service, not including items or services furnished in an emergency room of a hospital) furnished—
- (A) under the plan by any individual or entity during any period when the individual or entity is excluded from participation under title V, XVIII, or XX or under this title pursuant to section 1128, 1128A, 1156, or 1842(j)(2);
- (B) at the medical direction or on the prescription of a physician, during the period when such physician is excluded from participation under title V, XVIII, or XX or under this title pursuant to section 1128, 1128A, 1156, or 1842(j)(2) and when the person furnishing such item or service knew or had reason to know of the exclusion (after a reasonable time period after reasonable notice has been furnished to the person);
- (C) by any individual or entity to whom the State has failed to suspend payments under the plan during any period when there is pending an investigation of a credible allegation of fraud against the individual or entity, as determined by the State in accordance with regulations promulgated by the Secretary for purposes of section 1862(o) and this subparagraph, unless the State determines in accordance with such regulations there is good cause not to suspend such payments;
- (D) beginning on July 1, 2018, under the plan by any provider of services or person whose participation in the State plan is terminated (as described in section 1902(kk)(8)) after the date that is 60 days after the date on which such termination is included in the database or other system under section 1902(ll); or
- (E) with respect to any amount expended for such an item or service furnished during calendar quarters beginning on or after October 1, 2017, subject to section 1902(kk)(4)(A)(ii)(II), within a geographic area that is subject to a moratorium imposed under section 1866(j)(7) by a provider or supplier that meets the requirements specified in subparagraph (C)(iii) of such section, during the period of such moratorium; or
- (3) with respect to any amount expended for inpatient hospital services furnished under the plan (other than amounts attributable to the special situation of a hospital which serves a disproportionate number of low income patients with special needs) to the extent that such amount exceeds the hospital's customary charges with respect to such services or (if such services are furnished under the plan by a public institution free of charge or at nominal charges to the public) exceeds an amount determined on the basis of those items (specified in regulations prescribed by the Secretary) included in the deter-

mination of such payment which the Secretary finds will provide fair compensation to such institution for such services; or

(4) with respect to any amount expended for care or services furnished under the plan by a hospital unless such hospital has in effect a utilization review plan which meets the requirements imposed by section 1861(k) for purposes of title XVIII; and if such hospital has in effect such a utilization review plan for purposes of title XVIII, such plan shall serve as the plan required by this subsection (with the same standards and procedures and the same review committee or group) as a condition of payment under this title; the Secretary is authorized to waive the requirements of this paragraph if the State agency demonstrates to his satisfaction that it has in operation utilization review procedures which are superior in their effectiveness to the procedures required under section 1861(k); or

(5) with respect to any amount expended for any drug product for which payment may not be made under part B of title XVIII because of section 1862(c); or

(6) with respect to any amount expended for inpatient hospital tests (other than in emergency situations) not specifically ordered by the attending physician or other responsible practitioner; or

(7) with respect to any amount expended for clinical diagnostic laboratory tests performed by a physician, independent laboratory, or hospital, to the extent such amount exceeds the amount that would be recognized under section 1833(h) for such tests performed for an individual enrolled under part B of title XVIII; or

(8) with respect to any amount expended for medical assistance (A) for nursing facility services to reimburse (or otherwise compensate) a nursing facility for payment of a civil money penalty imposed under section 1919(h) or (B) for home and community care to reimburse (or otherwise compensate) a provider of such care for payment of a civil money penalty imposed under this title or title XI or for legal expenses in defense of an exclusion or civil money penalty under this title or title XI if there is no reasonable legal ground for the provider's case; or

(10)(A) with respect to covered outpatient drugs unless there is a rebate agreement in effect under section 1927 with respect to such drugs or unless section 1927(a)(3) applies,

(B) with respect to any amount expended for an innovator multiple source drug (as defined in section 1927(k)) dispensed on or after July 1, 1991, if, under applicable State law, a less expensive multiple source drug could have been dispensed, but only to the extent that such amount exceeds the upper payment limit for such multiple source drug;

(C) with respect to covered outpatient drugs described in section 1927(a)(7), unless information respecting utilization data and coding on such drugs that is required to be submitted under such section is submitted in accordance with such section, and

(D) with respect to any amount expended for reimbursement to a pharmacy under this title for the ingredient cost of a covered outpatient drug for which the pharmacy has already re-

ceived payment under this title (other than with respect to a reasonable restocking fee for such drug); or

(11) with respect to any amount expended for physicians' services furnished on or after the first day of the first quarter beginning more than 60 days after the date of establishment of the physician identifier system under section 1902(x), unless the claim for the services includes the unique physician identifier provided under such system; or

(13) with respect to any amount expended to reimburse (or otherwise compensate) a nursing facility for payment of legal expenses associated with any action initiated by the facility that is dismissed on the basis that no reasonable legal ground existed for the institution of such action; or

(14) with respect to any amount expended on administrative costs to carry out the program under section 1928; or

(15) with respect to any amount expended for a single-antigen vaccine and its administration in any case in which the administration of a combined-antigen vaccine was medically appropriate (as determined by the Secretary); or

(16) with respect to any amount expended for which funds may not be used under the Assisted Suicide Funding Restriction Act of 1997; or

(17) with respect to any amount expended for roads, bridges, stadiums, or any other item or service not covered under a State plan under this title; or

(18) with respect to any amount expended for home health care services provided by an agency or organization unless the agency or organization provides the State agency on a continuing basis a surety bond in a form specified by the Secretary under paragraph (7) of section 1861(o) and in an amount that is not less than \$50,000 or such comparable surety bond as the Secretary may permit under the last sentence of such section; or

(19) with respect to any amount expended on administrative costs to initiate or pursue litigation described in subsection (d)(3)(B);

(20) with respect to amounts expended for medical assistance provided to an individual described in subclause (XV) or (XVI) of section 1902(a)(10)(A)(ii) for a fiscal year unless the State demonstrates to the satisfaction of the Secretary that the level of State funds expended for such fiscal year for programs to enable working individuals with disabilities to work (other than for such medical assistance) is not less than the level expended for such programs during the most recent State fiscal year ending before the date of the enactment of this paragraph;

(21) with respect to amounts expended for covered outpatient drugs described in section 1927(d)(2)(C) (relating to drugs when used for cosmetic purposes or hair growth), except where medically necessary, and section 1927(d)(2)(K) (relating to drugs when used for treatment of sexual or erectile dysfunction);

(22) with respect to amounts expended for medical assistance for an individual who declares under section 1137(d)(1)(A) to be a citizen or national of the United States for purposes of estab-

lishing eligibility for benefits under this title, unless the requirement of section 1902(a)(46)(B) is met;

(23) with respect to amounts expended for medical assistance for covered outpatient drugs (as defined in section 1927(k)(2)) for which the prescription was executed in written (and non-electronic) form unless the prescription was executed on a tamper-resistant pad;

(24) if a State is required to implement an asset verification program under section 1940 and fails to implement such program in accordance with such section, with respect to amounts expended by such State for medical assistance for individuals subject to asset verification under such section, unless—

(A) the State demonstrates to the Secretary's satisfaction that the State made a good faith effort to comply;

(B) not later than 60 days after the date of a finding that the State is in noncompliance, the State submits to the Secretary (and the Secretary approves) a corrective action plan to remedy such noncompliance; and

(C) not later than 12 months after the date of such submission (and approval), the State fulfills the terms of such corrective action plan;

(25) with respect to any amounts expended for medical assistance for individuals for whom the State does not report enrollee encounter data (as defined by the Secretary) to the Medicaid Statistical Information System (MSIS) in a timely manner (as determined by the Secretary);

(26) with respect to any amounts expended for medical assistance for individuals described in subclause (VIII) of subsection (a)(10)(A)(i) other than medical assistance provided through benchmark coverage described in section 1937(b)(1) or benchmark equivalent coverage described in section 1937(b)(2); or

(27) with respect to any amounts expended by the State on the basis of a fee schedule for items described in section 1861(n) and furnished on or after January 1, 2018, as determined in the aggregate with respect to each class of such items as defined by the Secretary, in excess of the aggregate amount, if any, that would be paid for such items within such class on a fee-for-service basis under the program under part B of title XVIII, including, as applicable, under a competitive acquisition program under section 1847 in an area of the State.

Nothing in paragraph (1) shall be construed as permitting a State to provide services under its plan under this title that are not reasonable in amount, duration, and scope to achieve their purpose. Paragraphs (1), (2), (16), (17), and (18) shall apply with respect to items or services furnished and amounts expended by or through a managed care entity (as defined in section 1932(a)(1)(B)) in the same manner as such paragraphs apply to items or services furnished and amounts expended directly by the State.

(j) Notwithstanding the preceding provisions of this section, the amount determined under subsection (a)(1) for any State for any quarter shall be adjusted in accordance with section 1914.

(k) The Secretary is authorized to provide at the request of any State (and without cost to such State) such technical and actuarial assistance as may be necessary to assist such State to contract

with any medicaid managed care organization which meets the requirements of subsection (m) of this section for the purpose of providing medical care and services to individuals who are entitled to medical assistance under this title.

(1)(1) Subject to paragraphs (3) and (4), with respect to any amount expended for personal care services or home health care services requiring an in-home visit by a provider that are provided under a State plan under this title (or under a waiver of the plan) and furnished in a calendar quarter beginning on or after January 1, 2019 (or, in the case of home health care services, on or after January 1, 2023), unless a State requires the use of an electronic visit verification system for such services furnished in such quarter under the plan or such waiver, the Federal medical assistance percentage shall be reduced—

(A) in the case of personal care services—

(i) for calendar quarters in 2019 and 2020, by .25 percentage points;

(ii) for calendar quarters in 2021, by .5 percentage points;

(iii) for calendar quarters in 2022, by .75 percentage points; and

(iv) for calendar quarters in 2023 and each year thereafter, by 1 percentage point; and

(B) in the case of home health care services—

(i) for calendar quarters in 2023 and 2024, by .25 percentage points;

(ii) for calendar quarters in 2025, by .5 percentage points;

(iii) for calendar quarters in 2026, by .75 percentage points; and

(iv) for calendar quarters in 2027 and each year thereafter, by 1 percentage point.

(2) Subject to paragraphs (3) and (4), in implementing the requirement for the use of an electronic visit verification system under paragraph (1), a State shall—

(A) consult with agencies and entities that provide personal care services, home health care services, or both under the State plan (or under a waiver of the plan) to ensure that such system—

(i) is minimally burdensome;

(ii) takes into account existing best practices and electronic visit verification systems in use in the State; and

(iii) is conducted in accordance with the requirements of HIPAA privacy and security law (as defined in section 3009 of the Public Health Service Act);

(B) take into account a stakeholder process that includes input from beneficiaries, family caregivers, individuals who furnish personal care services or home health care services, and other stakeholders, as determined by the State in accordance with guidance from the Secretary; and

(C) ensure that individuals who furnish personal care services, home health care services, or both under the State plan (or under a waiver of the plan) are provided the opportunity for training on the use of such system.

(3) Paragraphs (1) and (2) shall not apply in the case of a State that, as of the date of the enactment of this subsection, requires the use of any system for the electronic verification of visits conducted as part of both personal care services and home health care services, so long as the State continues to require the use of such system with respect to the electronic verification of such visits.

(4)(A) In the case of a State described in subparagraph (B), the reduction under paragraph (1) shall not apply—

- (i) in the case of personal care services, for calendar quarters in 2019; and
- (ii) in the case of home health care services, for calendar quarters in 2023.

(B) For purposes of subparagraph (A), a State described in this subparagraph is a State that demonstrates to the Secretary that the State—

- (i) has made a good faith effort to comply with the requirements of paragraphs (1) and (2) (including by taking steps to adopt the technology used for an electronic visit verification system); and
- (ii) in implementing such a system, has encountered unavoidable system delays.

(5) In this subsection:

(A) The term “electronic visit verification system” means, with respect to personal care services or home health care services, a system under which visits conducted as part of such services are electronically verified with respect to—

- (i) the type of service performed;
- (ii) the individual receiving the service;
- (iii) the date of the service;
- (iv) the location of service delivery;
- (v) the individual providing the service; and
- (vi) the time the service begins and ends.

(B) The term “home health care services” means services described in section 1905(a)(7) provided under a State plan under this title (or under a waiver of the plan).

(C) The term “personal care services” means personal care services provided under a State plan under this title (or under a waiver of the plan), including services provided under section 1905(a)(24), 1915(c), 1915(i), 1915(j), or 1915(k) or under a wavier under section 1115.

(6)(A) In the case in which a State requires personal care service and home health care service providers to utilize an electronic visit verification system operated by the State or a contractor on behalf of the State, the Secretary shall pay to the State, for each quarter, an amount equal to 90 per centum of so much of the sums expended during such quarter as are attributable to the design, development, or installation of such system, and 75 per centum of so much of the sums for the operation and maintenance of such system.

(B) Subparagraph (A) shall not apply in the case in which a State requires personal care service and home health care service providers to utilize an electronic visit verification system that is not operated by the State or a contractor on behalf of the State.

(m)(1)(A) The term “medicaid managed care organization” means a health maintenance organization, an eligible organization with a

contract under section 1876 or a Medicare+Choice organization with a contract under part C of title XVIII, a provider sponsored organization, or any other public or private organization, which meets the requirement of section 1902(w) and—

(i) makes services it provides to individuals eligible for benefits under this title accessible to such individuals, within the area served by the organization, to the same extent as such services are made accessible to individuals (eligible for medical assistance under the State plan) not enrolled with the organization, and

(ii) has made adequate provision against the risk of insolvency, which provision is satisfactory to the State, meets the requirements of subparagraph (C)(i) (if applicable), and which assures that individuals eligible for benefits under this title are in no case held liable for debts of the organization in case of the organization's insolvency.

An organization that is a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Service Act) is deemed to meet the requirements of clauses (i) and (ii).

(B) The duties and functions of the Secretary, insofar as they involve making determinations as to whether an organization is a medicaid managed care organization within the meaning of subparagraph (A), shall be integrated with the administration of section 1312 (a) and (b) of the Public Health Service Act.

(C)(i) Subject to clause (ii), a provision meets the requirements of this subparagraph for an organization if the organization meets solvency standards established by the State for private health maintenance organizations or is licensed or certified by the State as a risk-bearing entity.

(ii) Clause (i) shall not apply to an organization if—

(I) the organization is not responsible for the provision (directly or through arrangements with providers of services) of inpatient hospital services and physicians' services;

(II) the organization is a public entity;

(III) the solvency of the organization is guaranteed by the State; or

(IV) the organization is (or is controlled by) one or more Federally-qualified health centers and meets solvency standards established by the State for such an organization.

For purposes of subclause (IV), the term "control" means the possession, whether direct or indirect, of the power to direct or cause the direction of the management and policies of the organization through membership, board representation, or an ownership interest equal to or greater than 50.1 percent.

(2)(A) Except as provided in subparagraphs (B), (C), and (G), no payment shall be made under this title to a State with respect to expenditures incurred by it for payment (determined under a prepaid capitation basis or under any other risk basis) for services provided by any entity (including a health insuring organization) which is responsible for the provision (directly or through arrangements with providers of services) of inpatient hospital services and any other service described in paragraph (2), (3), (4), (5), or (7) of section 1905(a) or for the provision of any three or more of the services described in such paragraphs unless—

(i) the Secretary has determined that the entity is a medicaid managed care organization organization as defined in paragraph (1);

(iii) such services are provided for the benefit of individuals eligible for benefits under this title in accordance with a contract between the State and the entity under which prepaid payments to the entity are made on an actuarially sound basis and under which the Secretary must provide prior approval for contracts providing for expenditures in excess of \$1,000,000 for 1998 and, for a subsequent year, the amount established under this clause for the previous year increased by the percentage increase in the consumer price index for all urban consumers over the previous year;

(iv) such contract provides that the Secretary and the State (or any person or organization designated by either) shall have the right to audit and inspect any books and records of the entity (and of any subcontractor) that pertain (I) to the ability of the entity to bear the risk of potential financial losses, or (II) to services performed or determinations of amounts payable under the contract;

(v) such contract provides that in the entity's enrollment, re-enrollment, or disenrollment of individuals who are eligible for benefits under this title and eligible to enroll, reenroll, or disenroll with the entity pursuant to the contract, the entity will not discriminate among such individuals on the basis of their health status or requirements for health care services;

(vi) such contract (I) permits individuals who have elected under the plan to enroll with the entity for provision of such benefits to terminate such enrollment in accordance with section 1932(a)(4), and (II) provides for notification in accordance with such section of each such individual, at the time of the individual's enrollment, of such right to terminate such enrollment;

(vii) such contract provides that, in the case of medically necessary services which were provided (I) to an individual enrolled with the entity under the contract and entitled to benefits with respect to such services under the State's plan and (II) other than through the organization because the services were immediately required due to an unforeseen illness, injury, or condition, either the entity or the State provides for reimbursement with respect to those services,

(viii) such contract provides for disclosure of information in accordance with section 1124 and paragraph (4) of this subsection;

(ix) such contract provides, in the case of an entity that has entered into a contract for the provision of services with a Federally-qualified health center or a rural health clinic, that the entity shall provide payment that is not less than the level and amount of payment which the entity would make for the services if the services were furnished by a provider which is not a Federally-qualified health center or a rural health clinic;

(x) any physician incentive plan that it operates meets the requirements described in section 1876(i)(8);

(xi) such contract provides for maintenance of sufficient patient encounter data to identify the physician who delivers

services to patients and for the provision of such data to the State at a frequency and level of detail to be specified by the Secretary;

(xii) such contract, and the entity complies with the applicable requirements of section 1932; and

(xiii) such contract provides that (I) covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the entity shall be subject to the same rebate required by the agreement entered into under section 1927 as the State is subject to and that the State shall collect such rebates from manufacturers, (II) capitation rates paid to the entity shall be based on actual cost experience related to rebates and subject to the Federal regulations requiring actuarially sound rates, and (III) the entity shall report to the State, on such timely and periodic basis as specified by the Secretary in order to include in the information submitted by the State to a manufacturer and the Secretary under section 1927(b)(2)(A), information on the total number of units of each dosage form and strength and package size by National Drug Code of each covered outpatient drug dispensed to individuals eligible for medical assistance who are enrolled with the entity and for which the entity is responsible for coverage of such drug under this subsection (other than covered outpatient drugs that under subsection (j)(1) of section 1927 are not subject to the requirements of that section) and such other data as the Secretary determines necessary to carry out this subsection.

(B) Subparagraph (A) except with respect to clause (ix) of subparagraph (A), does not apply with respect to payments under this title to a State with respect to expenditures incurred by it for payment for services provided by an entity which—

(i)(I) received a grant of at least \$100,000 in the fiscal year ending June 30, 1976, under section 329(d)(1)(A) or 330(d)(1) of the Public Health Service Act, and for the period beginning July 1, 1976, and ending on the expiration of the period for which payments are to be made under this title has been the recipient of a grant under either such section; and

(II) provides to its enrollees, on a prepaid capitation risk basis or on any other risk basis, all of the services and benefits described in paragraphs (1), (2), (3), (4)(C), and (5) of section 1905(a) and, to the extent required by section 1902(a)(10)(D) to be provided under a State plan for medical assistance, the services and benefits described in paragraph (7) of section 1905(a); or

(ii) is a nonprofit primary health care entity located in a rural area (as defined by the Appalachian Regional Commission)—

(I) which received in the fiscal year ending June 30, 1976, at least \$100,000 (by grant, subgrant, or sub-contract) under the Appalachian Regional Development Act of 1965, and

(II) for the period beginning July 1, 1976, and ending on the expiration of the period for which payments are to be made under this title either has been the recipient of a

grant, subgrant, or subcontract under such Act or has provided services under a contract (initially entered into during a year in which the entity was the recipient of such a grant, subgrant, or subcontract) with a State agency under this title on a prepaid capitation risk basis or on any other risk basis; or

(iii) which has contracted with the single State agency for the provision of services (but not including inpatient hospital services) to persons eligible under this title on a prepaid risk basis prior to 1970.

(G) In the case of an entity which is receiving (and has received during the previous two years) a grant of at least \$100,000 under section 329(d)(1)(A) or 330(d)(1) of the Public Health Service Act or is receiving (and has received during the previous two years) at least \$100,000 (by grant, subgrant, or subcontract) under the Appalachian Regional Development Act of 1965, clause (i) of subparagraph (A) shall not apply.

(H) In the case of an individual who—

(i) in a month is eligible for benefits under this title and enrolled with a medicaid managed care organization with a contract under this paragraph or with a primary care case manager with a contract described in section 1905(t)(3),

(ii) in the next month (or in the next 2 months) is not eligible for such benefits, but

(iii) in the succeeding month is again eligible for such benefits,

the State plan, subject to subparagraph (A)(vi), may enroll the individual for that succeeding month with the organization described in clause (i) if the organization continues to have a contract under this paragraph with the State or with the manager described in such clause if the manager continues to have a contract described in section 1905(t)(3) with the State.

(3) No payment shall be made under this title to a State with respect to expenditures incurred by the State for payment for services provided by a managed care entity (as defined under section 1932(a)(1)) under the State plan under this title (or under a waiver of the plan) unless the State—

(A) beginning on July 1, 2018, has a contract with such entity that complies with the requirement specified in section 1932(d)(5); and

(B) beginning on January 1, 2018, complies with the requirement specified in section 1932(d)(6)(A).

(4)(A) Each medicaid managed care organization which is not a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Service Act) must report to the State and, upon request, to the Secretary, the Inspector General of the Department of Health and Human Services, and the Comptroller General a description of transactions between the organization and a party in interest (as defined in section 1318(b) of such Act), including the following transactions:

(i) Any sale or exchange, or leasing of any property between the organization and such a party.

(ii) Any furnishing for consideration of goods, services (including management services), or facilities between the organization and such a party, but not including salaries paid to em-

employees for services provided in the normal course of their employment.

(iii) Any lending of money or other extension of credit between the organization and such a party.

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

(B) Each organization shall make the information reported pursuant to subparagraph (A) available to its enrollees upon reasonable request.

(5)(A) If the Secretary determines that an entity with a contract under this subsection—

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

(ii) imposes premiums on individuals enrolled under this subsection in excess of the premiums permitted under this title;

(iii) acts to discriminate among individuals in violation of the provision of paragraph (2)(A)(v), including expulsion or refusal to re-enroll an individual or engaging in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this subsection) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services;

(iv) misrepresents or falsifies information that is furnished—

(I) to the Secretary or the State under this subsection,

or

(II) to an individual or to any other entity under this subsection, or

(v) fails to comply with the requirements of section 1876(i)(8),

the Secretary may provide, in addition to any other remedies available under law, for any of the remedies described in subparagraph (B).

(B) The remedies described in this subparagraph are—

(i) civil money penalties of not more than \$25,000 for each determination under subparagraph (A), or, with respect to a determination under clause (iii) or (iv)(I) of such subparagraph, of not more than \$100,000 for each such determination, plus, with respect to a determination under subparagraph (A)(ii), double the excess amount charged in violation of such subparagraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and plus, with respect to a determination under subparagraph (A)(iii), \$15,000 for each individual not enrolled as a result of a practice described in such subparagraph, or

(ii) denial of payment to the State for medical assistance furnished under the contract under this subsection for individuals enrolled after the date the Secretary notifies the organization of a determination under subparagraph (A) and until the Sec-

retary is satisfied that the basis for such determination has been corrected and is not likely to recur.

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

(6)(A) For purposes of this subsection and section 1902(e)(2)(A), in the case of the State of New Jersey, the term “contract” shall be deemed to include an undertaking by the State agency, in the State plan under this title, to operate a program meeting all requirements of this subsection.

(B) The undertaking described in subparagraph (A) must provide—

(i) for the establishment of a separate entity responsible for the operation of a program meeting the requirements of this subsection, which entity may be a subdivision of the State agency administering the State plan under this title;

(ii) for separate accounting for the funds used to operate such program; and

(iii) for setting the capitation rates and any other payment rates for services provided in accordance with this subsection using a methodology satisfactory to the Secretary designed to ensure that total Federal matching payments under this title for such services will be lower than the matching payments that would be made for the same services, if provided under the State plan on a fee for service basis to an actuarially equivalent population.

(C) The undertaking described in subparagraph (A) shall be subject to approval (and annual re-approval) by the Secretary in the same manner as a contract under this subsection.

(D) The undertaking described in subparagraph (A) shall not be eligible for a waiver under section 1915(b).

(e) Notwithstanding the preceding provisions of this section, no payment shall be made to a State under the preceding provisions of this section for expenditures for medical assistance provided for an individual under its State plan approved under this title to the extent that a private insurer (as defined by the Secretary by regulation and including a group health plan (as defined in section 607(1) of the Employee Retirement Income Security Act of 1974), a service benefit plan, and a health maintenance organization) would have been obligated to provide such assistance but for a provision of its insurance contract which has the effect of limiting or excluding such obligation because the individual is eligible for or is provided medical assistance under the plan.

(p)(1) When a political subdivision of a State makes, for the State of which it is a political subdivision, or one State makes, for another State, the enforcement and collection of rights of support or payment assigned under section 1912, pursuant to a cooperative arrangement under such section (either within or outside of such State), there shall be paid to such political subdivision or such other State from amounts which would otherwise represent the Federal share of payments for medical assistance provided to the eligible individuals on whose behalf such enforcement and collection was made, an amount equal to 15 percent of any amount collected which is attributable to such rights of support or payment.

(2) Where more than one jurisdiction is involved in such enforcement or collection, the amount of the incentive payment determined under paragraph (1) shall be allocated among the jurisdictions in a manner to be prescribed by the Secretary.

(q) For the purposes of this section, the term “State medicaid fraud control unit” means a single identifiable entity of the State government which the Secretary certifies (and annually recertifies) as meeting the following requirements:

(1) The entity (A) is a unit of the office of the State Attorney General or of another department of State government which possesses statewide authority to prosecute individuals for criminal violations, (B) is in a State the constitution of which does not provide for the criminal prosecution of individuals by a statewide authority and has formal procedures, approved by the Secretary, that (i) assure its referral of suspected criminal violations relating to the program under this title to the appropriate authority or authorities in the State for prosecution and (ii) assure its assistance of, and coordination with, such authority or authorities in such prosecutions, or (C) has a formal working relationship with the office of the State Attorney General and has formal procedures (including procedures for its referral of suspected criminal violations to such office) which are approved by the Secretary and which provide effective coordination of activities between the entity and such office with respect to the detection, investigation, and prosecution of suspected criminal violations relating to the program under this title.

(2) The entity is separate and distinct from the single State agency that administers or supervises the administration of the State plan under this title.

(3) The entity’s function is conducting a statewide program for the investigation and prosecution of violations of all applicable State laws regarding any and all aspects of fraud in connection with (A) any aspect of the provision of medical assistance and the activities of providers of such assistance under the State plan under this title; and (B) upon the approval of the Inspector General of the relevant Federal agency, any aspect of the provision of health care services and activities of providers of such services under any Federal health care program (as defined in section 1128B(f)(1)), if the suspected fraud or violation of law in such case or investigation is primarily related to the State plan under this title.

(4)(A) The entity has—

(i) procedures for reviewing complaints of abuse or neglect of patients in health care facilities which receive payments under the State plan under this title;

(ii) at the option of the entity, procedures for reviewing complaints of abuse or neglect of patients residing in board and care facilities; and

(iii) procedures for acting upon such complaints under the criminal laws of the State or for referring such complaints to other State agencies for action.

(B) For purposes of this paragraph, the term “board and care facility” means a residential setting which receives payment (regardless of whether such payment is made under the State

plan under this title) from or on behalf of two or more unrelated adults who reside in such facility, and for whom one or both of the following is provided:

(i) Nursing care services provided by, or under the supervision of, a registered nurse, licensed practical nurse, or licensed nursing assistant.

(ii) A substantial amount of personal care services that assist residents with the activities of daily living, including personal hygiene, dressing, bathing, eating, toileting, ambulation, transfer, positioning, self-medication, body care, travel to medical services, essential shopping, meal preparation, laundry, and housework.

(5) The entity provides for the collection, or referral for collection to a single State agency, of overpayments that are made under the State plan or under any Federal health care program (as so defined) to health care facilities and that are discovered by the entity in carrying out its activities. All funds collected in accordance with this paragraph shall be credited exclusively to, and available for expenditure under, the Federal health care program (including the State plan under this title) that was subject to the activity that was the basis for the collection.

(6) The entity employs such auditors, attorneys, investigators, and other necessary personnel and is organized in such a manner as is necessary to promote the effective and efficient conduct of the entity's activities.

(7) The entity submits to the Secretary an application and annual reports containing such information as the Secretary determines, by regulation, to be necessary to determine whether the entity meets the other requirements of this subsection.

(r)(1) In order to receive payments under subsection (a) for use of automated data systems in administration of the State plan under this title, a State must, in addition to meeting the requirements of paragraph (3), have in operation mechanized claims processing and information retrieval systems that meet the requirements of this subsection and that the Secretary has found—

(A) are adequate to provide efficient, economical, and effective administration of such State plan;

(B) are compatible with the claims processing and information retrieval systems used in the administration of title XVIII, and for this purpose—

(i) have a uniform identification coding system for providers, other payees, and beneficiaries under this title or title XVIII;

(ii) provide liaison between States and carriers and intermediaries with agreements under title XVIII to facilitate timely exchange of appropriate data;

(iii) provide for exchange of data between the States and the Secretary with respect to persons sanctioned under this title or title XVIII; and

(iv) effective for claims filed on or after October 1, 2010, incorporate compatible methodologies of the National Correct Coding Initiative administered by the Secretary (or any successor initiative to promote correct coding and to control improper coding leading to inappropriate payment)

- and such other methodologies of that Initiative (or such other national correct coding methodologies) as the Secretary identifies in accordance with paragraph (4);
- (C) are capable of providing accurate and timely data;
- (D) are complying with the applicable provisions of part C of title XI;
- (E) are designed to receive provider claims in standard formats to the extent specified by the Secretary; and

(F) effective for claims filed on or after January 1, 1999, provide for electronic transmission of claims data in the format specified by the Secretary and consistent with the Medicaid Statistical Information System (MSIS) (including detailed individual enrollee encounter data and other information that the Secretary may find necessary and including, for data submitted to the Secretary on or after January 1, 2010, data elements from the automated data system that the Secretary determines to be necessary for program integrity, program oversight, and administration, at such frequency as the Secretary shall determine).

(2) In order to meet the requirements of this paragraph, mechanized claims processing and information retrieval systems must meet the following requirements:

(A) The systems must be capable of developing provider, physician, and patient profiles which are sufficient to provide specific information as to the use of covered types of services and items, including prescribed drugs.

(B) The State must provide that information on probable fraud or abuse which is obtained from, or developed by, the systems, is made available to the State's medicaid fraud control unit (if any) certified under subsection (q) of this section.

(C) The systems must meet all performance standards and other requirements for initial approval developed by the Secretary.

(3) In order to meet the requirements of this paragraph, a State must have in operation an eligibility determination system which provides for data matching through the Public Assistance Reporting Information System (PARIS) facilitated by the Secretary (or any successor system), including matching with medical assistance programs operated by other States.

(4) For purposes of paragraph (1)(B)(iv), the Secretary shall do the following:

(A) Not later than September 1, 2010:

(i) Identify those methodologies of the National Correct Coding Initiative administered by the Secretary (or any successor initiative to promote correct coding and to control improper coding leading to inappropriate payment) which are compatible to claims filed under this title.

(ii) Identify those methodologies of such Initiative (or such other national correct coding methodologies) that should be incorporated into claims filed under this title with respect to items or services for which States provide medical assistance under this title and no national correct coding methodologies have been established under such Initiative with respect to title XVIII.

(iii) Notify States of—

(I) the methodologies identified under subparagraphs (A) and (B) (and of any other national correct coding methodologies identified under subparagraph (B)); and

(II) how States are to incorporate such methodologies into claims filed under this title.

(B) Not later than March 1, 2011, submit a report to Congress that includes the notice to States under clause (iii) of subparagraph (A) and an analysis supporting the identification of the methodologies made under clauses (i) and (ii) of subparagraph (A).

(s) Notwithstanding the preceding provisions of this section, no payment shall be made to a State under this section for expenditures for medical assistance under the State plan consisting of a designated health service (as defined in subsection (h)(6) of section 1877) furnished to an individual on the basis of a referral that would result in the denial of payment for the service under title XVIII if such title provided for coverage of such service to the same extent and under the same terms and conditions as under the State plan, and subsections (f) and (g)(5) of such section shall apply to a provider of such a designated health service for which payment may be made under this title in the same manner as such subsections apply to a provider of such a service for which payment may be made under such title.

(t)(1) For purposes of subsection (a)(3)(F), the payments described in this paragraph to encourage the adoption and use of certified EHR technology are payments made by the State in accordance with this subsection —

(A) to Medicaid providers described in paragraph (2)(A) not in excess of 85 percent of net average allowable costs (as defined in paragraph (3)(E)) for certified EHR technology (and support services including maintenance and training that is for, or is necessary for the adoption and operation of, such technology) with respect to such providers; and

(B) to Medicaid providers described in paragraph (2)(B) not in excess of the maximum amount permitted under paragraph (5) for the provider involved.

(2) In this subsection and subsection (a)(3)(F), the term “Medicaid provider” means—

(A) an eligible professional (as defined in paragraph (3)(B))—

(i) who is not hospital-based and has at least 30 percent of the professional’s patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under this title;

(ii) who is not described in clause (i), who is a pediatrician, who is not hospital-based, and who has at least 20 percent of the professional’s patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under this title; and

(iii) who practices predominantly in a Federally qualified health center or rural health clinic and has at least 30 percent of the professional’s patient volume (as estimated in accordance with a methodology established by the Sec-

- retary) attributable to needy individuals (as defined in paragraph (3)(F)); and
- (B)(i) a children's hospital, or
  - (ii) an acute-care hospital that is not described in clause (i) and that has at least 10 percent of the hospital's patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under this title.

An eligible professional shall not qualify as a Medicaid provider under this subsection unless any right to payment under sections 1848(o) and 1853(l) with respect to the eligible professional has been waived in a manner specified by the Secretary. For purposes of calculating patient volume under subparagraph (A)(iii), insofar as it is related to uncompensated care, the Secretary may require the adjustment of such uncompensated care data so that it would be an appropriate proxy for charity care, including a downward adjustment to eliminate bad debt data from uncompensated care. In applying subparagraphs (A) and (B)(ii), the methodology established by the Secretary for patient volume shall include individuals enrolled in a Medicaid managed care plan (under section 1903(m) or section 1932).

(3) In this subsection and subsection (a)(3)(F):

(A) The term "certified EHR technology" means a qualified electronic health record (as defined in 3000(13) of the Public Health Service Act) that is certified pursuant to section 3001(c)(5) of such Act as meeting standards adopted under section 3004 of such Act that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).

(B) The term "eligible professional" means a—

- (i) physician;
- (ii) dentist;
- (iii) certified nurse mid-wife;
- (iv) nurse practitioner; and
- (v) physician assistant insofar as the assistant is practicing in a rural health clinic that is led by a physician assistant or is practicing in a Federally qualified health center that is so led.

(C) The term "average allowable costs" means, with respect to certified EHR technology of Medicaid providers described in paragraph (2)(A) for—

(i) the first year of payment with respect to such a provider, the average costs for the purchase and initial implementation or upgrade of such technology (and support services including training that is for, or is necessary for the adoption and initial operation of, such technology) for such providers, as determined by the Secretary based upon studies conducted under paragraph (4)(C); and

(ii) a subsequent year of payment with respect to such a provider, the average costs not described in clause (i) relating to the operation, maintenance, and use of such technology for such providers, as determined by the Secretary based upon studies conducted under paragraph (4)(C).

(D) The term “hospital-based” means, with respect to an eligible professional, a professional (such as a pathologist, anesthesiologist, or emergency physician) who furnishes substantially all of the individual’s professional services in a hospital inpatient or emergency room setting and through the use of the facilities and equipment, including qualified electronic health records, of the hospital. The determination of whether an eligible professional is a hospital-based eligible professional shall be made on the basis of the site of service (as defined by the Secretary) and without regard to any employment or billing arrangement between the eligible professional and any other provider.

(E) The term “net average allowable costs” means, with respect to a Medicaid provider described in paragraph (2)(A), average allowable costs reduced by the average payment the Secretary estimates will be made to such Medicaid providers (determined on a percentage or other basis for such classes or types of providers as the Secretary may specify) from other sources (other than under this subsection, or by the Federal government or a State or local government) that is directly attributable to payment for certified EHR technology or support services described in subparagraph (C).

(F) The term “needy individual” means, with respect to a Medicaid provider, an individual—

- (i) who is receiving assistance under this title;
- (ii) who is receiving assistance under title XXI;
- (iii) who is furnished uncompensated care by the provider; or
- (iv) for whom charges are reduced by the provider on a sliding scale basis based on an individual’s ability to pay.

(4)(A) With respect to a Medicaid provider described in paragraph (2)(A), subject to subparagraph (B), in no case shall—

- (i) the net average allowable costs under this subsection for the first year of payment (which may not be later than 2016), which is intended to cover the costs described in paragraph (3)(C)(i), exceed \$25,000 (or such lesser amount as the Secretary determines based on studies conducted under subparagraph (C));
- (ii) the net average allowable costs under this subsection for a subsequent year of payment, which is intended to cover costs described in paragraph (3)(C)(ii), exceed \$10,000; and
- (iii) payments be made for costs described in clause (ii) after 2021 or over a period of longer than 5 years.

(B) In the case of Medicaid provider described in paragraph (2)(A)(ii), the dollar amounts specified in subparagraph (A) shall be  $\frac{2}{3}$  of the dollar amounts otherwise specified.

(C) For the purposes of determining average allowable costs under this subsection, the Secretary shall study the average costs to Medicaid providers described in paragraph (2)(A) of purchase and initial implementation and upgrade of certified EHR technology described in paragraph (3)(C)(i) and the average costs to such providers of operations, maintenance, and use of such technology described in paragraph (3)(C)(ii). In determining such costs

for such providers, the Secretary may utilize studies of such amounts submitted by States.

(5)(A) In no case shall the payments described in paragraph (1)(B) with respect to a Medicaid provider described in paragraph (2)(B) exceed—

(i) in the aggregate the product of—

(I) the overall hospital EHR amount for the provider computed under subparagraph (B); and

(II) the Medicaid share for such provider computed under subparagraph (C);

(ii) in any year 50 percent of the product described in clause (i); and

(iii) in any 2-year period 90 percent of such product.

(B) For purposes of this paragraph, the overall hospital EHR amount, with respect to a Medicaid provider, is the sum of the applicable amounts specified in section 1886(n)(2)(A) for such provider for the first 4 payment years (as estimated by the Secretary) determined as if the Medicare share specified in clause (ii) of such section were 1. The Secretary shall establish, in consultation with the State, the overall hospital EHR amount for each such Medicaid provider eligible for payments under paragraph (1)(B). For purposes of this subparagraph in computing the amounts under section 1886(n)(2)(C) for payment years after the first payment year, the Secretary shall assume that in subsequent payment years discharges increase at the average annual rate of growth of the most recent 3 years for which discharge data are available per year.

(C) The Medicaid share computed under this subparagraph, for a Medicaid provider for a period specified by the Secretary, shall be calculated in the same manner as the Medicare share under section 1886(n)(2)(D) for such a hospital and period, except that there shall be substituted for the numerator under clause (i) of such section the amount that is equal to the number of inpatient-bed-days (as established by the Secretary) which are attributable to individuals who are receiving medical assistance under this title and who are not described in section 1886(n)(2)(D)(i). In computing inpatient-bed-days under the previous sentence, the Secretary shall take into account inpatient-bed-days attributable to inpatient-bed-days that are paid for individuals enrolled in a Medicaid managed care plan (under section 1903(m) or section 1932).

(D) In no case may the payments described in paragraph (1)(B) with respect to a Medicaid provider described in paragraph (2)(B) be paid—

(i) for any year beginning after 2016 unless the provider has been provided payment under paragraph (1)(B) for the previous year; and

(ii) over a period of more than 6 years of payment.

(6) Payments described in paragraph (1) are not in accordance with this subsection unless the following requirements are met:

(A)(i) The State provides assurances satisfactory to the Secretary that amounts received under subsection (a)(3)(F) with respect to payments to a Medicaid provider are paid, subject to clause (ii), directly to such provider (or to an employer or facility to which such provider has assigned payments) without any deduction or rebate.

(ii) Amounts described in clause (i) may also be paid to an entity promoting the adoption of certified EHR technology, as designated by the State, if participation in such a payment arrangement is voluntary for the eligible professional involved and if such entity does not retain more than 5 percent of such payments for costs not related to certified EHR technology (and support services including maintenance and training) that is for, or is necessary for the operation of, such technology.

(B) A Medicaid provider described in paragraph (2)(A) is responsible for payment of the remaining 15 percent of the net average allowable cost and shall be determined to have met such responsibility to the extent that the payment to the Medicaid provider is not in excess of 85 percent of the net average allowable cost.

(C)(i) Subject to clause (ii), with respect to payments to a Medicaid provider—

(I) for the first year of payment to the Medicaid provider under this subsection, the Medicaid provider demonstrates that it is engaged in efforts to adopt, implement, or upgrade certified EHR technology; and

(II) for a year of payment, other than the first year of payment to the Medicaid provider under this subsection, the Medicaid provider demonstrates meaningful use of certified EHR technology through a means that is approved by the State and acceptable to the Secretary, and that may be based upon the methodologies applied under section 1848(o) or 1886(n).

(ii) In the case of a Medicaid provider who has completed adopting, implementing, or upgrading such technology prior to the first year of payment to the Medicaid provider under this subsection, clause (i)(I) shall not apply and clause (i)(II) shall apply to each year of payment to the Medicaid provider under this subsection, including the first year of payment.

(D) To the extent specified by the Secretary, the certified EHR technology is compatible with State or Federal administrative management systems.

For purposes of subparagraph (B), a Medicaid provider described in paragraph (2)(A) may accept payments for the costs described in such subparagraph from a State or local government. For purposes of subparagraph (C), in establishing the means described in such subparagraph, which may include clinical quality reporting to the State, the State shall ensure that populations with unique needs, such as children, are appropriately addressed.

(7) With respect to Medicaid providers described in paragraph (2)(A), the Secretary shall ensure coordination of payment with respect to such providers under sections 1848(o) and 1853(l) and under this subsection to assure no duplication of funding. Such coordination shall include, to the extent practicable, a data matching process between State Medicaid agencies and the Centers for Medicare & Medicaid Services using national provider identifiers. For such purposes, the Secretary may require the submission of such data relating to payments to such Medicaid providers as the Secretary may specify.

(8) In carrying out paragraph (6)(C), the State and Secretary shall seek, to the maximum extent practicable, to avoid duplicative

requirements from Federal and State governments to demonstrate meaningful use of certified EHR technology under this title and title XVIII. In doing so, the Secretary may deem satisfaction of requirements for such meaningful use for a payment year under title XVIII to be sufficient to qualify as meaningful use under this subsection. The Secretary may also specify the reporting periods under this subsection in order to carry out this paragraph.

(9) In order to be provided Federal financial participation under subsection (a)(3)(F)(ii), a State must demonstrate to the satisfaction of the Secretary, that the State—

(A) is using the funds provided for the purposes of administering payments under this subsection, including tracking of meaningful use by Medicaid providers;

(B) is conducting adequate oversight of the program under this subsection, including routine tracking of meaningful use attestations and reporting mechanisms; and

(C) is pursuing initiatives to encourage the adoption of certified EHR technology to promote health care quality and the exchange of health care information under this title, subject to applicable laws and regulations governing such exchange.

(10) The Secretary shall periodically submit reports to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate on status, progress, and oversight of payments described in paragraph (1), including steps taken to carry out paragraph (7). Such reports shall also describe the extent of adoption of certified EHR technology among Medicaid providers resulting from the provisions of this subsection and any improvements in health outcomes, clinical quality, or efficiency resulting from such adoption.

(u)(1)(A) Notwithstanding subsection (a)(1), if the ratio of a State's erroneous excess payments for medical assistance (as defined in subparagraph (D)) to its total expenditures for medical assistance under the State plan approved under this title exceeds 0.03, for the period consisting of the third and fourth quarters of fiscal year 1983, or for any full fiscal year thereafter, then the Secretary shall make no payment for such period or fiscal year with respect to so much of such erroneous excess payments as exceeds such allowable error rate of 0.03.

(B) The Secretary may waive, in certain limited cases, all or part of the reduction required under subparagraph (A) with respect to any State if such State is unable to reach the allowable error rate for a period or fiscal year despite a good faith effort by such State.

(C) In estimating the amount to be paid to a State under subsection (d), the Secretary shall take into consideration the limitation on Federal financial participation imposed by subparagraph (A) and shall reduce the estimate he makes under subsection (d)(1), for purposes of payment to the State under subsection (d)(3), in light of any expected erroneous excess payments for medical assistance (estimated in accordance with such criteria, including sampling procedures, as he may prescribe and subject to subsequent adjustment, if necessary, under subsection (d)(2)).

(D)(i) For purposes of this subsection, the term "erroneous excess payments for medical assistance" means the total of—

(I) payments under the State plan with respect to ineligible individuals and families, and

(II) overpayments on behalf of eligible individuals and families by reason of error in determining the amount of expenditures for medical care required of an individual or family as a condition of eligibility.

(ii) In determining the amount of erroneous excess payments for medical assistance to an ineligible individual or family under clause (i)(I), if such ineligibility is the result of an error in determining the amount of the resources of such individual or family, the amount of the erroneous excess payment shall be the smaller of (I) the amount of the payment with respect to such individual or family, or (II) the difference between the actual amount of such resources and the allowable resource level established under the State plan.

(iii) In determining the amount of erroneous excess payments for medical assistance to an individual or family under clause (i)(II), the amount of the erroneous excess payment shall be the smaller of (I) the amount of the payment on behalf of the individual or family, or (II) the difference between the actual amount incurred for medical care by the individual or family and the amount which should have been incurred in order to establish eligibility for medical assistance.

(iv) In determining the amount of erroneous excess payments, there shall not be included any error resulting from a failure of an individual to cooperate or give correct information with respect to third-party liability as required under section 1912(a)(1)(C) or 402(a)(26)(C) or with respect to payments made in violation of section 1906.

(v) In determining the amount of erroneous excess payments, there shall not be included any erroneous payments made for ambulatory prenatal care provided during a presumptive eligibility period (as defined in section 1920(b)(1)), for items and services described in subsection (a) of section 1920A provided to a child during a presumptive eligibility period under such section, for medical assistance provided to an individual described in subsection (a) of section 1920B during a presumptive eligibility period under such section, or for medical assistance provided to an individual during a presumptive eligibility period resulting from a determination of presumptive eligibility made by a hospital that elects under section 1902(a)(47)(B) to be a qualified entity for such purpose.

(E) For purposes of subparagraph (D), there shall be excluded, in determining both erroneous excess payments for medical assistance and total expenditures for medical assistance—

(i) payments with respect to any individual whose eligibility therefor was determined exclusively by the Secretary under an agreement pursuant to section 1634 and such other classes of individuals as the Secretary may by regulation prescribe whose eligibility was determined in part under such an agreement; and

(ii) payments made as the result of a technical error.

(2) The State agency administering the plan approved under this title shall, at such times and in such form as the Secretary may specify, provide information on the rates of erroneous excess payments made (or expected, with respect to future periods specified by the Secretary) in connection with its administration of such

plan, together with any other data he requests that are reasonably necessary for him to carry out the provisions of this subsection.

(3)(A) If a State fails to cooperate with the Secretary in providing information necessary to carry out this subsection, the Secretary, directly or through contractual or such other arrangements as he may find appropriate, shall establish the error rates for that State on the basis of the best data reasonably available to him and in accordance with such techniques for sampling and estimating as he finds appropriate.

(B) In any case in which it is necessary for the Secretary to exercise his authority under subparagraph (A) to determine a State's error rates for a fiscal year, the amount that would otherwise be payable to such State under this title for quarters in such year shall be reduced by the costs incurred by the Secretary in making (directly or otherwise) such determination.

(4) This subsection shall not apply with respect to Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, or American Samoa.

(v)(1) Notwithstanding the preceding provisions of this section, except as provided in paragraphs (2) and (4), no payment may be made to a State under this section for medical assistance furnished to an alien who is not lawfully admitted for permanent residence or otherwise permanently residing in the United States under color of law.

(2) Payment shall be made under this section for care and services that are furnished to an alien described in paragraph (1) only if—

(A) such care and services are necessary for the treatment of an emergency medical condition of the alien,

(B) such alien otherwise meets the eligibility requirements for medical assistance under the State plan approved under this title (other than the requirement of the receipt of aid or assistance under title IV, supplemental security income benefits under title XVI, or a State supplementary payment), and

(C) such care and services are not related to an organ transplant procedure.

(3) For purposes of this subsection, the term “emergency medical condition” means a medical condition (including emergency labor and delivery) manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—

(A) placing the patient's health in serious jeopardy,

(B) serious impairment to bodily functions, or

(C) serious dysfunction of any bodily organ or part.

(4)(A) A State may elect (in a plan amendment under this title) to provide medical assistance under this title, notwithstanding sections 401(a), 402(b), 403, and 421 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, to children and pregnant women who are lawfully residing in the United States (including battered individuals described in section 431(c) of such Act) and who are otherwise eligible for such assistance, within either or both of the following eligibility categories:

(i) PREGNANT WOMEN.—Women during pregnancy (and during the 60-day period beginning on the last day of the pregnancy).

(ii) CHILDREN.—Individuals under 21 years of age, including optional targeted low-income children described in section 1905(u)(2)(B).

(B) In the case of a State that has elected to provide medical assistance to a category of aliens under subparagraph (A), no debt shall accrue under an affidavit of support against any sponsor of such an alien on the basis of provision of assistance to such category and the cost of such assistance shall not be considered as an unreimbursed cost.

(C) As part of the State's ongoing eligibility redetermination requirements and procedures for an individual provided medical assistance as a result of an election by the State under subparagraph (A), a State shall verify that the individual continues to lawfully reside in the United States using the documentation presented to the State by the individual on initial enrollment. If the State cannot successfully verify that the individual is lawfully residing in the United States in this manner, it shall require that the individual provide the State with further documentation or other evidence to verify that the individual is lawfully residing in the United States.

(w)(1)(A) Notwithstanding the previous provisions of this section, for purposes of determining the amount to be paid to a State (as defined in paragraph (7)(D)) under subsection (a)(1) for quarters in any fiscal year, the total amount expended during such fiscal year as medical assistance under the State plan (as determined without regard to this subsection) shall be reduced by the sum of any revenues received by the State (or by a unit of local government in the State) during the fiscal year—

(i) from provider-related donations (as defined in paragraph (2)(A)), other than—

(I) bona fide provider-related donations (as defined in paragraph (2)(B)), and

(II) donations described in paragraph (2)(C);

(ii) from health care related taxes (as defined in paragraph (3)(A)), other than broad-based health care related taxes (as defined in paragraph (3)(B));

(iii) from a broad-based health care related tax, if there is in effect a hold harmless provision (described in paragraph (4)) with respect to the tax; or

(iv) only with respect to State fiscal years (or portions thereof) occurring on or after January 1, 1992, and before October 1, 1995, from broad-based health care related taxes to the extent the amount of such taxes collected exceeds the limit established under paragraph (5).

(B) Notwithstanding the previous provisions of this section, for purposes of determining the amount to be paid to a State under subsection (a)(7) for all quarters in a Federal fiscal year (beginning with fiscal year 1993), the total amount expended during the fiscal year for administrative expenditures under the State plan (as determined without regard to this subsection) shall be reduced by the sum of any revenues received by the State (or by a unit of local government in the State) during such quarters from donations described in paragraph (2)(C), to the extent the amount of such donations exceeds 10 percent of the amounts expended under the State

plan under this title during the fiscal year for purposes described in paragraphs (2), (3), (4), (6), and (7) of subsection (a).

(C)(i) Except as otherwise provided in clause (ii), subparagraph (A)(i) shall apply to donations received on or after January 1, 1992.

(ii) Subject to the limits described in clause (iii) and subparagraph (E), subparagraph (A)(i) shall not apply to donations received before the effective date specified in subparagraph (F) if such donations are received under programs in effect or as described in State plan amendments or related documents submitted to the Secretary by September 30, 1991, and applicable to State fiscal year 1992, as demonstrated by State plan amendments, written agreements, State budget documentation, or other documentary evidence in existence on that date.

(iii) In applying clause (ii) in the case of donations received in State fiscal year 1993, the maximum amount of such donations to which such clause may be applied may not exceed the total amount of such donations received in the corresponding period in State fiscal year 1992 (or not later than 5 days after the last day of the corresponding period).

(D)(i) Except as otherwise provided in clause (ii), subparagraphs (A)(ii) and (A)(iii) shall apply to taxes received on or after January 1, 1992.

(ii) Subparagraphs (A)(ii) and (A)(iii) shall not apply to impermissible taxes (as defined in clause (iii)) received before the effective date specified in subparagraph (F) to the extent the taxes (including the tax rate or base) were in effect, or the legislation or regulations imposing such taxes were enacted or adopted, as of November 22, 1991.

(iii) In this subparagraph and subparagraph (E), the term "impermissible tax" means a health care related tax for which a reduction may be made under clause (ii) or (iii) of subparagraph (A).

(E)(i) In no case may the total amount of donations and taxes permitted under the exception provided in subparagraphs (C)(ii) and (D)(ii) for the portion of State fiscal year 1992 occurring during calendar year 1992 exceed the limit under paragraph (5) minus the total amount of broad-based health care related taxes received in the portion of that fiscal year.

(ii) In no case may the total amount of donations and taxes permitted under the exception provided in subparagraphs (C)(ii) and (D)(ii) for State fiscal year 1993 exceed the limit under paragraph (5) minus the total amount of broad-based health care related taxes received in that fiscal year.

(F) In this paragraph in the case of a State—

(i) except as provided in clause (iii), with a State fiscal year beginning on or before July 1, the effective date is October 1, 1992,

(ii) except as provided in clause (iii), with a State fiscal year that begins after July 1, the effective date is January 1, 1993, or

(iii) with a State legislature which is not scheduled to have a regular legislative session in 1992, with a State legislature which is not scheduled to have a regular legislative session in 1993, or with a provider-specific tax enacted on November 4, 1991, the effective date is July 1, 1993.

(2)(A) In this subsection (except as provided in paragraph (6)), the term “provider-related donation” means any donation or other voluntary payment (whether in cash or in kind) made (directly or indirectly) to a State or unit of local government by—

- (i) a health care provider (as defined in paragraph (7)(B)),
- (ii) an entity related to a health care provider (as defined in paragraph (7)(C)), or
- (iii) an entity providing goods or services under the State plan for which payment is made to the State under paragraph (2), (3), (4), (6), or (7) of subsection (a).

(B) For purposes of paragraph (1)(A)(i)(I), the term “bona fide provider-related donation” means a provider-related donation that has no direct or indirect relationship (as determined by the Secretary) to payments made under this title to that provider, to providers furnishing the same class of items and services as that provider, or to any related entity, as established by the State to the satisfaction of the Secretary. The Secretary may by regulation specify types of provider-related donations described in the previous sentence that will be considered to be bona fide provider-related donations.

(C) For purposes of paragraph (1)(A)(i)(II), donations described in this subparagraph are funds expended by a hospital, clinic, or similar entity for the direct cost (including costs of training and of preparing and distributing outreach materials) of State or local agency personnel who are stationed at the hospital, clinic, or entity to determine the eligibility of individuals for medical assistance under this title and to provide outreach services to eligible or potentially eligible individuals.

(3)(A) In this subsection (except as provided in paragraph (6)), the term “health care related tax” means a tax (as defined in paragraph (7)(F)) that—

- (i) is related to health care items or services, or to the provision of, the authority to provide, or payment for, such items or services, or
- (ii) is not limited to such items or services but provides for treatment of individuals or entities that are providing or paying for such items or services that is different from the treatment provided to other individuals or entities.

In applying clause (i), a tax is considered to relate to health care items or services if at least 85 percent of the burden of such tax falls on health care providers.

(B) In this subsection, the term “broad-based health care related tax” means a health care related tax which is imposed with respect to a class of health care items or services (as described in paragraph (7)(A)) or with respect to providers of such items or services and which, except as provided in subparagraphs (D), (E), and (F)—

- (i) is imposed at least with respect to all items or services in the class furnished by all non-Federal, nonpublic providers in the State (or, in the case of a tax imposed by a unit of local government, the area over which the unit has jurisdiction) or is imposed with respect to all non-Federal, nonpublic providers in the class; and
- (ii) is imposed uniformly (in accordance with subparagraph (C)).

(C)(i) Subject to clause (ii), for purposes of subparagraph (B)(ii), a tax is considered to be imposed uniformly if—

(I) in the case of a tax consisting of a licensing fee or similar tax on a class of health care items or services (or providers of such items or services), the amount of the tax imposed is the same for every provider providing items or services within the class;

(II) in the case of a tax consisting of a licensing fee or similar tax imposed on a class of health care items or services (or providers of such services) on the basis of the number of beds (licensed or otherwise) of the provider, the amount of the tax is the same for each bed of each provider of such items or services in the class;

(III) in the case of a tax based on revenues or receipts with respect to a class of items or services (or providers of items or services) the tax is imposed at a uniform rate for all items and services (or providers of such items of services) in the class on all the gross revenues or receipts, or net operating revenues, relating to the provision of all such items or services (or all such providers) in the State (or, in the case of a tax imposed by a unit of local government within the State, in the area over which the unit has jurisdiction); or

(IV) in the case of any other tax, the State establishes to the satisfaction of the Secretary that the tax is imposed uniformly.

(ii) Subject to subparagraphs (D) and (E), a tax imposed with respect to a class of health care items and services is not considered to be imposed uniformly if the tax provides for any credits, exclusions, or deductions which have as their purpose or effect the return to providers of all or a portion of the tax paid in a manner that is inconsistent with subclauses (I) and (II) of subparagraph (E)(i) or provides for a hold harmless provision described in paragraph (4).

(D) A tax imposed with respect to a class of health care items and services is considered to be imposed uniformly—

(i) notwithstanding that the tax is not imposed with respect to items or services (or the providers thereof) for which payment is made under a State plan under this title or title XVIII, or

(ii) in the case of a tax described in subparagraph (C)(i)(III), notwithstanding that the tax provides for exclusion (in whole or in part) of revenues or receipts from a State plan under this title or title XVIII.

(E)(i) A State may submit an application to the Secretary requesting that the Secretary treat a tax as a broad-based health care related tax, notwithstanding that the tax does not apply to all health care items or services in class (or all providers of such items and services), provides for a credit, deduction, or exclusion, is not applied uniformly, or otherwise does not meet the requirements of subparagraph (B) or (C). Permissible waivers may include exemptions for rural or sole-community providers.

(ii) The Secretary shall approve such an application if the State establishes to the satisfaction of the Secretary that—

(I) the net impact of the tax and associated expenditures under this title as proposed by the State is generally redistributive in nature, and

(II) the amount of the tax is not directly correlated to payments under this title for items or services with respect to which the tax is imposed.

The Secretary shall by regulation specify types of credits, exclusions, and deductions that will be considered to meet the requirements of this subparagraph.

(F) In no case shall a tax not qualify as a broad-based health care related tax under this paragraph because it does not apply to a hospital that is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a) of such Code and that does not accept payment under the State plan under this title or under title XVIII.

(4) For purposes of paragraph (1)(A)(iii), there is in effect a hold harmless provision with respect to a broad-based health care related tax imposed with respect to a class of items or services if the Secretary determines that any of the following applies:

(A) The State or other unit of government imposing the tax provides (directly or indirectly) for a payment (other than under this title) to taxpayers and the amount of such payment is positively correlated either to the amount of such tax or to the difference between the amount of the tax and the amount of payment under the State plan.

(B) All or any portion of the payment made under this title to the taxpayer varies based only upon the amount of the total tax paid.

(C)(i) The State or other unit of government imposing the tax provides (directly or indirectly) for any payment, offset, or waiver that guarantees to hold taxpayers harmless for any portion of the costs of the tax.

(ii) For purposes of clause (i), a determination of the existence of an indirect guarantee shall be made under paragraph (3)(i) of section 433.68(f) of title 42, Code of Federal Regulations, as in effect on November 1, 2006, except that for portions of fiscal years beginning on or after January 1, 2008, and before October 1, 2011, "5.5 percent" shall be substituted for "6 percent" each place it appears.

The provisions of this paragraph shall not prevent use of the tax to reimburse health care providers in a class for expenditures under this title nor preclude States from relying on such reimbursement to justify or explain the tax in the legislative process.

(5)(A) For purposes of this subsection, the limit under this subparagraph with respect to a State is an amount equal to 25 percent (or, if greater, the State base percentage, as defined in subparagraph (B)) of the non-Federal share of the total amount expended under the State plan during a State fiscal year (or portion thereof), as it would be determined pursuant to paragraph (1)(A) without regard to paragraph (1)(A)(iv).

(B)(i) In subparagraph (A), the term "State base percentage" means, with respect to a State, an amount (expressed as a percentage) equal to—

(I) the total of the amount of health care related taxes (whether or not broad-based) and the amount of provider-related donations (whether or not bona fide) projected to be collected (in accordance with clause (ii)) during State fiscal year 1992, divided by

(II) the non-Federal share of the total amount estimated to be expended under the State plan during such State fiscal year.

(ii) For purposes of clause (i)(I), in the case of a tax that is not in effect throughout State fiscal year 1992 or the rate (or base) of which is increased during such fiscal year, the Secretary shall project the amount to be collected during such fiscal year as if the tax (or increase) were in effect during the entire State fiscal year.

(C)(i) The total amount of health care related taxes under subparagraph (B)(i)(I) shall be determined by the Secretary based on only those taxes (including the tax rate or base) which were in effect, or for which legislation or regulations imposing such taxes were enacted or adopted, as of November 22, 1991.

(ii) The amount of provider-related donations under subparagraph (B)(i)(I) shall be determined by the Secretary based on programs in effect on September 30, 1991, and applicable to State fiscal year 1992, as demonstrated by State plan amendments, written agreements, State budget documentation, or other documentary evidence in existence on that date.

(iii) The amount of expenditures described in subparagraph (B)(i)(II) shall be determined by the Secretary based on the best data available as of the date of the enactment of this subsection.

(6)(A) Notwithstanding the provisions of this subsection, the Secretary may not restrict States' use of funds where such funds are derived from State or local taxes (or funds appropriated to State university teaching hospitals) transferred from or certified by units of government within a State as the non-Federal share of expenditures under this title, regardless of whether the unit of government is also a health care provider, except as provided in section 1902(a)(2), unless the transferred funds are derived by the unit of government from donations or taxes that would not otherwise be recognized as the non-Federal share under this section.

(B) For purposes of this subsection, funds the use of which the Secretary may not restrict under subparagraph (A) shall not be considered to be a provider-related donation or a health care related tax.

(7) For purposes of this subsection:

(A) Each of the following shall be considered a separate class of health care items and services:

(i) Inpatient hospital services.

(ii) Outpatient hospital services.

(iii) Nursing facility services (other than services of intermediate care facilities for the mentally retarded).

(iv) Services of intermediate care facilities for the mentally retarded.

(v) Physicians' services.

(vi) Home health care services.

(vii) Outpatient prescription drugs.

(viii) Services of managed care organizations (including health maintenance organizations, preferred provider organizations, and such other similar organizations as the Secretary may specify by regulation).

(ix) Such other classification of health care items and services consistent with this subparagraph as the Secretary may establish by regulation.

(B) The term “health care provider” means an individual or person that receives payments for the provision of health care items or services.

(C) An entity is considered to be “related” to a health care provider if the entity—

(i) is an organization, association, corporation or partnership formed by or on behalf of health care providers;

(ii) is a person with an ownership or control interest (as defined in section 1124(a)(3)) in the provider;

(iii) is the employee, spouse, parent, child, or sibling of the provider (or of a person described in clause (ii)); or

(iv) has a similar, close relationship (as defined in regulations) to the provider.

(D) The term “State” means only the 50 States and the District of Columbia but does not include any State whose entire program under this title is operated under a waiver granted under section 1115.

(E) The “State fiscal year” means, with respect to a specified year, a State fiscal year ending in that specified year.

(F) The term “tax” includes any licensing fee, assessment, or other mandatory payment, but does not include payment of a criminal or civil fine or penalty (other than a fine or penalty imposed in lieu of or instead of a fee, assessment, or other mandatory payment).

(G) The term “unit of local government” means, with respect to a State, a city, county, special purpose district, or other governmental unit in the State.

(x)(1) For purposes of section 1902(a)(46)(B)(i), the requirement of this subsection is, with respect to an individual declaring to be a citizen or national of the United States, that, subject to paragraph (2), there is presented satisfactory documentary evidence of citizenship or nationality (as defined in paragraph (3)) of the individual.

(2) The requirement of paragraph (1) shall not apply to an individual declaring to be a citizen or national of the United States who is eligible for medical assistance under this title—

(A) and is entitled to or enrolled for benefits under any part of title XVIII;

(B) and is receiving—

(i) disability insurance benefits under section 223 or monthly insurance benefits under section 202 based on such individual’s disability (as defined in section 223(d)); or

(ii) supplemental security income benefits under title XVI;

(C) and with respect to whom—

(i) child welfare services are made available under part B of title IV on the basis of being a child in foster care; or

(ii) adoption or foster care assistance is made available under part E of title IV;

(D) pursuant to the application of section 1902(e)(4) (and, in the case of an individual who is eligible for medical assistance on such basis, the individual shall be deemed to have provided satisfactory documentary evidence of citizenship or nationality

and shall not be required to provide further documentary evidence on any date that occurs during or after the period in which the individual is eligible for medical assistance on such basis); or

(E) on such basis as the Secretary may specify under which satisfactory documentary evidence of citizenship or nationality has been previously presented.

(3)(A) For purposes of this subsection, the term “satisfactory documentary evidence of citizenship or nationality” means—

(i) any document described in subparagraph (B); or

(ii) a document described in subparagraph (C) and a document described in subparagraph (D).

(B) The following are documents described in this subparagraph:

(i) A United States passport.

(ii) Form N-550 or N-570 (Certificate of Naturalization).

(iii) Form N-560 or N-561 (Certificate of United States Citizenship).

(iv) A valid State-issued driver’s license or other identity document described in section 274A(b)(1)(D) of the Immigration and Nationality Act, but only if the State issuing the license or such document requires proof of United States citizenship before issuance of such license or document or obtains a social security number from the applicant and verifies before certification that such number is valid and assigned to the applicant who is a citizen.

(v)(I) Except as provided in subclause (II), a document issued by a federally recognized Indian tribe evidencing membership or enrollment in, or affiliation with, such tribe (such as a tribal enrollment card or certificate of degree of Indian blood).

(II) With respect to those federally recognized Indian tribes located within States having an international border whose membership includes individuals who are not citizens of the United States, the Secretary shall, after consulting with such tribes, issue regulations authorizing the presentation of such other forms of documentation (including tribal documentation, if appropriate) that the Secretary determines to be satisfactory documentary evidence of citizenship or nationality for purposes of satisfying the requirement of this subsection.

(vi) Such other document as the Secretary may specify, by regulation, that provides proof of United States citizenship or nationality and that provides a reliable means of documentation of personal identity.

(C) The following are documents described in this subparagraph:

(i) A certificate of birth in the United States.

(ii) Form FS-545 or Form DS-1350 (Certification of Birth Abroad).

(iii) Form I-197 (United States Citizen Identification Card).

(iv) Form FS-240 (Report of Birth Abroad of a Citizen of the United States).

(v) Such other document (not described in subparagraph (B)(iv)) as the Secretary may specify that provides proof of United States citizenship or nationality.

(D) The following are documents described in this subparagraph:

(i) Any identity document described in section 274A(b)(1)(D) of the Immigration and Nationality Act.

(ii) Any other documentation of personal identity of such other type as the Secretary finds, by regulation, provides a reliable means of identification.

(E) A reference in this paragraph to a form includes a reference to any successor form.

(4) In the case of an individual declaring to be a citizen or national of the United States with respect to whom a State requires the presentation of satisfactory documentary evidence of citizenship or nationality under section 1902(a)(46)(B)(i), the individual shall be provided at least the reasonable opportunity to present satisfactory documentary evidence of citizenship or nationality under this subsection as is provided under clauses (i) and (ii) of section 1137(d)(4)(A) to an individual for the submittal to the State of evidence indicating a satisfactory immigration status.

(5) Nothing in subparagraph (A) or (B) of section 1902(a)(46), the preceding paragraphs of this subsection, or the Deficit Reduction Act of 2005, including section 6036 of such Act, shall be construed as changing the requirement of section 1902(e)(4) that a child born in the United States to an alien mother for whom medical assistance for the delivery of such child is available as treatment of an emergency medical condition pursuant to subsection (v) shall be deemed eligible for medical assistance during the first year of such child's life.

(y) PAYMENTS FOR ESTABLISHMENT OF ALTERNATE NON-EMERGENCY SERVICES PROVIDERS.—

(1) PAYMENTS.—In addition to the payments otherwise provided under subsection (a), subject to paragraph (2), the Secretary shall provide for payments to States under such subsection for the establishment of alternate non-emergency service providers (as defined in section 1916A(e)(5)(B)), or networks of such providers.

(2) LIMITATION.—The total amount of payments under this subsection shall not exceed \$50,000,000 during the 4-year period beginning with 2006. This subsection constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this subsection.

(3) PREFERENCE.—In providing for payments to States under this subsection, the Secretary shall provide preference to States that establish, or provide for, alternate non-emergency services providers or networks of such providers that—

(A) serve rural or underserved areas where beneficiaries under this title may not have regular access to providers of primary care services; or

(B) are in partnership with local community hospitals.

(4) FORM AND MANNER OF PAYMENT.—Payment to a State under this subsection shall be made only upon the filing of such application in such form and in such manner as the Secretary shall specify. Payment to a State under this subsection shall be made in the same manner as other payments under section 1903(a).

(z) MEDICAID TRANSFORMATION PAYMENTS.—

(1) IN GENERAL.—In addition to the payments provided under subsection (a), subject to paragraph (4), the Secretary shall provide for payments to States for the adoption of innova-

tive methods to improve the effectiveness and efficiency in providing medical assistance under this title.

(2) PERMISSIBLE USES OF FUNDS.—The following are examples of innovative methods for which funds provided under this subsection may be used:

(A) Methods for reducing patient error rates through the implementation and use of electronic health records, electronic clinical decision support tools, or e-prescribing programs.

(B) Methods for improving rates of collection from estates of amounts owed under this title.

(C) Methods for reducing waste, fraud, and abuse under the program under this title, such as reducing improper payment rates as measured by annual payment error rate measurement (PERM) project rates.

(D) Implementation of a medication risk management program as part of a drug use review program under section 1927(g).

(E) Methods in reducing, in clinically appropriate ways, expenditures under this title for covered outpatient drugs, particularly in the categories of greatest drug utilization, by increasing the utilization of generic drugs through the use of education programs and other incentives to promote greater use of generic drugs.

(F) Methods for improving access to primary and specialty physician care for the uninsured using integrated university-based hospital and clinic systems.

(3) APPLICATION; TERMS AND CONDITIONS.—

(A) IN GENERAL.—No payments shall be made to a State under this subsection unless the State applies to the Secretary for such payments in a form, manner, and time specified by the Secretary.

(B) TERMS AND CONDITIONS.—Such payments are made under such terms and conditions consistent with this subsection as the Secretary prescribes.

(C) ANNUAL REPORT.—Payment to a State under this subsection is conditioned on the State submitting to the Secretary an annual report on the programs supported by such payment. Such report shall include information on—

(i) the specific uses of such payment;

(ii) an assessment of quality improvements and clinical outcomes under such programs; and

(iii) estimates of cost savings resulting from such programs.

(4) FUNDING.—

(A) LIMITATION ON FUNDS.—The total amount of payments under this subsection shall be equal to, and shall not exceed—

(i) \$75,000,000 for fiscal year 2007; and

(ii) \$75,000,000 for fiscal year 2008.

This subsection constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this subsection.

(B) ALLOCATION OF FUNDS.—The Secretary shall specify a method for allocating the funds made available under this subsection among States. Such method shall provide preference for States that design programs that target health providers that treat significant numbers of Medicaid beneficiaries. Such method shall provide that not less than 25 percent of such funds shall be allocated among States the population of which (as determined according to data collected by the United States Census Bureau) as of July 1, 2004, was more than 105 percent of the population of the respective State (as so determined) as of April 1, 2000.

(C) FORM AND MANNER OF PAYMENT.—Payment to a State under this subsection shall be made in the same manner as other payments under section 1903(a). There is no requirement for State matching funds to receive payments under this subsection.

(5) MEDICATION RISK MANAGEMENT PROGRAM.—

(A) IN GENERAL.—For purposes of this subsection, the term “medication risk management program” means a program for targeted beneficiaries that ensures that covered outpatient drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events.

(B) ELEMENTS.—Such program may include the following elements:

(i) The use of established principles and standards for drug utilization review and best practices to analyze prescription drug claims of targeted beneficiaries and identify outlier physicians.

(ii) On an ongoing basis provide outlier physicians—

(I) a comprehensive pharmacy claims history for each targeted beneficiary under their care;

(II) information regarding the frequency and cost of relapses and hospitalizations of targeted beneficiaries under the physician’s care; and

(III) applicable best practice guidelines and empirical references.

(iii) Monitor outlier physician’s prescribing, such as failure to refill, dosage strengths, and provide incentives and information to encourage the adoption of best clinical practices.

(C) TARGETED BENEFICIARIES.—For purposes of this paragraph, the term “targeted beneficiaries” means Medicaid eligible beneficiaries who are identified as having high prescription drug costs and medical costs, such as individuals with behavioral disorders or multiple chronic diseases who are taking multiple medications.

*(aa) DEMONSTRATION PROJECT TO INCREASE SUBSTANCE USE PROVIDER CAPACITY.—*

*(1) IN GENERAL.—Not later than the date that is 180 days after the date of the enactment of this section, the Secretary shall, in consultation, as appropriate, with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, conduct a 5-*

year demonstration project for the purpose described in paragraph (2) under which the Secretary shall—

(A) for the first 18-month period of such project, award planning grants described in paragraph (3); and

(B) for the remaining 42-month period of such project, provide to each State selected under paragraph (4) payments in accordance with paragraph (5).

(2) *PURPOSE.*—The purpose described in this paragraph is for each State selected under paragraph (4) to increase the treatment capacity of providers participating under the State plan (or a waiver of such plan) to provide substance use disorder treatment or recovery services under such plan (or waiver) through the following activities:

(A) For the purpose described in paragraph (3)(C)(i), activities that support an ongoing assessment of the behavioral health treatment needs of the State, taking into account the matters described in subclauses (I) through (IV) of such paragraph.

(B) Activities that, taking into account the results of the assessment described in subparagraph (A), support the recruitment, training, and provision of technical assistance for providers participating under the State plan (or a waiver of such plan) that offer substance use disorder treatment or recovery services.

(C) Improved reimbursement for and expansion of, through the provision of education, training, and technical assistance, the number or treatment capacity of providers participating under the State plan (or waiver) that—

(i) are authorized to dispense drugs approved by the Food and Drug Administration for individuals with a substance use disorder who need withdrawal management or maintenance treatment for such disorder;

(ii) have in effect a registration or waiver under section 303(g) of the Controlled Substances Act for purposes of dispensing narcotic drugs to individuals for maintenance treatment or detoxification treatment and are in compliance with any regulation promulgated by the Assistant Secretary for Mental Health and Substance Use for purposes of carrying out the requirements of such section 303(g); and

(iii) are qualified under applicable State law to provide substance use disorder treatment or recovery services.

(D) Improved reimbursement for and expansion of, through the provision of education, training, and technical assistance, the number or treatment capacity of providers participating under the State plan (or waiver) that have the qualifications to address the treatment or recovery needs of—

(i) individuals enrolled under the State plan (or a waiver of such plan) who have neonatal abstinence syndrome, in accordance with guidelines issued by the American Academy of Pediatrics and American College of Obstetricians and Gynecologists relating to maternal

care and infant care with respect to neonatal abstinence syndrome;

(ii) pregnant women, postpartum women, and infants, particularly the concurrent treatment, as appropriate, and comprehensive case management of pregnant women, post-partum women and infants, enrolled under the State plan (or a waiver of such plan);

(iii) adolescents and young adults between the ages of 12 and 21 enrolled under the State plan (or a waiver of such plan); or

(iv) American Indian and Alaska Native individuals enrolled under the State plan (or a waiver of such plan).

(3) **PLANNING GRANTS.**—

(A) **IN GENERAL.**—The Secretary shall, with respect to the first 18-month period of the demonstration project conducted under paragraph (1), award planning grants to at least 10 States selected in accordance with subparagraph (B) for purposes of preparing an application described in paragraph (4)(C) and carrying out the activities described in subparagraph (C).

(B) **SELECTION.**—In selecting States for purposes of this paragraph, the Secretary shall—

(i) select States that have a State plan (or waiver of the State plan) approved under this title;

(ii) select States in a manner that ensures geographic diversity; and

(iii) give preference to States with a prevalence of substance use disorders (in particular opioid use disorders) that is comparable to or higher than the national average prevalence, as measured by aggregate per capita drug overdoses, or any other measure that the Secretary deems appropriate.

(C) **ACTIVITIES DESCRIBED.**—Activities described in this subparagraph are, with respect to a State, each of the following:

(i) Activities that support the development of an initial assessment of the behavioral health treatment needs of the State to determine the extent to which providers are needed (including the types of such providers and geographic area of need) to improve the network of providers that treat substance use disorders under the State plan (or waiver), including the following:

(I) An estimate of the number of individuals enrolled under the State plan (or a waiver of such plan) who have a substance use disorder.

(II) Information on the capacity of providers to provide substance use disorder treatment or recovery services to individuals enrolled under the State plan (or waiver), including information on providers who provide such services and their participation under the State plan (or waiver).

(III) Information on the gap in substance use disorder treatment or recovery services under the

*State plan (or waiver) based on the information described in subclauses (I) and (II).*

*(IV) Projections regarding the extent to which the State participating under the demonstration project would increase the number of providers offering substance use disorder treatment or recovery services under the State plan (or waiver) during the period of the demonstration project.*

*(ii) Activities that, taking into account the results of the assessment described in clause (i), support the development of State infrastructure to, with respect to the provision of substance use disorder treatment or recovery services under the State plan (or a waiver of such plan), recruit prospective providers and provide training and technical assistance to such providers.*

*(D) FUNDING.—For purposes of subparagraph (A), there is appropriated, out of any funds in the Treasury not otherwise appropriated, \$50,000,000, to remain available until expended.*

**(4) POST-PLANNING STATES.—**

*(A) IN GENERAL.—The Secretary shall, with respect to the remaining 42-month period of the demonstration project conducted under paragraph (1), select not more than 5 States in accordance with subparagraph (B) for purposes of carrying out the activities described in paragraph (2) and receiving payments in accordance with paragraph (5).*

*(B) SELECTION.—In selecting States for purposes of this paragraph, the Secretary shall—*

*(i) select States that received a planning grant under paragraph (3);*

*(ii) select States that submit to the Secretary an application in accordance with the requirements in subparagraph (C), taking into consideration the quality of each such application;*

*(iii) select States in a manner that ensures geographic diversity; and*

*(iv) give preference to States with a prevalence of substance use disorders (in particular opioid use disorders) that is comparable to or higher than the national average prevalence, as measured by aggregate per capita drug overdoses, or any other measure that the Secretary deems appropriate.*

**(C) APPLICATIONS.—**

*(i) IN GENERAL.—A State seeking to be selected for purposes of this paragraph shall submit to the Secretary, at such time and in such form and manner as the Secretary requires, an application that includes such information, provisions, and assurances, as the Secretary may require, in addition to the following:*

*(I) A proposed process for carrying out the ongoing assessment described in paragraph (2)(A), taking into account the results of the initial assessment described in paragraph (3)(C)(i).*

*(II) A review of reimbursement methodologies and other policies related to substance use disorder*

*treatment or recovery services under the State plan (or waiver) that may create barriers to increasing the number of providers delivering such services.*

*(III) The development of a plan, taking into account activities carried out under paragraph (3)(C)(ii), that will result in long-term and sustainable provider networks under the State plan (or waiver) that will offer a continuum of care for substance use disorders. Such plan shall include the following:*

*(aa) Specific activities to increase the number of providers (including providers that specialize in providing substance use disorder treatment or recovery services, hospitals, health care systems, Federally qualified health centers, and, as applicable, certified community behavioral health clinics) that offer substance use disorder treatment, recovery, or support services, including short-term detoxification services, outpatient substance use disorder services, and evidence-based peer recovery services.*

*(bb) Strategies that will incentivize providers described in subparagraphs (C) and (D) of paragraph (2) to obtain the necessary training, education, and support to deliver substance use disorder treatment or recovery services in the State.*

*(cc) Milestones and timeliness for implementing activities set forth in the plan.*

*(dd) Specific measurable targets for increasing the substance use disorder treatment and recovery provider network under the State plan (or a waiver of such plan).*

*(IV) A proposed process for reporting the information required under paragraph (6)(A), including information to assess the effectiveness of the efforts of the State to expand the capacity of providers to deliver substance use disorder treatment or recovery services during the period of the demonstration project under this subsection.*

*(V) The expected financial impact of the demonstration project under this subsection on the State.*

*(VI) A description of all funding sources available to the State to provide substance use disorder treatment or recovery services in the State.*

*(VII) A preliminary plan for how the State will sustain any increase in the capacity of providers to deliver substance use disorder treatment or recovery services resulting from the demonstration project under this subsection after the termination of such demonstration project.*

*(VIII) A description of how the State will coordinate the goals of the demonstration project with*

any waiver received pursuant to section 1115 for the delivery of substance use services under the State plan, as applicable.

(ii) *CONSULTATION.*—In completing an application under clause (i), a State shall consult with relevant stakeholders, including Medicaid managed care plans, health care providers, and Medicaid beneficiary advocates, and include in such application a description of such consultation.

(5) *PAYMENT.*—

(A) *IN GENERAL.*—For each quarter occurring during the period for which the demonstration project is conducted (after the first 18 months of such period), the Secretary shall pay under this subsection, subject to subparagraphs (C) and (D), to each State selected under paragraph (4) an amount equal to 80 percent of so much of the qualified sums expended during such quarter.

(B) *QUALIFIED SUMS DEFINED.*—For purposes of subparagraph (A), the term “qualified sums” means, with respect to a State and a quarter, the amount equal to the amount (if any) by which the sums expended by the State during such quarter attributable to substance use treatment or recovery services furnished by providers participating under the State plan (or a waiver of such plan) exceeds 1/4 of such sums expended by the State during fiscal year 2018 attributable to substance use treatment or recovery services.

(C) *NON-DUPLICATION OF PAYMENT.*—In the case that payment is made under subparagraph (A) with respect to expenditures for substance use treatment or recovery services furnished by providers participating under the State plan (or a waiver of such plan), payment may not also be made under subsection (a) with respect to expenditures for the same services so furnished.

(D) *CONDITIONS.*—In the case of a State selected under paragraph (4) that provides substance use disorder treatment and recovery services under a waiver under section 1115, such State shall, as a condition of receiving payments under subparagraph (A)—

(i) coordinate such services under such waiver with substance use disorder treatment and recovery services provided under the demonstration project under this subsection; and

(ii) take such actions as appropriate under the demonstration project to expand such services under such waiver.

(6) *REPORTS.*—

(A) *STATE REPORTS.*—A State receiving payments under paragraph (5) shall, for the period of the demonstration project under this subsection, submit to the Secretary a quarterly report, with respect to expenditures for substance use treatment or recovery services for which payment is made to the State under this subsection, on the following:

(i) The specific activities with respect to which payment under this subsection was provided.

(ii) *The number of providers that delivered substance use disorder treatment or recovery services in the State under the demonstration project compared to the estimated number of providers that would have otherwise delivered such services in the absence of such demonstration project.*

(iii) *The number of individuals enrolled under the State plan (or a waiver of such plan) who received substance use disorder treatment or recovery services under the demonstration project compared to the estimated number of such individuals who would have otherwise received such services in the absence of such demonstration project.*

(iv) *Other matters as determined by the Secretary.*

**(B) CMS REPORTS.—**

(i) *INITIAL REPORT.—Not later than October 1, 2020, the Administrator of the Centers for Medicare & Medicaid Services shall, in consultation with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, submit to Congress an initial report on—*

*(I) the States awarded planning grants under paragraph (3);*

*(II) the criteria used in such selection; and*

*(III) the activities carried out by such States under such planning grants.*

(ii) *INTERIM REPORT.—Not later than October 1, 2022, the Administrator of the Centers for Medicare & Medicaid Services shall, in consultation with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, submit to Congress an interim report—*

*(I) on activities carried out under the demonstration project under this subsection;*

*(II) on the extent to which States selected under paragraph (4) have achieved the stated goals submitted in their applications under subparagraph (C) of such paragraph;*

*(III) with a description of the strengths and limitations of such demonstration project; and*

*(IV) with a plan for the sustainability of such project.*

(iii) *FINAL REPORT.—Not later than October 1, 2024, the Administrator of the Centers for Medicare & Medicaid Services shall, in consultation with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, submit to Congress a final report—*

*(I) providing updates on the matters reported in the interim report under clause (ii);*

*(II) including a description of any changes made with respect to the demonstration project under this subsection after the submission of such interim report; and*

*(III) evaluating such demonstration project.*

(C) *AHRQ REPORT.*—Not later than three years after the date of the enactment of this subsection, the Director of the Agency for Healthcare Research and Quality shall submit to Congress a summary on the experiences of States awarded planning grants under paragraph (3) and States selected under paragraph (4).

(7) *DATA SHARING AND BEST PRACTICES.*—During the period of the demonstration project under this subsection, the Secretary shall, in collaboration with States selected under paragraph (4), facilitate data sharing and the development of best practices between such States and States that were not so selected.

(8) *CMS FUNDING.*—There is appropriated, out of any funds in the Treasury not otherwise appropriated, \$5,000,000 to the Centers for Medicare & Medicaid Services for purposes of implementing this subsection. Such amount shall remain available until expended.

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