115TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
115–728

MEDICAID DRUG REVIEW, UTILIZATION, GOOD GOVERNANCE IMPROVEMENT 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. 5799]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 5799) to amend title XIX of the Social Security Act to require as a condition of receipt of full Federal medical assistance percentage under Medicaid that State Medicaid plans have in place certain drug utilization review activities, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

CONTENTS

The amendments are as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medicaid Drug Review, Utilization, Good Governance Improvement Act" or the "Medicaid DRUG Improvement Act".

SEC. 2. MEDICAID DRUG UTILIZATION REVIEW.

(a) STATE PLAN REQUIREMENT.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) is amended—

(1) in paragraph (82), at the end, by striking "and";

(2) in paragraph (83), at the end, by striking the period and inserting "; and"; and

(3) by inserting after paragraph (83) the following new paragraph:

"(84) provide that the State is in compliance with the drug review and utilization requirements under subsection (nn)(1).".

(b) DRUG REVIEW AND UTILIZATION REQUIREMENTS.—Section 1902 of the Social Security Act (42 U.S.C. 1396a) is amended by adding at the end the following new subsection:

"(nn) DRUG REVIEW AND UTILIZATION REQUIREMENTS.—

"(1) IN GENERAL.—For purposes of subsection (a)(84), the drug review and utilization requirements under this subsection are, subject to paragraph (3) and beginning October 1, 2019, the following:

"(A) CLAIMS REVIEW LIMITATIONS.—

"(i) IN GENERAL.—The State has in place—

"(I) safety edits (as specified by the State) for subsequent fills for opioids and a claims review automated process (as designed and implemented by the State) that indicates when an individual enrolled under the State plan (or under a waiver of the State plan) is prescribed a subsequent fill of opioids in excess of any limitation that may be identified by the State;

"(II) safety edits (as specified by the State) on the maximum daily morphine equivalent that can be prescribed to an individual enrolled under the State plan (or under a waiver of the State plan) for treatment of chronic pain and a claims review automated process (as designed and implemented by the State) that indicates when an individual enrolled under the plan (or waiver) is prescribed the morphine equivalent for such treatment in excess of any limitation that may be identified by the State; and

"(III) a claims review automated process (as designed and implemented by the State) that monitors when an individual enrolled under the State plan (or under a waiver of the State plan) is concurrently prescribed opioids and—

"(aa) benzodiazepines; or

"(bb) antipsychotics.

"(ii) MANAGED CARE ENTITIES.—The State requires each managed care entity (as defined in section 1932(a)(1)(B)) with respect to which the State has a contract under section 1903(m) or under section 1905(t)(3) to have in place, subject to paragraph (3), with respect to individuals who are eligible for medical assistance under the State plan (or under a waiver of the State plan) and who are enrolled with the entity, the limitations described in subclauses (I) and (II) of clause (i) and a claims review automated process described in subclause (III) of such clause.

"(iii) RULES OF CONSTRUCTION.—Nothing in this subparagraph may be construed as prohibiting a State or managed care entity from designing and implementing a claims review automated process under this subparagraph that provides for prospective or retrospective reviews of claims. Nothing in this subparagraph shall be understood as prohibiting the exercise of clinical judgment from a provider enrolled as a participating provider in a State plan (or waiver of the State plan) or contracting with a managed care entity regarding the best items and services for an individual enrolled under such State plan (or waiver).

"(B) PROGRAM TO MONITOR ANTIPSYCHOTIC MEDICATIONS BY CHILDREN.—The State has in place a program (as designed and implemented by the State), including such a program that the State had in place before the date of the enactment of this subsection, to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the State plan (or under a waiver of the State plan) and submits annually to the Secretary such information as the Secretary may require on activities carried out under such program for individuals not more than the age of 18 years generally and children in foster care specifically.

"(C) FRAUD AND ABUSE IDENTIFICATION.—The State has in place a process (as designed and implemented by the State), including such a process that the State had in place before the date of the enactment of this subsection, that identifies potential fraud or abuse of controlled substances by individuals enrolled under the State plan (or under a waiver of the State plan), health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled.

"(D) REPORTS.—The State shall include in the annual report submitted to the Secretary under section 1927(g)(3)(D) information on the limitations, requirement, program, and processes applied by the State under subparagraphs (A) through (C) in accordance with such manner and time as specified by the Secretary.

"(2) ANNUAL REPORT BY SECRETARY.—For each fiscal year beginning with fiscal year 2020, the Secretary shall submit to Congress a report on the most recent information submitted by States under paragraph (1)(D).

"(3) EXCEPTIONS.—

"(A) CERTAIN INDIVIDUALS EXEMPTED.—The drug review and utilization requirements under this subsection shall not apply with respect to an individual who—

"(i) is receiving—

"(I) hospice or palliative care; or

"(II) treatment for cancer;

"(ii) is a resident of a long-term care facility, of a facility described in section 1905(d), or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or

"(iii) the State elects to treat as exempted from such requirements.

"(B) EXCEPTION RELATING TO ENSURING ACCESS.—In order to ensure reasonable access to health care, the Secretary may waive the drug review and utilization requirements under this subsection, with respect to a State, in the case of natural disasters and similar situations, and in the case of the provision of emergency services (as defined for purposes of section 1860D–4(c)(5)(D)(ii)(II)).".

(c) MANAGED CARE ENTITIES.—Section 1932 of the Social Security Act (42 U.S.C. 1396u–2) is amended by adding at the end the following new subsection:

"(i) DRUG UTILIZATION REVIEW ACTIVITIES AND REQUIREMENTS.—Beginning not later than October 1, 2019, each contract under a State plan with a managed care entity (other than a primary care case manager) under section 1903(m) shall provide that the entity is in compliance with the applicable provisions of section 438.3(s)(2) of title 42 of the Code of Federal Regulations, section 483.3(s)(4)) of such title, and section 483.3(s)(5) of such title, as such provisions were in effect on March 31, 2018.".

SEC. 3. IDENTIFYING AND ADDRESSING INAPPROPRIATE PRESCRIBING AND BILLING PRACTICES UNDER MEDICAID.

(a) IN GENERAL.—Section 1927(g) of the Social Security Act (42 U.S.C. 1396r–8(g)) is amended—

(1) in paragraph (1)(A)—

(A) by striking "of section 1903(i)(10)(B)" and inserting "of section 1902(a)(54)";

(B) by striking ", by not later than January 1, 1993,";

(C) by inserting after "gross overuse," the following: "excessive utilization,"; and

(D) by striking "or inappropriate or medically unnecessary care" and inserting "inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization"; and

(2) in paragraph (2)(B)—

(A) by inserting after "gross overuse," the following: "excessive utilization,";

(B) by striking "or inappropriate or medically unnecessary care" and inserting "inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization"; and

(C) by adding at the end the following new sentence: "In the case that the program identifies a pattern described in the previous sentence, the State shall take such remedial actions as determined necessary to address such pattern.".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect with respect to retrospective drug use reviews conducted on or after October 1, 2020.

Amend the title so as to read:

A bill to amend title XIX of the Social Security Act to require under Medicaid that State Medicaid plans have in place certain drug utilization review activities, and to require States to identify and address inappropriate prescribing and billing practices under Medicaid.

PURPOSE AND SUMMARY

H.R. 5799 was introduced on May 15, 2018, by Rep. Marsha Blackburn (R–TN). The bill builds on current state Medicaid drug utilization review (DUR) activities to help combat the opioid crisis. Under the bill, state Medicaid programs will be required to have safety edits in place for opioid refills, monitor concurrent prescribing of opioids and certain other drugs, and monitor antipsychotic prescribing for children.

BACKGROUND AND NEED FOR LEGISLATION

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

While the impacts to Americans' health outcomes are staggering, the opioid crisis has negatively impacted society in numerous ways. The Centers for Disease Control and Prevention note that life expectancy dropped in 2015 and 2106 and that one of the reasons was an increase in unintentional injuries, a category that includes drug overdoses.[2] The opioid crisis has also resulted in a contraction in the labor force by almost 1 million workers in the years between 1999 and 2015, which resulted in a loss of $702 billion in real output.[3] In 2015, the total economic burden of the opioid epidemic was estimated to be $504 billion.[4] While all states were negatively impacted, there is geographic variation in the burden. West Virginia had the greatest loss per person ($4,378) and Nebraska had the lowest loss per person ($394).[4] One recent analysis found that the annual cost for private sector employers for treating opioid addiction and overdoses has increased more than eight-fold since 2004, and more than one in five persons aged 55 to 64 had at least one opioid prescription in 2016.[5]

Medicaid is the largest source of federal funding for behavioral health services—mental health and substance use disorder serv-

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

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

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

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

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

ices—with nearly $71 billion in projected 2017 spending.[6] As the Medicaid and CHIP Payment and Access Commission (MACPAC) stated in 2017, "the opioid epidemic, which has reached most communities across the U.S., disproportionately affects Medicaid beneficiaries."[7] 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.[8] 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.[9]

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."[10] 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."[11]

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."[12] 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.

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

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

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

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

[10] 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.

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

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

However, as MACPAC noted, "there are gaps in the continuum of care, and states vary in the extent to which they cover needed treatment." [13] 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." [14] 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.

Prescription drugs are an optional Medicaid benefit, but all states cover outpatient drugs. States are required to cover most prescription drugs offered by drug manufacturers that participate in the Medicaid rebate program. States may use drug utilization management tools to help administer the Medicaid outpatient prescription drug benefit.[15] In addition to drug utilization tools to help appropriately administer the Medicaid drug benefit, states may receive federal financial support to implement information technology systems to process Medicaid prescription drug claims and collect and report DUR data.[16]

State Medicaid programs are required to report annually to the Centers for Medicare and Medicaid Services their DUR program activities and processes to ensure appropriate drug utilization, including appropriate opioid utilization (which could include placing safety edits on opioids, monitoring the concurrent use of opioids and benzodiazepines, employing a prescription drug monitoring program requirement, and using tools to measure morphine milligram equivalents per day). States are required to include in their annual DUR reports the drug utilization of Medicaid beneficiaries served by managed care organizations under contract to the state Medicaid program. The 2016 CMS Drug Utilization Review report noted that Medicaid programs saved on average about 18 percent on expenditures compared to the total Medicaid expenditures.[17]

State coverage of SUD treatment drugs varies, but all states cover some SUD drugs, which may include buprenorphine or buprenorphine/naloxone combination drugs. All states may cover buprenorphine and buprenorphine/naloxone combination products under some circumstances through a formulary or by prior authorization. State formularies may limit the daily dose of buprenorphine or buprenorphine/naloxone combination drugs that beneficiaries can receive. In 2016, 86 percent of states limited the

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

[14] 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.

[15] Social Security Act (SSA) Section 1927, Payment for Covered Outpatient Drugs.

[16] SSA Section 1927(h), Electronic Claims Management. All states operate outpatient prescription drug claim processing information technology systems.

[17] Centers for Medicare and Medicaid Services, Center for Medicaid & CHIP Services. "Medicaid Drug Utilization Review State Comparison/ Summary Report FFY 2016 Annual Report." October 2017. Available at: https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/2016-dur-summary-report.pdf.

total amount of buprenorphine and buprenorphine/naloxone combination products that Medicaid beneficiaries could receive.[18]

State Medicaid programs are required to cover most children when their family income is below a certain percentage of the federal poverty guideline. In addition, state Medicaid programs are required to cover children in foster care. Children in foster care are children that states have removed from their homes and placed in another setting such as a foster family home, a group home, or a child care institution.

Psychotropic drugs are used to treat mental health conditions such as attention disorders, depression, anxiety, conduct disorders, and other disorders. Youth covered by Medicaid are more likely to be prescribed psychotropic drugs than in private insurance plans.[19] Foster care children are more likely to have mental health care needs than children generally and may be prescribed psychotropic medications as part of their treatment.[20] Currently, 43 states have programs in place to either manage or monitor the appropriate use of antipsychotic medications in children.[21]

COMMITTEE ACTION

On April 11 and 12, 2018, the Subcommittee on Health held a hearing on a discussion draft entitled "Medicaid Drug Improvement Act." The Subcommittee received testimony from:

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

On April 25, 2018, the Subcommittee on Health met in open markup session and forwarded the discussion draft, without amendment, to the full Committee by a record vote of 18 yeas and 9 nays. On May 17, 2018, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 5799, as amended, favorably reported to the House by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII requires the Committee to list the record votes on the motion to report legislation and amendments thereto.

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[18] Centers for Medicare and Medicaid Services, Center for Medicaid & CHIP Services. "Medicaid Drug Utilization Review State Comparison/ Summary Report FFY 2016 Annual Report." October 2017. Available at: https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/2016-dur-summary-report.pdf.

[19] Crystal S, Olfson M, Huang C, Pincus H, and T. Gerhard. "Broadened Use of Atypical Antipsychotics: Safety, Effectiveness, and Policy Challenges." Health Affairs 28, no. 5.

[20] National Resource Center for Family-Centered Practice and Permanency Planning. "Information Packet: Mental Health Care Issues of Children and Youth in Foster Care" April 2008. Available at http://www.ncsl.org/research/human-services/mental-health-and-foster-care.aspx.

[21] Centers for Medicare and Medicaid Services, Center for Medicaid & CHIP Services. "Medicaid Drug Utilization Review State Comparison/ Summary Report FFY 2016 Annual Report." October 2017. Available at: https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/2016-dur-summary-report.pdf.

There were no record votes taken in connection with ordering H.R. 5799 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. 5799 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

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

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

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

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

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

Sincerely,

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

Enclosure.

Opioid Legislation

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

- Provide grants to facilities and providers that treat people with substance use disorders,
- Direct various agencies within the Department of Health and Human Services (HHS) to explore nonopioid approaches to treating pain and to educate providers about those alternatives,
- Modify requirements under Medicaid and Medicare for prescribing controlled substances,
- Expand Medicaid coverage for substance abuse treatment, and

- Direct the Food and Drug Administration (FDA) to modify its oversight of opioid drugs and other medications that are used to manage pain.

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

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

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

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

Estimated cost to the Federal Government: The estimates in this document do not include the effects of interactions among the bills. If all 59 bills were combined and enacted as one piece of legislation, the budgetary effects would be different from the sum of the estimates in this document, although CBO expects that any such differences would be small. The costs of this legislation fall within budget functions 550 (health), 570 (Medicare), 750 (administration of justice), and 800 (general government).

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

Uncertainty

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

could differ from those provided in CBO's analyses depending on those decisions.

Direct spending and revenues

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

TABLE 1.—ESTIMATED CHANGES IN MANDATORY SPENDING AND REVENUES

	By fiscal year, in millions of dollars—												
	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2019–2023	2019–2028
INCREASES OR DECREASES (−) IN DIRECT SPENDING													
Legislation Primarily Affecting Medicaid:													
H.R. 1925, At-Risk Youth Medicaid Protection Act of 2017	0	*	5	5	5	10	10	10	10	10	10	25	75
H.R. 4998, Health Insurance for Former Foster Youth Act	0	0	0	0	0	*	10	21	33	46	61	*	171
H.R. 5477, Rural Development of Opioid Capacity Services Act	0	13	35	58	68	83	27	9	3	3	3	256	301
H.R. 5583, a bill to amend title XI of the Social Security Act to require States to annually report on certain adult health quality measures, and for other purposes	0	*	*	*	*	*	*	*	*	*	*	*	*
H.R. 5797, IMD CARE Act	0	38	158	251	265	279	0	0	0	0	0	991	991
H.R. 5799, Medicaid DRUG Improvement Act [a]	0	*	*	1	1	1	1	1	1	1	1	2	5
H.R. 5801 Medicaid Providers Are Required To Note Experiences in Record Systems to Help In-Need Patients (PARTNERSHIP) Act [a]	0	*	*	*	*	*	*	*	*	*	*	*	*
H.R. 5808, Medicaid Pharmaceutical Home Act of 2018 [a]	0	*	−1	−1	−1	−1	−2	−2	−2	−2	−2	−4	−13
H.R. 5810, Medicaid Health HOME Act	0	94	58	62	56	52	48	43	38	32	25	323	509
Legislation Primarily Affecting Medicare:													
H.R. 3528, Every Prescription Conveyed Securely Act	0	0	0	−24	−35	−33	−30	−33	−32	−31	−32	−92	−250
H.R. 4841, Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018	0	0	0	*	*	*	*	*	*	*	*	*	*
H.R. 5603, Access to Telehealth Services for Opioid Use Disorders Act	0	2	*	*	*	1	1	1	2	2	2	3	11
H.R. 5605, Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act	0	0	0	15	26	24	23	23	10	1	*	65	122
H.R. 5675, a bill to amend title XVIII of the Social Security Act to require prescription drug plan sponsors under the Medicare program to establish drug management programs for at-risk beneficiaries	0	0	0	−6	−7	−7	−7	−8	−9	−9	−11	−20	−64
H.R. 5684, Protecting Seniors From Opioid Abuse Act	0	0	0	*	*	*	*	*	*	*	*	*	*
H.R. 5796, Responsible Education Achieves Care and Healthy Outcomes for Users' Treatment Act of 2018	0	10	25	50	10	5	0	0	0	0	0	100	100
H.R. 5798, Opioid Screening and Chronic Pain Management Alternatives for Seniors Act	0	0	*	1	1	1	1	1	1	1	1	2	5
H.R. 5804, Post-Surgical Injections as an Opioid Alternative Act [a]	0	0	25	30	25	20	10	5	0	0	0	100	115
H.R. 5809, Postoperative Opioid Prevention Act of 2018	0	0	0	0	10	15	20	25	30	35	45	25	180
Legislation Primarily Affecting the Food and Drug Administration:													

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

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

Annual amounts may not sum to totals because of rounding. * = between −$500,000 and $500,000. Budget authority is equivalent to outlays.
[a] This bill also would affect spending subject to appropriation.
[b] One additional bill, H.R. 5228, the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act, would have a negligible effect on revenues.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Spending subject to appropriation

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

- Bills that would have no budgetary effect,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

	By fiscal year, in millions of dollars—						
	2018	2019	2020	2021	2022	2023	2019–2023
INCREASES IN SPENDING SUBJECT TO APPROPRIATION							
H.R. 449, Synthetic Drug Awareness Act of 2018:							
Estimated Authorization Level	0	*	*	*	0	0	1
Estimated Outlays	0	*	*	*	0	0	1
H.R. 4005, Medicaid Reentry Act:							
Estimated Authorization Level	*	*	0	0	0	0	*
Estimated Outlays	*	*	0	0	0	0	*
H.R. 4275, Empowering Pharmacists in the Fight Against Opioid Abuse Act:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5009, Jessie's Law:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5041, Safe Disposal of Unused Medication Act:	0	*	*	*	*	*	*
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5272, Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse Act of 2018:							
Estimated Authorization Level	0	1	1	1	1	1	4
Estimated Outlays	0	1	1	1	1	1	4
H.R. 5333, Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018: [a]							
Food and Drug Administration:							
Collections from fees:							
Estimated Authorization Level	0	−22	−22	−26	−35	−42	−147
Estimated Outlays	0	−22	−22	−26	−35	−42	−147
Spending of fees:							
Estimated Authorization Level	0	22	22	26	35	42	147
Estimated Outlays	0	6	17	30	44	41	137
Net effect on FDA:							
Estimated Authorization Level	0	0	0	0	0	0	0
Estimated Outlays	0	−17	−6	4	9	*	−10
Government Accountability Office:							
Estimated Authorization Level	0	0	0	0	0	*	*
Estimated Outlays	0	0	0	0	0	*	*
Total, H.R. 5333:							
Estimated Authorization Level	0	0	0	0	0	*	*
Estimated Outlays	0	−17	−6	4	9	*	−10
H.R. 5473, Better Pain Management Through Better Data Act of 2018:							
Estimated Authorization Level	0	*	*	*	*	0	1
Estimated Outlays	0	*	*	*	*	*	1
H.R. 5483, Special Registration for Telemedicine Clarification Act of 2018:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5554, Animal Drug and Animal Generic Drug User Fee Amendments of 2018:							
Collections from fees:							
Animal drug fees	0	−30	−31	−32	−33	−34	−159
Generic animal drug fees	0	−18	−19	−19	−20	−21	−97
Total, Estimated Authorization Level	0	−49	−50	−51	−53	−55	−257
Total, Estimated Outlays	0	−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
Total, H.R. 5554:							
Estimated Authorization Level	0	3	1	1	1	1	6
Estimated Outlays	0	−8	−2	1	*	*	−8
H.R. 5582, Abuse Deterrent Access Act of 2018:							
Estimated Authorization Level	0	0	*	0	0	0	*
Estimated Outlays	0	0	*	0	0	0	*
H.R. 5590, Opioid Addiction Action Plan Act:							
Estimated Authorization Level	*	*	*	*	*	*	2
Estimated Outlays	*	*	*	*	*	*	2
H.R. 5687, Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5715, Strengthening Partnerships to Prevent Opioid Abuse Act:							
Estimated Authorization Level	0	2	2	2	2	2	9
Estimated Outlays	0	2	2	2	2	2	9
H.R. 5789, a bill to require the Secretary of Health and Human Services to issue guidance to improve care for infants with neonatal abstinence syndrome and their mothers, and to require the Comptroller General of the United States to conduct a study on gaps in Medicaid coverage for pregnant and postpartum women with substance use disorder:							
Estimated Authorization Level	0	2	0	0	0	0	2
Estimated Outlays	0	2	0	0	0	0	2
H.R. 5795, Overdose Prevention and Patient Safety Act:							
Estimated Authorization Level	0	1	0	0	0	0	1
Estimated Outlays	0	1	0	0	0	0	1
H.R. 5800, Medicaid IMD ADDITIONAL INFO Act:							
Estimated Authorization Level	0	1	0	0	0	0	1
Estimated Outlays	0	*	*	0	0	0	1
H.R. 5804, Post-Surgical Injections as an Opioid Alternative Act: [a]							
Estimated Authorization Level	0	0	0	0	1	1	1
Estimated Outlays	0	0	0	0	1	1	1
H.R. 5811, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to postapproval study requirements for certain controlled substances, and for other purposes:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*

Annual amounts may not sum to totals because of rounding. * = between −$500,000 and $500,000.
[a] This bill also would affect mandatory spending (see Table 1).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

H.R. 5789, a bill to require the Secretary of Health and Human Services to issue guidance to improve care for infants with neonatal abstinence syndrome and their mothers, and to require the Comptroller General of the United States to conduct a study on gaps in Medicaid coverage for pregnant and postpartum women with substance use disorder, would direct the Secretary of HHS to issue guidance to states on best practices under Medicaid and CHIP for treating infants with neonatal abstinence syndrome. H.R. 5789 also would direct the Government Accountability Office to study Medicaid coverage for pregnant and postpartum women with substance use disorders. Based on inforation 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 build on current state Medicaid drug utilization review activities to help combat the opioid crisis.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 5799 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. 5799 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. 5799 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 "Medicaid Drug Review, Utilization, Good Governance Improvement Act" or the "Medicaid DRUG Improvement Act."

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

Section 2 amends section 1902 of the Social Security Act by requiring states to amend their state Medicaid plans to comply with new Medicaid drug review and utilization requirements.

Section 2 requires state Medicaid programs and Medicaid managed care plans to have in place safety edits (as specified by the State) on:

- Subsequent fills for opioids;[22] and
- Safety edit on the daily milligrams of the maximum daily morphine equivalent prescribed to an enrollee for treatment of chronic pain.

These requirements would have to be in place by October 1, 2019.

Section 2 also requires automated processes for claims review for the concurrent prescription for opioids and benzodiazepines and/or antipsychotics. State Medicaid programs are required to have as in place a program (as designed and implemented by the State) to monitor and manage the appropriate use of antipsychotic medications by children in Medicaid as well as have a program in place that identifies potential fraud and abuse of controlled substances by individuals enrolled under the State plan.

[22] Currently, 37 states (74%) have edits in place to limit the quantity of short-acting opioids and 39 states (78%) have edits in place to limit the quantity of long-acting opioids.

Section 2 has important exceptions from the requirement, including individuals in hospice, palliative care, or residents of long term care facilities and exceptions for natural disasters and emergencies.

Finally, section 2 codifies a current regulatory requirement that Medicaid managed care plans have in place a drug utilization review program mirroring the requirements on Medicaid programs.

Section 3. Identifying and addressing inappropriate prescribing and billing practices under Medicaid

Section 3 requires states have in place drug utilization activities to identify and report inappropriate prescribing and billing practices under Medicaid as a requirement in the state plan.

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 (existing law proposed to be omitted is enclosed in black brackets, 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

* * * * * * *

STATE PLANS FOR MEDICAL ASSISTANCE

SEC. 1902. (a) A State plan for medical assistance must—

(1) provide that it shall be in effect in all political subdivisions of the State, and, if administered by them, be mandatory upon them;

(2) provide for financial participation by the State equal to not less than 40 per centum of the non-Federal share of the expenditures under the plan with respect to which payments under section 1903 are authorized by this title; and, effective July 1, 1969, provide for financial participation by the State equal to all of such non-Federal share or provide for distribution of funds from Federal or State sources, for carrying out the State plan, on an equalization or other basis which will assure that the lack of adequate funds from local sources will not result in lowering the amount, duration, scope, or quality of care and services available under the plan;

(3) provide for granting an opportunity for a fair hearing before the State agency to any individual whose claim for medical assistance under the plan is denied or is not acted upon with reasonable promptness;

(4) provide (A) such methods of administration (including methods relating to the establishment and maintenance of personnel standards on a merit basis, except that the Secretary shall exercise no authority with respect to the selection, tenure of office, and compensation of any individual employed in accordance with such methods, and including provision for utili-

zation of professional medical personnel in the administration and, where administered locally, supervision of administration of the plan) as are found by the Secretary to be necessary for the proper and efficient operation of the plan, (B) for the training and effective use of paid subprofessional staff, with particular emphasis on the full-time or part-time employment of recipients and other persons of low income, as community service aides, in the administration of the plan and for the use of nonpaid or partially paid volunteers in a social service volunteer program in providing services to applicants and recipients and in assisting any advisory committees established by the State agency, (C) that each State or local officer, employee, or independent contractor who is responsible for the expenditure of substantial amounts of funds under the State plan, each individual who formerly was such an officer, employee, or contractor, and each partner of such an officer, employee, or contractor shall be prohibited from committing any act, in relation to any activity under the plan, the commission of which, in connection with any activity concerning the United States Government, by an officer or employee of the United States Government, an individual who was such an officer or employee, or a partner of such an officer or employee is prohibited by section 207 or 208 of title 18, United States Code, and (D) that each State or local officer, employee, or independent contractor who is responsible for selecting, awarding, or otherwise obtaining items and services under the State plan shall be subject to safeguards against conflicts of interest that are at least as stringent as the safeguards that apply under section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423) to persons described in subsection (a)(2) of such section of that Act;

(5) either provide for the establishment or designation of a single State agency to administer or to supervise the administration of the plan; or provide for the establishment or designation of a single State agency to administer or to supervise the administration of the plan, except that the determination of eligibility for medical assistance under the plan shall be made by the State or local agency administering the State plan approved under title I or XVI (insofar as it relates to the aged) if the State is eligible to participate in the State plan program established under title XVI, or by the agency or agencies administering the supplemental security income program established under title XVI or the State plan approved under part A of title IV if the State is not eligible to participate in the State plan program established under title XVI;

(6) provide that the State agency will make such reports, in such form and containing such information, as the Secretary may from time to time require, and comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports;

(7) provide—

(A) safeguards which restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with—

(i) the administration of the plan; and

(ii) the exchange of information necessary to certify or verify the certification of eligibility of children for free or reduced price breakfasts under the Child Nutrition Act of 1966 and free or reduced price lunches under the Richard B. Russell National School Lunch Act, in accordance with section 9(b) of that Act, using data standards and formats established by the State agency; and

(B) that, notwithstanding the Express Lane option under subsection (e)(13), the State may enter into an agreement with the State agency administering the school lunch program established under the Richard B. Russell National School Lunch Act under which the State shall establish procedures to ensure that—

(i) a child receiving medical assistance under the State plan under this title whose family income does not exceed 133 percent of the poverty line (as defined in section 673(2) of the Community Services Block Grant Act, including any revision required by such section), as determined without regard to any expense, block, or other income disregard, applicable to a family of the size involved, may be certified as eligible for free lunches under the Richard B. Russell National School Lunch Act and free breakfasts under the Child Nutrition Act of 1966 without further application; and

(ii) the State agencies responsible for administering the State plan under this title, and for carrying out the school lunch program established under the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 et seq.) or the school breakfast program established by section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773), cooperate in carrying out paragraphs (3)(F) and (15) of section 9(b) of that Act;

(8) provide that all individuals wishing to make application for medical assistance under the plan shall have opportunity to do so, and that such assistance shall be furnished with reasonable promptness to all eligible individuals;

(9) provide—

(A) that the State health agency, or other appropriate State medical agency (whichever is utilized by the Secretary for the purpose specified in the first sentence of section 1864(a)), shall be responsible for establishing and maintaining health standards for private or public institutions in which recipients of medical assistance under the plan may receive care or services,

(B) for the establishment or designation of a State authority or authorities which shall be responsible for establishing and maintaining standards, other than those relating to health, for such institutions,

(C) that any laboratory services paid for under such plan must be provided by a laboratory which meets the applicable requirements of section 1861(e)(9) or paragraphs (16) and (17) of section 1861(s), or, in the case of a laboratory which is in a rural health clinic, of section 1861(aa)(2)(G), and

(D) that the State maintain a consumer-oriented website providing useful information to consumers regarding all skilled nursing facilities and all nursing facilities in the State, including for each facility, Form 2567 State inspection reports (or a successor form), complaint investigation reports, the facility's plan of correction, and such other information that the State or the Secretary considers useful in assisting the public to assess the quality of long term care options and the quality of care provided by individual facilities;

(10) provide—

(A) for making medical assistance available, including at least the care and services listed in paragraphs (1) through (5), (17), (21), and (28) of section 1905(a), to—

(i) all individuals—

(I) who are receiving aid or assistance under any plan of the State approved under title I, X, XIV, or XVI, or part A or part E of title IV (including individuals eligible under this title by reason of section 402(a)(37), 406(h), or 473(b), or considered by the State to be receiving such aid as authorized under section 482(e)(6)),

(II)(aa) with respect to whom supplemental security income benefits are being paid under title XVI (or were being paid as of the date of the enactment of section 211(a) of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (P.L. 104–193) and would continue to be paid but for the enactment of that section), (bb) who are qualified severely impaired individuals (as defined in section 1905(q)), or (cc) who are under 21 years of age and with respect to whom supplemental security income benefits would be paid under title XVI if subparagraphs (A) and (B) of section 1611(c)(7) were applied without regard to the phrase "the first day of the month following",

(III) who are qualified pregnant women or children as defined in section 1905(n),

(IV) who are described in subparagraph (A) or (B) of subsection (l)(1) and whose family income does not exceed the minimum income level the State is required to establish under subsection (l)(2)(A) for such a family;

(V) who are qualified family members as defined in section 1905(m)(1),

(VI) who are described in subparagraph (C) of subsection (l)(1) and whose family income does not exceed the income level the State is required to establish under subsection (l)(2)(B) for such a family,

(VII) who are described in subparagraph (D) of subsection (l)(1) and whose family income does not exceed the income level the State is required to

establish under subsection (l)(2)(C) for such a family;

(VIII) beginning January 1, 2014, who are under 65 years of age, not pregnant, not entitled to, or enrolled for, benefits under part A of title XVIII, or enrolled for benefits under part B of title XVIII, and are not described in a previous subclause of this clause, and whose income (as determined under subsection (e)(14)) does not exceed 133 percent of the poverty line (as defined in section 2110(c)(5)) applicable to a family of the size involved, subject to subsection (k); or

(IX) who—

(aa) are under 26 years of age;

(bb) are not described in or enrolled under any of subclauses (I) through (VII) of this clause or are described in any of such subclauses but have income that exceeds the level of income applicable under the State plan for eligibility to enroll for medical assistance under such subclause;

(cc) were in foster care under the responsibility of the State on the date of attaining 18 years of age or such higher age as the State has elected under section 475(8)(B)(iii); and

(dd) were enrolled in the State plan under this title or under a waiver of the plan while in such foster care;

(ii) at the option of the State, to any group or groups of individuals described in section 1905(a) (or, in the case of individuals described in section 1905(a)(i), to any reasonable categories of such individuals) who are not individuals described in clause (i) of this subparagraph but—

(I) who meet the income and resources requirements of the appropriate State plan described in clause (i) or the supplemental security income program (as the case may be),

(II) who would meet the income and resources requirements of the appropriate State plan described in clause (i) if their work-related child care costs were paid from their earnings rather than by a State agency as a service expenditure,

(III) who would be eligible to receive aid under the appropriate State plan described in clause (i) if coverage under such plan was as broad as allowed under Federal law,

(IV) with respect to whom there is being paid, or who are eligible, or would be eligible if they were not in a medical institution, to have paid with respect to them, aid or assistance under the appropriate State plan described in clause (i), supplemental security income benefits under title XVI, or a State supplementary payment;

(V) who are in a medical institution for a period of not less than 30 consecutive days (with eligibility by reason of this subclause beginning on the first day of such period), who meet the resource requirements of the appropriate State plan described in clause (i) or the supplemental security income program, and whose income does not exceed a separate income standard established by the State which is consistent with the limit established under section 1903(f)(4)(C),

(VI) who would be eligible under the State plan under this title if they were in a medical institution, with respect to whom there has been a determination that but for the provision of home or community-based services described in subsection (c), (d), or (e) of section 1915 they would require the level of care provided in a hospital, nursing facility or intermediate care facility for the mentally retarded the cost of which could be reimbursed under the State plan, and who will receive home or community-based services pursuant to a waiver granted by the Secretary under subsection (c), (d), or (e) of section 1915,

(VII) who would be eligible under the State plan under this title if they were in a medical institution, who are terminally ill, and who will receive hospice care pursuant to a voluntary election described in section 1905(o);

(VIII) who is a child described in section 1905(a)(i)—

(aa) for whom there is in effect an adoption assistance agreement (other than an agreement under part E of title IV) between the State and an adoptive parent or parents,

(bb) who the State agency responsible for adoption assistance has determined cannot be placed with adoptive parents without medical assistance because such child has special needs for medical or rehabilitative care, and

(cc) who was eligible for medical assistance under the State plan prior to the adoption assistance agreement being entered into, or who would have been eligible for medical assistance at such time if the eligibility standards and methodologies of the State's foster care program under part E of title IV were applied rather than the eligibility standards and methodologies of the State's aid to families with dependent children program under part A of title IV;

(IX) who are described in subsection (l)(1) and are not described in clause (i)(IV), clause (i)(VI), or clause (i)(VII);

(X) who are described in subsection (m)(1);

(XI) who receive only an optional State supplementary payment based on need and paid on a regular basis, equal to the difference between the individual's countable income and the income standard used to determine eligibility for such supplementary payment (with countable income being the income remaining after deductions as established by the State pursuant to standards that may be more restrictive than the standards for supplementary security income benefits under title XVI), which are available to all individuals in the State (but which may be based on different income standards by political subdivision according to cost of living differences), and which are paid by a State that does not have an agreement with the Commissioner of Social Security under section 1616 or 1634;

(XII) who are described in subsection (z)(1) (relating to certain TB-infected individuals);

(XIII) who are in families whose income is less than 250 percent of the income official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved, and who but for earnings in excess of the limit established under section 1905(q)(2)(B), would be considered to be receiving supplemental security income (subject, notwithstanding section 1916, to payment of premiums or other cost-sharing charges (set on a sliding scale based on income) that the State may determine);

(XIV) who are optional targeted low-income children described in section 1905(u)(2)(B);

(XV) who, but for earnings in excess of the limit established under section 1905(q)(2)(B), would be considered to be receiving supplemental security income, who is at least 16, but less than 65, years of age, and whose assets, resources, and earned or unearned income (or both) do not exceed such limitations (if any) as the State may establish;

(XVI) who are employed individuals with a medically improved disability described in section 1905(v)(1) and whose assets, resources, and earned or unearned income (or both) do not exceed such limitations (if any) as the State may establish, but only if the State provides medical assistance to individuals described in subclause (XV);

(XVII) who are independent foster care adolescents (as defined in section 1905(w)(1)), or who are within any reasonable categories of such adolescents specified by the State;

(XVIII) who are described in subsection (aa) (relating to certain breast or cervical cancer patients);

(XIX) who are disabled children described in subsection (cc)(1);

(XX) beginning January 1, 2014, who are under 65 years of age and are not described in or enrolled under a previous subclause of this clause, and whose income (as determined under subsection (e)(14)) exceeds 133 percent of the poverty line (as defined in section 2110(c)(5)) applicable to a family of the size involved but does not exceed the highest income eligibility level established under the State plan or under a waiver of the plan, subject to subsection (hh);

(XXI) who are described in subsection (ii) (relating to individuals who meet certain income standards); or

(XXII) who are eligible for home and community-based services under needs-based criteria established under paragraph (1)(A) of section 1915(i), or who are eligible for home and community-based services under paragraph (6) of such section, and who will receive home and community-based services pursuant to a State plan amendment under such subsection;

(B) that the medical assistance made available to any individual described in subparagraph (A)—

(i) shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual, and

(ii) shall not be less in amount, duration, or scope than the medical assistance made available to individuals not described in subparagraph (A);

(C) that if medical assistance is included for any group of individuals described in section 1905(a) who are not described in subparagraph (A) or (E), then—

(i) the plan must include a description of (I) the criteria for determining eligibility of individuals in the group for such medical assistance, (II) the amount, duration, and scope of medical assistance made available to individuals in the group, and (III) the single standard to be employed in determining income and resource eligibility for all such groups, and the methodology to be employed in determining such eligibility, which shall be no more restrictive than the methodology which would be employed under the supplemental security income program in the case of groups consisting of aged, blind, or disabled individuals in a State in which such program is in effect, and which shall be no more restrictive than the methodology which would be employed under the appropriate State plan (described in subparagraph (A)(i)) to which such group is most closely categorically related in the case of other groups;

(ii) the plan must make available medical assistance—

(I) to individuals under the age of 18 who (but for income and resources) would be eligible for medical assistance as an individual described in subparagraph (A)(i), and

(II) to pregnant women, during the course of their pregnancy, who (but for income and resources) would be eligible for medical assistance as an individual described in subparagraph (A);

(iii) such medical assistance must include (I) with respect to children under 18 and individuals entitled to institutional services, ambulatory services, and (II) with respect to pregnant women, prenatal care and delivery services; and

(iv) if such medical assistance includes services in institutions for mental diseases or in an intermediate care facility for the mentally retarded (or both) for any such group, it also must include for all groups covered at least the care and services listed in paragraphs (1) through (5) and (17) of section 1905(a) or the care and services listed in any 7 of the paragraphs numbered (1) through (24) of such section;

(D) for the inclusion of home health services for any individual who, under the State plan, is entitled to nursing facility services;

(E)(i) for making medical assistance available for medicare cost-sharing (as defined in section 1905(p)(3)) for qualified medicare beneficiaries described in section 1905(p)(1);

(ii) for making medical assistance available for payment of medicare cost-sharing described in section 1905(p)(3)(A)(i) for qualified disabled and working individuals described in section 1905(s);

(iii) for making medical assistance available for medicare cost sharing described in section 1905(p)(3)(A)(ii) subject to section 1905(p)(4), for individuals who would be qualified medicare beneficiaries described in section 1905(p)(1) but for the fact that their income exceeds the income level established by the State under section 1905(p)(2) but is less than 110 percent in 1993 and 1994, and 120 percent in 1995 and years thereafter of the official poverty line (referred to in such section) for a family of the size involved; and

(iv) subject to sections 1933 and 1905(p)(4), for making medical assistance available for medicare cost-sharing described in section 1905(p)(3)(A)(ii) for individuals who would be qualified medicare beneficiaries described in section 1905(p)(1) but for the fact that their income exceeds the income level established by the State under section 1905(p)(2) and is at least 120 percent, but less than 135 percent, of the official poverty line (referred to in such section) for a family of the size involved and who are not otherwise eligible for medical assistance under the State plan;

(F) at the option of a State, for making medical assistance available for COBRA premiums (as defined in sub-

section (u)(2)) for qualified COBRA continuation beneficiaries described in section 1902(u)(1); and

(G) that, in applying eligibility criteria of the supplemental security income program under title XVI for purposes of determining eligibility for medical assistance under the State plan of an individual who is not receiving supplemental security income, the State will disregard the provisions of subsections (c) and (e) of section 1613;

except that (I) the making available of the services described in paragraph (4), (14), or (16) of section 1905(a) to individuals meeting the age requirements prescribed therein shall not, by reason of this paragraph (10), require the making available of any such services, or the making available of such services of the same amount, duration, and scope, to individuals of any other ages, (II) the making available of supplementary medical insurance benefits under part B of title XVIII to individuals eligible therefor (either pursuant to an agreement entered into under section 1843 or by reason of the payment of premiums under such title by the State agency on behalf of such individuals), or provision for meeting part or all of the cost of deductibles, cost sharing, or similar charges under part B of title XVIII for individuals eligible for benefits under such part, shall not, by reason of this paragraph (10), require the making available of any such benefits, or the making available of services of the same amount, duration, and scope, to any other individuals, (III) the making available of medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in clause (A) to any classification of individuals approved by the Secretary with respect to whom there is being paid, or who are eligible, or would be eligible if they were not in a medical institution, to have paid with respect to them, a State supplementary payment shall not, by reason of this paragraph (10), require the making available of any such assistance, or the making available of such assistance of the same amount, duration, and scope, to any other individuals not described in clause (A), (IV) the imposition of a deductible, cost sharing, or similar charge for any item or service furnished to an individual not eligible for the exemption under section 1916(a)(2) or (b)(2) shall not require the imposition of a deductible, cost sharing, or similar charge for the same item or service furnished to an individual who is eligible for such exemption, (V) the making available to pregnant women covered under the plan of services relating to pregnancy (including prenatal, delivery, and postpartum services) or to any other condition which may complicate pregnancy shall not, by reason of this paragraph (10), require the making available of such services, or the making available of such services of the same amount, duration, and scope, to any other individuals, provided such services are made available (in the same amount, duration, and scope) to all pregnant women covered under the State plan, (VI) with respect to the making available of medical assistance for hospice care to terminally ill individuals who have made a voluntary election described in section 1905(o) to receive hospice care instead of medical assistance for certain other services, such assistance may not be

made available in an amount, duration, or scope less than that provided under title XVIII, and the making available of such assistance shall not, by reason of this paragraph (10), require the making available of medical assistance for hospice care to other individuals or the making available of medical assistance for services waived by such terminally ill individuals, (VII) the medical assistance made available to an individual described in subsection (l)(1)(A) who is eligible for medical assistance only because of subparagraph (A)(i)(IV) or (A)(ii)(IX) shall be limited to medical assistance for services related to pregnancy (including prenatal, delivery, postpartum, and family planning services) and to other conditions which may complicate pregnancy, (VIII) the medical assistance made available to a qualified medicare beneficiary described in section 1905(p)(1) who is only entitled to medical assistance because the individual is such a beneficiary shall be limited to medical assistance for medicare cost-sharing (described in section 1905(p)(3)), subject to the provisions of subsection (n) and section 1916(b), (IX) the making available of respiratory care services in accordance with subsection (e)(9) shall not, by reason of this paragraph (10), require the making available of such services, or the making available of such services of the same amount, duration, and scope, to any individuals not included under subsection (e)(9)(A), provided such services are made available (in the same amount, duration, and scope) to all individuals described in such subsection, (X) if the plan provides for any fixed durational limit on medical assistance for inpatient hospital services (whether or not such a limit varies by medical condition or diagnosis), the plan must establish exceptions to such a limit for medically necessary inpatient hospital services furnished with respect to individuals under one year of age in a hospital defined under the State plan, pursuant to section 1923(a)(1)(A), as a disproportionate share hospital and subparagraph (B) (relating to comparability) shall not be construed as requiring such an exception for other individuals, services, or hospitals, (XI) the making available of medical assistance to cover the costs of premiums, deductibles, coinsurance, and other cost-sharing obligations for certain individuals for private health coverage as described in section 1906 shall not, by reason of paragraph (10), require the making available of any such benefits or the making available of services of the same amount, duration, and scope of such private coverage to any other individuals, (XII) the medical assistance made available to an individual described in subsection (u)(1) who is eligible for medical assistance only because of subparagraph (F) shall be limited to medical assistance for COBRA continuation premiums (as defined in subsection (u)(2)), (XIII) the medical assistance made available to an individual described in subsection (z)(1) who is eligible for medical assistance only because of subparagraph (A)(ii)(XII) shall be limited to medical assistance for TB-related services (described in subsection (z)(2)), (XIV) the medical assistance made available to an individual described in subsection (aa) who is eligible for medical assistance only because of subparagraph (A)(10)(ii)(XVIII) shall be limited to medical assistance provided during the period in

which such an individual requires treatment for breast or cervical cancer (XV) the medical assistance made available to an individual described in subparagraph (A)(i)(VIII) shall be limited to medical assistance described in subsection (k)(1), (XVI) the medical assistance made available to an individual described in subsection (ii) shall be limited to family planning services and supplies described in section 1905(a)(4)(C) including medical diagnosis and treatment services that are provided pursuant to a family planning service in a family planning setting and (XVII) if an individual is described in subclause (IX) of subparagraph (A)(i) and is also described in subclause (VIII) of that subparagraph, the medical assistance shall be made available to the individual through subclause (IX) instead of through subclause (VIII);

(11)(A) provide for entering into cooperative arrangements with the State agencies responsible for administering or supervising the administration of health services and vocational rehabilitation services in the State looking toward maximum utilization of such services in the provision of medical assistance under the plan, (B) provide, to the extent prescribed by the Secretary, for entering into agreements, with any agency, institution, or organization receiving payments under (or through an allotment under) title V, (i) providing for utilizing such agency, institution, or organization in furnishing care and services which are available under such title or allotment and which are included in the State plan approved under this section (ii) making such provision as may be appropriate for reimbursing such agency, institution, or organization for the cost of any such care and services furnished any individual for which payment would otherwise be made to the State with respect to the individual under section 1903, and (iii) providing for coordination of information and education on pediatric vaccinations and delivery of immunization services, and (C) provide for coordination of the operations under this title, including the provision of information and education on pediatric vaccinations and the delivery of immunization services, with the State's operations under the special supplemental nutrition program for women, infants, and children under section 17 of the Child Nutrition Act of 1966;

(12) provide that, in determining whether an individual is blind, there shall be an examination by a physician skilled in the diseases of the eye or by an optometrist, whichever the individual may select;

(13) provide—

(A) for a public process for determination of rates of payment under the plan for hospital services, nursing facility services, and services of intermediate care facilities for the mentally retarded under which—

(i) proposed rates, the methodologies underlying the establishment of such rates, and justifications for the proposed rates are published,

(ii) providers, beneficiaries and their representatives, and other concerned State residents are given a reasonable opportunity for review and comment on the proposed rates, methodologies, and justifications,

(iii) final rates, the methodologies underlying the establishment of such rates, and justifications for such final rates are published, and

(iv) in the case of hospitals, such rates take into account (in a manner consistent with section 1923) the situation of hospitals which serve a disproportionate number of low-income patients with special needs;

(B) for payment for hospice care in amounts no lower than the amounts, using the same methodology, used under part A of title XVIII and for payment of amounts under section 1905(o)(3); except that in the case of hospice care which is furnished to an individual who is a resident of a nursing facility or intermediate care facility for the mentally retarded, and who would be eligible under the plan for nursing facility services or services in an intermediate care facility for the mentally retarded if he had not elected to receive hospice care, there shall be paid an additional amount, to take into account the room and board furnished by the facility, equal to at least 95 percent of the rate that would have been paid by the State under the plan for facility services in that facility for that individual; and

(C) payment for primary care services (as defined in subsection (jj)) furnished in 2013 and 2014 by a physician with a primary specialty designation of family medicine, general internal medicine, or pediatric medicine at a rate not less than 100 percent of the payment rate that applies to such services and physician under part B of title XVIII (or, if greater, the payment rate that would be applicable under such part if the conversion factor under section 1848(d) for the year involved were the conversion factor under such section for 2009);

(14) provide that enrollment fees, premiums, or similar charges, and deductions, cost sharing, or similar charges, may be imposed only as provided in section 1916;

(15) provide for payment for services described in clause (B) or (C) of section 1905(a)(2) under the plan in accordance with subsection (bb);

(16) provide for inclusion, to the extent required by regulations prescribed by the Secretary, of provisions (conforming to such regulations) with respect to the furnishing of medical assistance under the plan to individuals who are residents of the State but are absent therefrom;

(17) except as provided in subsections (e)(14), (e)(15), (l)(3), (m)(3), and (m)(4), include reasonable standards (which shall be comparable for all groups and may, in accordance with standards prescribed by the Secretary, differ with respect to income levels, but only in the case of applicants or recipients of assistance under the plan who are not receiving aid or assistance under any plan of the State approved under title I, X, XIV, or XVI, or part A of title IV, and with respect to whom supplemental security income benefits are not being paid under title XVI, based on the variations between shelter costs in urban areas and in rural areas) for determining eligibility for and the extent of medical assistance under the plan which

(A) are consistent with the objectives of this title, (B) provide for taking into account only such income and resources as are, as determined in accordance with standards prescribed by the Secretary, available to the applicant or recipient and (in the case of any applicant or recipient who would, except for income and resources, be eligible for aid or assistance in the form of money payments under any plan of the State approved under title I, X, XIV, or XVI, or part A of title IV, or to have paid with respect to him supplemental security income benefits under title XVI) as would not be disregarded (or set aside for future needs) in determining his eligibility for such aid, assistance, or benefits, (C) provide for reasonable evaluation of any such income or resources, and (D) do not take into account the financial responsibility of any individual for any applicant or recipient of assistance under the plan unless such applicant or recipient is such individual's spouse or such individual's child who is under age 21 or (with respect to States eligible to participate in the State program established under title XVI), is blind or permanently and totally disabled, or is blind or disabled as defined in section 1614 (with respect to States which are not eligible to participate in such program); and provide for flexibility in the application of such standards with respect to income by taking into account, except to the extent prescribed by the Secretary, the costs (whether in the form of insurance premiums, payments made to the State under section 1903(f)(2)(B), or otherwise and regardless of whether such costs are reimbursed under another public program of the State or political subdivision thereof) incurred for medical care or for any other type of remedial care recognized under State law;

(18) comply with the provisions of section 1917 with respect to liens, adjustments and recoveries of medical assistance correctly paid, transfers of assets, and treatment of certain trusts;

(19) provide such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients;

(20) if the State plan includes medical assistance in behalf of individuals 65 years of age or older who are patients in institutions for mental diseases—

(A) provide for having in effect such agreements or other arrangements with State authorities concerned with mental diseases, and, where appropriate, with such institutions, as may be necessary for carrying out the State plan, including arrangements for joint planning and for development of alternate methods of care, arrangements providing assurance of immediate readmittance to institutions where needed for individuals under alternate plans of care, and arrangements providing for access to patients and facilities, for furnishing information, and for making reports;

(B) provide for an individual plan for each such patient to assure that the institutional care provided to him is in his best interests, including, to that end, assurances that there will be initial and periodic review of his medical and other needs, that he will be given appropriate medical

treatment within the institution, and that there will be a periodic determination of his need for continued treatment in the institution; and

(C) provide for the development of alternate plans of care, making maximum utilization of available resources, for recipients 65 years of age or older who would otherwise need care in such institutions, including appropriate medical treatment and other aid or assistance; for services referred to in section 3(a)(4)(A)(i) and (ii) or section 1603(a)(4)(A)(i) and (ii) which are appropriate for such recipients and for such patients; and for methods of administration necessary to assure that the responsibilities of the State agency under the State plan with respect to such recipients and such patients will be effectively carried out;

(21) if the State plan includes medical assistance in behalf of individuals 65 years of age or older who are patients in public institutions for mental diseases, show that the State is making satisfactory progress toward developing and implementing a comprehensive mental health program, including provision for utilization of community mental health centers, nursing facilities, and other alternatives to care in public institutions for mental diseases;

(22) include descriptions of (A) the kinds and numbers of professional medical personnel and supporting staff that will be used in the administration of the plan and of the responsibilities they will have, (B) the standards, for private or public institutions in which recipients of medical assistance under the plan may receive care or services, that will be utilized by the State authority or authorities responsible for establishing and maintaining such standards, (C) the cooperative arrangements with State health agencies and State vocational rehabilitation agencies entered into with a view to maximum utilization of and coordination of the provision of medical assistance with the services administered or supervised by such agencies, and (D) other standards and methods that the State will use to assure that medical or remedial care and services provided to recipients of medical assistance are of high quality;

(23) provide that (A) any individual eligible for medical assistance (including drugs) may obtain such assistance from any institution, agency, community pharmacy, or person, qualified to perform the service or services required (including an organization which provides such services, or arranges for their availability, on a prepayment basis), who undertakes to provide him such services, and (B) an enrollment of an individual eligible for medical assistance in a primary care case-management system (described in section 1915(b)(1)), a medicaid managed care organization, or a similar entity shall not restrict the choice of the qualified person from whom the individual may receive services under section 1905(a)(4)(C), except as provided in subsection (g) and in section 1915, except that this paragraph shall not apply in the case of Puerto Rico, the Virgin Islands, and Guam, and except that nothing in this paragraph shall be construed as requiring a State to provide medical assistance for such services furnished by a person or entity convicted of a felony under Federal or State law for an offense

which the State agency determines is inconsistent with the best interests of beneficiaries under the State plan or by a provider or supplier to which a moratorium under subsection (kk)(4) is applied during the period of such moratorium';

(24) effective July 1, 1969, provide for consultative services by health agencies and other appropriate agencies of the State to hospitals, nursing facilities, home health agencies, clinics, laboratories, and such other institutions as the Secretary may specify in order to assist them (A) to qualify for payments under this Act, (B) to establish and maintain such fiscal records as may be necessary for the proper and efficient administration of this Act, and (C) to provide information needed to determine payments due under this Act on account of care and services furnished to individuals;

(25) provide—

(A) that the State or local agency administering such plan will take all reasonable measures to ascertain the legal liability of third parties (including health insurers, self-insured plans, group health plans (as defined in section 607(1) of the Employee Retirement Income Security Act of 1974), service benefit plans, managed care organizations, pharmacy benefit managers, or other parties that are, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service) to pay for care and services available under the plan, including—

(i) the collection of sufficient information (as specified by the Secretary in regulations) to enable the State to pursue claims against such third parties, with such information being collected at the time of any determination or redetermination of eligibility for medical assistance, and

(ii) the submission to the Secretary of a plan (subject to approval by the Secretary) for pursuing claims against such third parties, which plan shall be integrated with, and be monitored as a part of the Secretary's review of, the State's mechanized claims processing and information retrieval systems required under section 1903(r);

(B) that in any case where such a legal liability is found to exist after medical assistance has been made available on behalf of the individual and where the amount of reimbursement the State can reasonably expect to recover exceeds the costs of such recovery, the State or local agency will seek reimbursement for such assistance to the extent of such legal liability;

(C) that in the case of an individual who is entitled to medical assistance under the State plan with respect to a service for which a third party is liable for payment, the person furnishing the service may not seek to collect from the individual (or any financially responsible relative or representative of that individual) payment of an amount for that service (i) if the total of the amount of the liabilities of third parties for that service is at least equal to the amount payable for that service under the plan (dis-

regarding section 1916), or (ii) in an amount which exceeds the lesser of (I) the amount which may be collected under section 1916, or (II) the amount by which the amount payable for that service under the plan (disregarding section 1916) exceeds the total of the amount of the liabilities of third parties for that service;

(D) that a person who furnishes services and is participating under the plan may not refuse to furnish services to an individual (who is entitled to have payment made under the plan for the services the person furnishes) because of a third party's potential liability for payment for the service;

(E) that in the case of preventive pediatric care (including early and periodic screening and diagnosis services under section 1905(a)(4)(B)) covered under the State plan, the State shall—

(i) make payment for such service in accordance with the usual payment schedule under such plan for such services without regard to the liability of a third party for payment for such services; and

(ii) seek reimbursement from such third party in accordance with subparagraph (B);

(F) that in the case of any services covered under such plan which are provided to an individual on whose behalf child support enforcement is being carried out by the State agency under part D of title IV of this Act, the State shall—

(i) make payment for such service in accordance with the usual payment schedule under such plan for such services without regard to any third-party liability for payment for such services, if such third-party liability is derived (through insurance or otherwise) from the parent whose obligation to pay support is being enforced by such agency, if payment has not been made by such third party within 30 days after such services are furnished;

(ii) seek reimbursement from such third party in accordance with subparagraph (B);

(G) that the State prohibits any health insurer (including a group health plan, as defined in section 607(1) of the Employee Retirement Income Security Act of 1974, a self-insured plan, a service benefit plan, a managed care organization, a pharmacy benefit manager, or other party that is, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service), in enrolling an individual or in making any payments for benefits to the individual or on the individual's behalf, from taking into account that the individual is eligible for or is provided medical assistance under a plan under this title for such State, or any other State;

(H) that to the extent that payment has been made under the State plan for medical assistance in any case where a third party has a legal liability to make payment for such assistance, the State has in effect laws under which, to the extent that payment has been made under

the State plan for medical assistance for health care items or services furnished to an individual, the State is considered to have acquired the rights of such individual to payment by any other party for such health care items or services; and

(I) that the State shall provide assurances satisfactory to the Secretary that the State has in effect laws requiring health insurers, including self-insured plans, group health plans (as defined in section 607(1) of the Employee Retirement Income Security Act of 1974), service benefit plans, managed care organizations, pharmacy benefit managers, or other parties that are, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service, as a condition of doing business in the State, to—

(i) provide, with respect to individuals who are eligible (and, at State option, individuals who apply or whose eligibility for medical assistance is being evaluated in accordance with section 1902(e)(13)(D)) for, or are provided, medical assistance under a State plan (or under a waiver of the plan) under this title and child health assistance under title XXI, upon the request of the State, information to determine during what period the individual or their spouses or their dependents may be (or may have been) covered by a health insurer and the nature of the coverage that is or was provided by the health insurer (including the name, address, and identifying number of the plan) in a manner prescribed by the Secretary;

(ii) accept the State's right of recovery and the assignment to the State of any right of an individual or other entity to payment from the party for an item or service for which payment has been made under the State plan;

(iii) respond to any inquiry by the State regarding a claim for payment for any health care item or service that is submitted not later than 3 years after the date of the provision of such health care item or service; and

(iv) agree not to deny a claim submitted by the State solely on the basis of the date of submission of the claim, the type or format of the claim form, or a failure to present proper documentation at the point-of-sale that is the basis of the claim, if—

(I) the claim is submitted by the State within the 3-year period beginning on the date on which the item or service was furnished; and

(II) any action by the State to enforce its rights with respect to such claim is commenced within 6 years of the State's submission of such claim;

(26) if the State plan includes medical assistance for inpatient mental hospital services, provide, with respect to each patient receiving such services, for a regular program of medical review (including medical evaluation) of his need for such services, and for a written plan of care;

(27) provide for agreements with every person or institution providing services under the State plan under which such person or institution agrees (A) to keep such records as are necessary fully to disclose the extent of the services provided to individuals receiving assistance under the State plan, and (B) to furnish the State agency or the Secretary with such information, regarding any payments claimed by such person or institution for providing services under the State plan, as the State agency or the Secretary may from time to time request;

(28) provide—

(A) that any nursing facility receiving payments under such plan must satisfy all the requirements of subsections (b) through (d) of section 1919 as they apply to such facilities;

(B) for including in "nursing facility services" at least the items and services specified (or deemed to be specified) by the Secretary under section 1919(f)(7) and making available upon request a description of the items and services so included;

(C) for procedures to make available to the public the data and methodology used in establishing payment rates for nursing facilities under this title; and

(D) for compliance (by the date specified in the respective sections) with the requirements of—

(i) section 1919(e);

(ii) section 1919(g) (relating to responsibility for survey and certification of nursing facilities); and

(iii) sections 1919(h)(2)(B) and 1919(h)(2)(D) (relating to establishment and application of remedies);

(29) include a State program which meets the requirements set forth in section 1908, for the licensing of administrators of nursing homes;

(30)(A) provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1903(i)(4)) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area; and

(B) provide, under the program described in subparagraph (A), that—

(i) each admission to a hospital, intermediate care facility for the mentally retarded, or hospital for mental diseases is reviewed or screened in accordance with criteria established by medical and other professional personnel who are not themselves directly responsible for the care of the patient involved, and who do not have a significant financial interest in any such institution and are not, except in the case of a hospital, employed by the institution providing the care involved, and

(ii) the information developed from such review or screening, along with the data obtained from prior reviews

of the necessity for admission and continued stay of patients by such professional personnel, shall be used as the basis for establishing the size and composition of the sample of admissions to be subject to review and evaluation by such personnel, and any such sample may be of any size up to 100 percent of all admissions and must be of sufficient size to serve the purpose of (I) identifying the patterns of care being provided and the changes occurring over time in such patterns so that the need for modification may be ascertained, and (II) subjecting admissions to early or more extensive review where information indicates that such consideration is warranted to a hospital, intermediate care facility for the mentally retarded, or hospital for mental diseases;

(31) with respect to services in an intermediate care facility for the mentally retarded (where the State plan includes medical assistance for such services) provide, with respect to each patient receiving such services, for a written plan of care, prior to admission to or authorization of benefits in such facility, in accordance with regulations of the Secretary, and for a regular program of independent professional review (including medical evaluation) which shall periodically review his need for such services;

(32) provide that no payment under the plan for any care or service provided to an individual shall be made to anyone other than such individual or the person or institution providing such care or service, under an assignment or power of attorney or otherwise; except that—

(A) in the case of any care or service provided by a physician, dentist, or other individual practitioner, such payment may be made (i) to the employer of such physician, dentist, or other practitioner if such physician, dentist, or practitioner is required as a condition of his employment to turn over his fee for such care or service to his employer, or (ii) (where the care or service was provided in a hospital, clinic, or other facility) to the facility in which the care or service was provided if there is a contractual arrangement between such physician, dentist, or practitioner and such facility under which such facility submits the bill for such care or service;

(B) nothing in this paragraph shall be construed (i) to prevent the making of such a payment in accordance with an assignment from the person or institution providing the care or service involved if such assignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (ii) to preclude an agent of such person or institution from receiving any such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services for or in connection with the billing or collection of payments due such person or institution under the plan is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment;

(C) in the case of services furnished (during a period that does not exceed 14 continuous days in the case of an informal reciprocal arrangement or 90 continuous days (or such longer period as the Secretary may provide) in the case of an arrangement involving per diem or other fee-for-time compensation) by, or incident to the services of, one physician to the patients of another physician who submits the claim for such services, payment shall be made to the physician submitting the claim (as if the services were furnished by, or incident to, the physician's services), but only if the claim identifies (in a manner specified by the Secretary) the physician who furnished the services; and

(D) in the case of payment for a childhood vaccine administered before October 1, 1994, to individuals entitled to medical assistance under the State plan, the State plan may make payment directly to the manufacturer of the vaccine under a voluntary replacement program agreed to by the State pursuant to which the manufacturer (i) supplies doses of the vaccine to providers administering the vaccine, (ii) periodically replaces the supply of the vaccine, and (iii) charges the State the manufacturer's price to the Centers for Disease Control and Prevention for the vaccine so administered (which price includes a reasonable amount to cover shipping and the handling of returns);

(33) provide—

(A) that the State health agency, or other appropriate State medical agency, shall be responsible for establishing a plan, consistent with regulations prescribed by the Secretary, for the review by appropriate professional health personnel of the appropriateness and quality of care and services furnished to recipients of medical assistance under the plan in order to provide guidance with respect thereto in the administration of the plan to the State agency established or designated pursuant to paragraph (5) and, where applicable, to the State agency described in the second sentence of this subsection; and

(B) that, except as provided in section 1919(g), the State or local agency utilized by the Secretary for the purpose specified in the first sentence of section 1864(a), or, if such agency is not the State agency which is responsible for licensing health institutions, the State agency responsible for such licensing, will perform for the State agency administering or supervising the administration of the plan approved under this title the function of determining whether institutions and agencies meet the requirements for participation in the program under such plan, except that, if the Secretary has cause to question the adequacy of such determinations, the Secretary is authorized to validate State determinations and, on that basis, make independent and binding determinations concerning the extent to which individual institutions and agencies meet the requirements for participation;

(34) provide that in the case of any individual who has been determined to be eligible for medical assistance under the plan, such assistance will be made available to him for care and

services included under the plan and furnished in or after the third month before the month in which he made application (or application was made on his behalf in the case of a deceased individual) for such assistance if such individual was (or upon application would have been) eligible for such assistance at the time such care and services were furnished;

(35) provide that any disclosing entity (as defined in section 1124(a)(2)) receiving payments under such plan complies with the requirements of section 1124;

(36) provide that within 90 days following the completion of each survey of any health care facility, laboratory, agency, clinic, or organization, by the appropriate State agency described in paragraph (9), such agency shall (in accordance with regulations of the Secretary) make public in readily available form and place the pertinent findings of each such survey relating to the compliance of each such health care facility, laboratory, clinic, agency, or organization with (A) the statutory conditions of participation imposed under this title, and (B) the major additional conditions which the Secretary finds necessary in the interest of health and safety of individuals who are furnished care or services by any such facility, laboratory, clinic, agency, or organization;

(37) provide for claims payment procedures which (A) ensure that 90 per centum of claims for payment (for which no further written information or substantiation is required in order to make payment) made for services covered under the plan and furnished by health care practitioners through individual or group practices or through shared health facilities are paid within 30 days of the date of receipt of such claims and that 99 per centum of such claims are paid within 90 days of the date of receipt of such claims, and (B) provide for procedures of prepayment and postpayment claims review, including review of appropriate data with respect to the recipient and provider of a service and the nature of the service for which payment is claimed, to ensure the proper and efficient payment of claims and management of the program;

(38) require that an entity (other than an individual practitioner or a group of practitioners) that furnishes, or arranges for the furnishing of, items or services under the plan, shall supply (within such period as may be specified in regulations by the Secretary or by the single State agency which administers or supervises the administration of the plan) upon request specifically addressed to such entity by the Secretary or such State agency, the information described in section 1128(b)(9);

(39) provide that the State agency shall exclude any specified individual or entity from participation in the program under the State plan for the period specified by the Secretary, when required by him to do so pursuant to section 1128 or section 1128A, terminate the participation of any individual or entity in such program if (subject to such exceptions as are permitted with respect to exclusion under sections 1128(c)(3)(B) and 1128(d)(3)(B)) participation of such individual or entity is terminated under title XVIII, any other State plan under this title (or waiver of the plan), or any State child health plan under

title XXI (or waiver of the plan) and such termination is included by the Secretary in any database or similar system developed pursuant to section 6401(b)(2) of the Patient Protection and Affordable Care Act, and provide that no payment may be made under the plan with respect to any item or service furnished by such individual or entity during such period;

(40) require each health services facility or organization which receives payments under the plan and of a type for which a uniform reporting system has been established under section 1121(a) to make reports to the Secretary of information described in such section in accordance with the uniform reporting system (established under such section) for that type of facility or organization;

(41) provide, in accordance with subsection (kk)(8) (as applicable), that whenever a provider of services or any other person is terminated, suspended, or otherwise sanctioned or prohibited from participating under the State plan, the State agency shall promptly notify the Secretary and, in the case of a physician and notwithstanding paragraph (7), the State medical licensing board of such action;

(42) provide that—

(A) the records of any entity participating in the plan and providing services reimbursable on a cost-related basis will be audited as the Secretary determines to be necessary to insure that proper payments are made under the plan; and

(B) not later than December 31, 2010, the State shall—

(i) establish a program under which the State contracts (consistent with State law and in the same manner as the Secretary enters into contracts with recovery audit contractors under section 1893(h), subject to such exceptions or requirements as the Secretary may require for purposes of this title or a particular State) with 1 or more recovery audit contractors for the purpose of identifying underpayments and overpayments and recouping overpayments under the State plan and under any waiver of the State plan with respect to all services for which payment is made to any entity under such plan or waiver; and

(ii) provide assurances satisfactory to the Secretary that—

(I) under such contracts, payment shall be made to such a contractor only from amounts recovered;

(II) from such amounts recovered, payment—

(aa) shall be made on a contingent basis for collecting overpayments; and

(bb) may be made in such amounts as the State may specify for identifying underpayments;

(III) the State has an adequate process for entities to appeal any adverse determination made by such contractors; and

(IV) such program is carried out in accordance with such requirements as the Secretary shall specify, including—

(aa) for purposes of section 1903(a)(7), that amounts expended by the State to carry out the program shall be considered amounts expended as necessary for the proper and efficient administration of the State plan or a waiver of the plan;

(bb) that section 1903(d) shall apply to amounts recovered under the program; and

(cc) that the State and any such contractors under contract with the State shall coordinate such recovery audit efforts with other contractors or entities performing audits of entities receiving payments under the State plan or waiver in the State, including efforts with Federal and State law enforcement with respect to the Department of Justice, including the Federal Bureau of Investigations, the Inspector General of the Department of Health and Human Services, and the State medicaid fraud control unit; and

(43) provide for—

(A) informing all persons in the State who are under the age of 21 and who have been determined to be eligible for medical assistance including services described in section 1905(a)(4)(B), of the availability of early and periodic screening, diagnostic, and treatment services as described in section 1905(r) and the need for age-appropriate immunizations against vaccine-preventable diseases,

(B) providing or arranging for the provision of such screening services in all cases where they are requested,

(C) arranging for (directly or through referral to appropriate agencies, organizations, or individuals) corrective treatment the need for which is disclosed by such child health screening services, and

(D) reporting to the Secretary (in a uniform form and manner established by the Secretary, by age group and by basis of eligibility for medical assistance, and by not later than April 1 after the end of each fiscal year, beginning with fiscal year 1990) the following information relating to early and periodic screening, diagnostic, and treatment services provided under the plan during each fiscal year:

(i) the number of children provided child health screening services,

(ii) the number of children referred for corrective treatment (the need for which is disclosed by such child health screening services),

(iii) the number of children receiving dental services, and other information relating to the provision of dental services to such children described in section 2108(e) and

(iv) the State's results in attaining the participation goals set for the State under section 1905(r);

(44) in each case for which payment for inpatient hospital services, services in an intermediate care facility for the men-

tally retarded, or inpatient mental hospital services is made under the State plan—

(A) a physician (or, in the case of skilled nursing facility services or intermediate care facility services, a physician, or a nurse practitioner or clinical nurse specialist who is not an employee of the facility but is working in collaboration with a physician) certifies at the time of admission, or, if later, the time the individual applies for medical assistance under the State plan (and a physician, a physician assistant under the supervision of a physician, or, in the case of skilled nursing facility services or intermediate care facility services, a physician, or a nurse practitioner or clinical nurse specialist who is not an employee of the facility but is working in collaboration with a physician, recertifies, where such services are furnished over a period of time, in such cases, at least as often as required under section 1903(g)(6) (or, in the case of services that are services provided in an intermediate care facility for the mentally retarded, every year), and accompanied by such supporting material, appropriate to the case involved, as may be provided in regulations of the Secretary), that such services are or were required to be given on an inpatient basis because the individual needs or needed such services, and

(B) such services were furnished under a plan established and periodically reviewed and evaluated by a physician, or, in the case of skilled nursing facility services or intermediate care facility services, a physician, or a nurse practitioner or clinical nurse specialist who is not an employee of the facility but is working in collaboration with a physician;

(45) provide for mandatory assignment of rights of payment for medical support and other medical care owed to recipients, in accordance with section 1912;

(46)(A) provide that information is requested and exchanged for purposes of income and eligibility verification in accordance with a State system which meets the requirements of section 1137 of this Act; and

(B) provide, with respect to an individual declaring to be a citizen or national of the United States for purposes of establishing eligibility under this title, that the State shall satisfy the requirements of—

(i) section 1903(x); or

(ii) subsection (ee);

(47) provide—

(A) at the option of the State, for making ambulatory prenatal care available to pregnant women during a presumptive eligibility period in accordance with section 1920 and provide for making medical assistance for items and services described in subsection (a) of section 1920A available to children during a presumptive eligibility period in accordance with such section and provide for making medical assistance available to individuals described in subsection (a) of section 1920B during a presumptive eligibility period in accordance with such section and provide

for making medical assistance available to individuals described in subsection (a) of section 1920C during a presumptive eligibility period in accordance with such section; and

(B) that any hospital that is a participating provider under the State plan may elect to be a qualified entity for purposes of determining, on the basis of preliminary information, whether any individual is eligible for medical assistance under the State plan or under a waiver of the plan for purposes of providing the individual with medical assistance during a presumptive eligibility period, in the same manner, and subject to the same requirements, as apply to the State options with respect to populations described in section 1920, 1920A, 1920B, or 1920C (but without regard to whether the State has elected to provide for a presumptive eligibility period under any such sections), subject to such guidance as the Secretary shall establish;

(48) provide a method of making cards evidencing eligibility for medical assistance available to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address;

(49) provide that the State will provide information and access to certain information respecting sanctions taken against health care practitioners and providers by State licensing authorities in accordance with section 1921;

(50) provide, in accordance with subsection (q), for a monthly personal needs allowance for certain institutionalized individuals and couples;

(51) meet the requirements of section 1924 (relating to protection of community spouses);

(52) meet the requirements of section 1925 (relating to extension of eligibility for medical assistance);

(53) provide—

(A) for notifying in a timely manner all individuals in the State who are determined to be eligible for medical assistance and who are pregnant women, breastfeeding or postpartum women (as defined in section 17 of the Child Nutrition Act of 1966), or children below the age of 5, of the availability of benefits furnished by the special supplemental nutrition program under such section, and

(B) for referring any such individual to the State agency responsible for administering such program;

(54) in the case of a State plan that provides medical assistance for covered outpatient drugs (as defined in section 1927(k)), comply with the applicable requirements of section 1927;

(55) provide for receipt and initial processing of applications of individuals for medical assistance under subsection (a)(10)(A)(i)(IV), (a)(10)(A)(i)(VI), (a)(10)(A)(i)(VII), or (a)(10)(A)(ii)(IX)—

(A) at locations which are other than those used for the receipt and processing of applications for aid under part A of title IV and which include facilities defined as disproportionate share hospitals under section 1923(a)(1)(A) and

Federally-qualified health centers described in section 1905(1)(2)(B), and

(B) using applications which are other than those used for applications for aid under such part;

(56) provide, in accordance with subsection (s), for adjusted payments for certain inpatient hospital services;

(57) provide that each hospital, nursing facility, provider of home health care or personal care services, hospice program, or medicaid managed care organization (as defined in section 1903(m)(1)(A)) receiving funds under the plan shall comply with the requirements of subsection (w);

(58) provide that the State, acting through a State agency, association, or other private nonprofit entity, develop a written description of the law of the State (whether statutory or as recognized by the courts of the State) concerning advance directives that would be distributed by providers or organizations under the requirements of subsection (w);

(59) maintain a list (updated not less often than monthly, and containing each physician's unique identifier provided under the system established under subsection (x)) of all physicians who are certified to participate under the State plan;

(60) provide that the State agency shall provide assurances satisfactory to the Secretary that the State has in effect the laws relating to medical child support required under section 1908A;

(61) provide that the State must demonstrate that it operates a medicaid fraud and abuse control unit described in section 1903(q) that effectively carries out the functions and requirements described in such section, as determined in accordance with standards established by the Secretary, unless the State demonstrates to the satisfaction of the Secretary that the effective operation of such a unit in the State would not be cost-effective because minimal fraud exists in connection with the provision of covered services to eligible individuals under the State plan, and that beneficiaries under the plan will be protected from abuse and neglect in connection with the provision of medical assistance under the plan without the existence of such a unit;

(62) provide for a program for the distribution of pediatric vaccines to program-registered providers for the immunization of vaccine-eligible children in accordance with section 1928;

(63) provide for administration and determinations of eligibility with respect to individuals who are (or seek to be) eligible for medical assistance based on the application of section 1931;

(64) provide, not later than 1 year after the date of the enactment of this paragraph, a mechanism to receive reports from beneficiaries and others and compile data concerning alleged instances of waste, fraud, and abuse relating to the operation of this title;

(65) provide that the State shall issue provider numbers for all suppliers of medical assistance consisting of durable medical equipment, as defined in section 1861(n), and the State shall not issue or renew such a supplier number for any such supplier unless—

(A)(i) full and complete information as to the identity of each person with an ownership or control interest (as defined in section 1124(a)(3)) in the supplier or in any subcontractor (as defined by the Secretary in regulations) in which the supplier directly or indirectly has a 5 percent or more ownership interest; and

(ii) to the extent determined to be feasible under regulations of the Secretary, the name of any disclosing entity (as defined in section 1124(a)(2)) with respect to which a person with such an ownership or control interest in the supplier is a person with such an ownership or control interest in the disclosing entity; and

(B) a surety bond in a form specified by the Secretary under section 1834(a)(16)(B) and in an amount that is not less than $50,000 or such comparable surety bond as the Secretary may permit under the second sentence of such section;

(66) provide for making eligibility determinations under section 1935(a);

(67) provide, with respect to services covered under the State plan (but not under title XVIII) that are furnished to a PACE program eligible individual enrolled with a PACE provider by a provider participating under the State plan that does not have a contract or other agreement with the PACE provider that establishes payment amounts for such services, that such participating provider may not require the PACE provider to pay the participating provider an amount greater than the amount that would otherwise be payable for the service to the participating provider under the State plan for the State where the PACE provider is located (in accordance with regulations issued by the Secretary);

(68) provide that any entity that receives or makes annual payments under the State plan of at least $5,000,000, as a condition of receiving such payments, shall—

(A) establish written policies for all employees of the entity (including management), and of any contractor or agent of the entity, that provide detailed information about the False Claims Act established under sections 3729 through 3733 of title 31, United States Code, administrative remedies for false claims and statements established under chapter 38 of title 31, United States Code, any State laws pertaining to civil or criminal penalties for false claims and statements, and whistleblower protections under such laws, with respect to the role of such laws in preventing and detecting fraud, waste, and abuse in Federal health care programs (as defined in section 1128B(f));

(B) include as part of such written policies, detailed provisions regarding the entity's policies and procedures for detecting and preventing fraud, waste, and abuse; and

(C) include in any employee handbook for the entity, a specific discussion of the laws described in subparagraph (A), the rights of employees to be protected as whistleblowers, and the entity's policies and procedures for detecting and preventing fraud, waste, and abuse;

(69) provide that the State must comply with any requirements determined by the Secretary to be necessary for carrying out the Medicaid Integrity Program established under section 1936;

(70) at the option of the State and notwithstanding paragraphs (1), (10)(B), and (23), provide for the establishment of a non-emergency medical transportation brokerage program in order to more cost-effectively provide transportation for individuals eligible for medical assistance under the State plan who need access to medical care or services and have no other means of transportation which—

(A) may include a wheelchair van, taxi, stretcher car, bus passes and tickets, secured transportation, and such other transportation as the Secretary determines appropriate; and

(B) may be conducted under contract with a broker who—

(i) is selected through a competitive bidding process based on the State's evaluation of the broker's experience, performance, references, resources, qualifications, and costs;

(ii) has oversight procedures to monitor beneficiary access and complaints and ensure that transport personnel are licensed, qualified, competent, and courteous;

(iii) is subject to regular auditing and oversight by the State in order to ensure the quality of the transportation services provided and the adequacy of beneficiary access to medical care and services; and

(iv) complies with such requirements related to prohibitions on referrals and conflict of interest as the Secretary shall establish (based on the prohibitions on physician referrals under section 1877 and such other prohibitions and requirements as the Secretary determines to be appropriate);

(71) provide that the State will implement an asset verification program as required under section 1940;

(72) provide that the State will not prevent a Federally-qualified health center from entering into contractual relationships with private practice dental providers in the provision of Federally-qualified health center services;

(73) in the case of any State in which 1 or more Indian Health Programs or Urban Indian Organizations furnishes health care services, provide for a process under which the State seeks advice on a regular, ongoing basis from designees of such Indian Health Programs and Urban Indian Organizations on matters relating to the application of this title that are likely to have a direct effect on such Indian Health Programs and Urban Indian Organizations and that—

(A) shall include solicitation of advice prior to submission of any plan amendments, waiver requests, and proposals for demonstration projects likely to have a direct effect on Indians, Indian Health Programs, or Urban Indian Organizations; and

(B) may include appointment of an advisory committee and of a designee of such Indian Health Programs and Urban Indian Organizations to the medical care advisory committee advising the State on its State plan under this title;

(74) provide for maintenance of effort under the State plan or under any waiver of the plan in accordance with subsection (gg); and

(75) provide that, beginning January 2015, and annually thereafter, the State shall submit a report to the Secretary that contains—

(A) the total number of enrolled and newly enrolled individuals in the State plan or under a waiver of the plan for the fiscal year ending on September 30 of the preceding calendar year, disaggregated by population, including children, parents, nonpregnant childless adults, disabled individuals, elderly individuals, and such other categories or sub-categories of individuals eligible for medical assistance under the State plan or under a waiver of the plan as the Secretary may require;

(B) a description, which may be specified by population, of the outreach and enrollment processes used by the State during such fiscal year; and

(C) any other data reporting determined necessary by the Secretary to monitor enrollment and retention of individuals eligible for medical assistance under the State plan or under a waiver of the plan;

(76) provide that any data collected under the State plan meets the requirements of section 3101 of the Public Health Service Act;

(77) provide that the State shall comply with provider and supplier screening, oversight, and reporting requirements in accordance with subsection (kk);

(78) provide that, not later than January 1, 2017, in the case of a State that pursuant to its State plan or waiver of the plan for medical assistance pays for medical assistance on a fee-for-service basis, the State shall require each provider furnishing items and services to, or ordering, prescribing, referring, or certifying eligibility for, services for individuals eligible to receive medical assistance under such plan to enroll with the State agency and provide to the State agency the provider's identifying information, including the name, specialty, date of birth, Social Security number, national provider identifier (if applicable), Federal taxpayer identification number, and the State license or certification number of the provider (if applicable);

(79) provide that any agent, clearinghouse, or other alternate payee (as defined by the Secretary) that submits claims on behalf of a health care provider must register with the State and the Secretary in a form and manner specified by the Secretary;

(80) provide that the State shall not provide any payments for items or services provided under the State plan or under a waiver to any financial institution or entity located outside of the United States;

(81) provide for implementation of the payment models specified by the Secretary under section 1115A(c) for implementa-

tion on a nationwide basis unless the State demonstrates to the satisfaction of the Secretary that implementation would not be administratively feasible or appropriate to the health care delivery system of the State;

(82) provide that the State agency responsible for administering the State plan under this title provides assurances to the Secretary that the State agency is in compliance with subparagraphs (A), (B), and (C) of section 1128K(b)(2); **[**and**]**

(83) provide that, not later than January 1, 2017, in the case of a State plan (or waiver of the plan) that provides medical assistance on a fee-for-service basis or through a primary care case-management system described in section 1915(b)(1) (other than a primary care case management entity (as defined by the Secretary)), the State shall publish (and update on at least an annual basis) on the public website of the State agency administering the State plan, a directory of the physicians described in subsection (mm) and, at State option, other providers described in such subsection that—

(A) includes—

(i) with respect to each such physician or provider—

(I) the name of the physician or provider;

(II) the specialty of the physician or provider;

(III) the address at which the physician or provider provides services; and

(IV) the telephone number of the physician or provider; and

(ii) with respect to any such physician or provider participating in such a primary care case-management system, information regarding—

(I) whether the physician or provider is accepting as new patients individuals who receive medical assistance under this title; and

(II) the physician's or provider's cultural and linguistic capabilities, including the languages spoken by the physician or provider or by the skilled medical interpreter providing interpretation services at the physician's or provider's office; and

(B) may include, at State option, with respect to each such physician or provider—

(i) the Internet website of such physician or provider; or

(ii) whether the physician or provider is accepting as new patients individuals who receive medical assistance under this title**[**.**]***; and*

(84) provide that the State is in compliance with the drug review and utilization requirements under subsection (nn)(1).

Notwithstanding paragraph (5), if on January 1, 1965, and on the date on which a State submits its plan for approval under this title, the State agency which administered or supervised the administration of the plan of such State approved under title X (or title XVI, insofar as it relates to the blind) was different from the State agency which administered or supervised the administration of the State plan approved under title I (or title XVI, insofar as it relates to the aged), the State agency which administered or super-

vised the administration of such plan approved under title X (or title XVI, insofar as it relates to the blind) may be designated to administer or supervise the administration of the portion of the State plan for medical assistance which relates to blind individuals and a different State agency may be established or designated to administer or supervise the administration of the rest of the State plan for medical assistance; and in such case the part of the plan which each such agency administers, or the administration of which each such agency supervises, shall be regarded as a separate plan for purposes of this title (except for purposes of paragraph (10)). The provisions of paragraphs (9)(A), (31), and (33) and of section 1903(i)(4) shall not apply to a religious nonmedical health care institution (as defined in section 1861(ss)(1)).

For purposes of paragraph (10) any individual who, for the month of August 1972, was eligible for or receiving aid or assistance under a State plan approved under title I, X, XIV, or XVI, or part A of title IV and who for such month was entitled to monthly insurance benefits under title II shall for purposes of this title only be deemed to be eligible for financial aid or assistance for any month thereafter if such individual would have been eligible for financial aid or assistance for such month had the increase in monthly insurance benefits under title II resulting from enactment of Public Law 92-336 not been applicable to such individual.

The requirement of clause (A) of paragraph (37) with respect to a State plan may be waived by the Secretary if he finds that the State has exercised good faith in trying to meet such requirement.

For purposes of this title, any child who meets the requirements of paragraph (1) or (2) of section 473(b) shall be deemed to be a dependent child as defined in section 406 and shall be deemed to be a recipient of aid to families with dependent children under part A of title IV in the State where such child resides. Notwithstanding paragraph (10)(B) or any other provision of this subsection, a State plan shall provide medical assistance with respect to an alien who is not lawfully admitted for permanent residence or otherwise permanently residing in the United States under color of law only in accordance with section 1903(v).

(b) The Secretary shall approve any plan which fulfills the conditions specified in subsection (a) of this section, except that he shall not approve any plan which imposes, as a condition of eligibility for medical assistance under the plan—

(1) an age requirement of more than 65 years; or

(2) any residence requirement which excludes any individual who resides in the State, regardless of whether or not the residence is maintained permanently or at a fixed address; or

(3) any citizenship requirement which excludes any citizen of the United States.

(c) Notwithstanding subsection (b), the Secretary shall not approve any State plan for medical assistance if the State requires individuals described in subsection (l)(1) to apply for assistance under the State program funded under part A of title IV as a condition of applying for or receiving medical assistance under this title.

(d) If a State contracts with an entity which meets the requirements of section 1152, as determined by the Secretary, or a utilization and quality control peer review organization having a contract with the Secretary under part B of title XI for the performance of

medical or utilization review functions (including quality review functions described in subsection (a)(30)(C)) required under this title of a State plan with respect to specific services or providers (or services or providers in a geographic area of the State), such requirements shall be deemed to be met for those services or providers (or services or providers in that area) by delegation to such an entity or organization under the contract of the State's authority to conduct such review activities if the contract provides for the performance of activities not inconsistent with part B of title XI and provides for such assurances of satisfactory performance by such an entity or organization as the Secretary may prescribe.

(e)(1) Beginning April 1, 1990, for provisions relating to the extension of eligibility for medical assistance for certain families who have received aid pursuant to a State plan approved under part A of title IV and have earned income, see section 1925.

(2)(A) In the case of an individual who is enrolled with a medicaid managed care organization (as defined in section 1903(m)(1)(A)), with a primary care case manager (as defined in section 1905(t)), or with an eligible organization with a contract under section 1876 and who would (but for this paragraph) lose eligibility for benefits under this title before the end of the minimum enrollment period (defined in subparagraph (B)), the State plan may provide, notwithstanding any other provision of this title, that the individual shall be deemed to continue to be eligible for such benefits until the end of such minimum period, but, except for benefits furnished under section 1905(a)(4)(C), only with respect to such benefits provided to the individual as an enrollee of such organization or entity or by or through the case manager.

(B) For purposes of subparagraph (A), the term "minimum enrollment period" means, with respect to an individual's enrollment with an organization or entity under a State plan, a period, established by the State, of not more than six months beginning on the date the individual's enrollment with the organization or entity becomes effective.

(3) At the option of the State, any individual who—

(A) is 18 years of age or younger and qualifies as a disabled individual under section 1614(a);

(B) with respect to whom there has been a determination by the State that—

(i) the individual requires a level of care provided in a hospital, nursing facility, or intermediate care facility for the mentally retarded,

(ii) it is appropriate to provide such care for the individual outside such an institution, and

(iii) the estimated amount which would be expended for medical assistance for the individual for such care outside an institution is not greater than the estimated amount which would otherwise be expended for medical assistance for the individual within an appropriate institution; and

(C) if the individual were in a medical institution, would be eligible for medical assistance under the State plan under this title,

shall be deemed, for purposes of this title only, to be an individual with respect to whom a supplemental security income

payment, or State supplemental payment, respectively, is being paid under title XVI.

(4) A child born to a woman eligible for and receiving medical assistance under a State plan on the date of the child's birth shall be deemed to have applied for medical assistance and to have been found eligible for such assistance under such plan on the date of such birth and to remain eligible for such assistance for a period of one year. During the period in which a child is deemed under the preceding sentence to be eligible for medical assistance, the medical assistance eligibility identification number of the mother shall also serve as the identification number of the child, and all claims shall be submitted and paid under such number (unless the State issues a separate identification number for the child before such period expires). Notwithstanding the preceding sentence, in the case of a child who is born in the United States to an alien mother for whom medical assistance for the delivery of the child is made available pursuant to section 1903(v), the State immediately shall issue a separate identification number for the child upon notification by the facility at which such delivery occurred of the child's birth.

(5) A woman who, while pregnant, is eligible for, has applied for, and has received medical assistance under the State plan, shall continue to be eligible under the plan, as though she were pregnant, for all pregnancy-related and postpartum medical assistance under the plan, through the end of the month in which the 60-day period (beginning on the last day of her pregnancy) ends.

(6) In the case of a pregnant woman described in subsection (a)(10) who, because of a change in income of the family of which she is a member, would not otherwise continue to be described in such subsection, the woman shall be deemed to continue to be an individual described in subsection (a)(10)(A)(i)(IV) and subsection (l)(1)(A) without regard to such change of income through the end of the month in which the 60-day period (beginning on the last day of her pregnancy) ends. The preceding sentence shall not apply in the case of a woman who has been provided ambulatory prenatal care pursuant to section 1920 during a presumptive eligibility period and is then, in accordance with such section, determined to be ineligible for medical assistance under the State plan.

(7) In the case of an infant or child described in subparagraph (B), (C), or (D) of subsection (l)(1) or paragraph (2) of section 1905(n)—

(A) who is receiving inpatient services for which medical assistance is provided on the date the infant or child attains the maximum age with respect to which coverage is provided under the State plan for such individuals, and

(B) who, but for attaining such age, would remain eligible for medical assistance under such subsection,

the infant or child shall continue to be treated as an individual described in such respective provision until the end of the stay for which the inpatient services are furnished.

(8) If an individual is determined to be a qualified medicare beneficiary (as defined in section 1905(p)(1)), such determination shall apply to services furnished after the end of the month in which the determination first occurs. For purposes of payment to a State under section 1903(a), such determination shall be considered to be

valid for an individual for a period of 12 months, except that a State may provide for such determinations more frequently, but not more frequently than once every 6 months for an individual.

(9)(A) At the option of the State, the plan may include as medical assistance respiratory care services for any individual who—

(i) is medically dependent on a ventilator for life support at least six hours per day;

(ii) has been so dependent for at least 30 consecutive days (or the maximum number of days authorized under the State plan, whichever is less) as an inpatient;

(iii) but for the availability of respiratory care services, would require respiratory care as an inpatient in a hospital, nursing facility, or intermediate care facility for the mentally retarded and would be eligible to have payment made for such inpatient care under the State plan;

(iv) has adequate social support services to be cared for at home; and

(v) wishes to be cared for at home.

(B) The requirements of subparagraph (A)(ii) may be satisfied by a continuous stay in one or more hospitals, nursing facilities, or intermediate care facilities for the mentally retarded.

(C) For purposes of this paragraph, respiratory care services means services provided on a part-time basis in the home of the individual by a respiratory therapist or other health care professional trained in respiratory therapy (as determined by the State), payment for which is not otherwise included within other items and services furnished to such individual as medical assistance under the plan.

(10)(A) The fact that an individual, child, or pregnant woman may be denied aid under part A of title IV pursuant to section 402(a)(43) shall not be construed as denying (or permitting a State to deny) medical assistance under this title to such individual, child, or woman who is eligible for assistance under this title on a basis other than the receipt of aid under such part.

(B) If an individual, child, or pregnant woman is receiving aid under part A of title IV and such aid is terminated pursuant to section 402(a)(43), the State may not discontinue medical assistance under this title for the individual, child, or woman until the State has determined that the individual, child, or woman is not eligible for assistance under this title on a basis other than the receipt of aid under such part.

(11)(A) In the case of an individual who is enrolled with a group health plan under section 1906 and who would (but for this paragraph) lose eligibility for benefits under this title before the end of the minimum enrollment period (defined in subparagraph (B)), the State plan may provide, notwithstanding any other provision of this title, that the individual shall be deemed to continue to be eligible for such benefits until the end of such minimum period, but only with respect to such benefits provided to the individual as an enrollee of such plan.

(B) For purposes of subparagraph (A), the term "minimum enrollment period" means, with respect to an individual's enrollment with a group health plan, a period established by the State, of not more than 6 months beginning on the date the individual's enrollment under the plan becomes effective.

(12) At the option of the State, the plan may provide that an individual who is under an age specified by the State (not to exceed 19 years of age) and who is determined to be eligible for benefits under a State plan approved under this title under subsection (a)(10)(A) shall remain eligible for those benefits until the earlier of—

(A) the end of a period (not to exceed 12 months) following the determination; or

(B) the time that the individual exceeds that age.

(13) EXPRESS LANE OPTION.—

(A) IN GENERAL.—

(i) OPTION TO USE A FINDING FROM AN EXPRESS LANE AGENCY.—At the option of the State, the State plan may provide that in determining eligibility under this title for a child (as defined in subparagraph (G)), the State may rely on a finding made within a reasonable period (as determined by the State) from an Express Lane agency (as defined in subparagraph (F)) when it determines whether a child satisfies one or more components of eligibility for medical assistance under this title. The State may rely on a finding from an Express Lane agency notwithstanding sections 1902(a)(46)(B) and 1137(d) or any differences in budget unit, disregard, deeming or other methodology, if the following requirements are met:

(I) PROHIBITION ON DETERMINING CHILDREN INELIGIBLE FOR COVERAGE.—If a finding from an Express Lane agency would result in a determination that a child does not satisfy an eligibility requirement for medical assistance under this title and for child health assistance under title XXI, the State shall determine eligibility for assistance using its regular procedures.

(II) NOTICE REQUIREMENT.—For any child who is found eligible for medical assistance under the State plan under this title or child health assistance under title XXI and who is subject to premiums based on an Express Lane agency's finding of such child's income level, the State shall provide notice that the child may qualify for lower premium payments if evaluated by the State using its regular policies and of the procedures for requesting such an evaluation.

(III) COMPLIANCE WITH SCREEN AND ENROLL REQUIREMENT.—The State shall satisfy the requirements under subparagraphs (A) and (B) of section 2102(b)(3) (relating to screen and enroll) before enrolling a child in child health assistance under title XXI. At its option, the State may fulfill such requirements in accordance with either option provided under subparagraph (C) of this paragraph.

(IV) VERIFICATION OF CITIZENSHIP OR NATIONALITY STATUS.—The State shall satisfy the requirements of section 1902(a)(46)(B) or 2105(c)(9), as applicable for verifications of citizenship or nationality status.

(V) CODING.—The State meets the requirements of subparagraph (E).

(ii) OPTION TO APPLY TO RENEWALS AND REDETERMINATIONS.—The State may apply the provisions of this paragraph when conducting initial determinations of eligibility, redeterminations of eligibility, or both, as described in the State plan.

(B) RULES OF CONSTRUCTION.—Nothing in this paragraph shall be construed—

(i) to limit or prohibit a State from taking any actions otherwise permitted under this title or title XXI in determining eligibility for or enrolling children into medical assistance under this title or child health assistance under title XXI; or

(ii) to modify the limitations in section 1902(a)(5) concerning the agencies that may make a determination of eligibility for medical assistance under this title.

(C) OPTIONS FOR SATISFYING THE SCREEN AND ENROLL REQUIREMENT.—

(i) IN GENERAL.—With respect to a child whose eligibility for medical assistance under this title or for child health assistance under title XXI has been evaluated by a State agency using an income finding from an Express Lane agency, a State may carry out its duties under subparagraphs (A) and (B) of section 2102(b)(3) (relating to screen and enroll) in accordance with either clause (ii) or clause (iii).

(ii) ESTABLISHING A SCREENING THRESHOLD.—

(I) IN GENERAL.—Under this clause, the State establishes a screening threshold set as a percentage of the Federal poverty level that exceeds the highest income threshold applicable under this title to the child by a minimum of 30 percentage points or, at State option, a higher number of percentage points that reflects the value (as determined by the State and described in the State plan) of any differences between income methodologies used by the program administered by the Express Lane agency and the methodologies used by the State in determining eligibility for medical assistance under this title.

(II) CHILDREN WITH INCOME NOT ABOVE THRESHOLD.—If the income of a child does not exceed the screening threshold, the child is deemed to satisfy the income eligibility criteria for medical assistance under this title regardless of whether such child would otherwise satisfy such criteria.

(III) CHILDREN WITH INCOME ABOVE THRESHOLD.—If the income of a child exceeds the screening threshold, the child shall be considered to have an income above the Medicaid applicable income level described in section 2110(b)(4) and to satisfy the requirement under section 2110(b)(1)(C) (relating to the requirement that CHIP matching funds be used only for children not eligible for Medicaid). If such a child is enrolled in child health assistance under title XXI, the State shall provide the parent, guardian, or custodial relative with the following:

(aa) Notice that the child may be eligible to receive medical assistance under the State plan under this title if evaluated for such assistance under the State's regular procedures and notice of the process through which a parent, guardian, or custodial relative can request that the State evaluate the child's eligibility for medical assistance under this title using such regular procedures.

(bb) A description of differences between the medical assistance provided under this title and child health assistance under title XXI, including differences in cost-sharing requirements and covered benefits.

(iii) TEMPORARY ENROLLMENT IN CHIP PENDING SCREEN AND ENROLL.—

(I) IN GENERAL.—Under this clause, a State enrolls a child in child health assistance under title XXI for a temporary period if the child appears eligible for such assistance based on an income finding by an Express Lane agency.

(II) DETERMINATION OF ELIGIBILITY.—During such temporary enrollment period, the State shall determine the child's eligibility for child health assistance under title XXI or for medical assistance under this title in accordance with this clause.

(III) PROMPT FOLLOW UP.—In making such a determination, the State shall take prompt action to determine whether the child should be enrolled in medical assistance under this title or child health assistance under title XXI pursuant to subparagraphs (A) and (B) of section 2102(b)(3) (relating to screen and enroll).

(IV) REQUIREMENT FOR SIMPLIFIED DETERMINATION.—In making such a determination, the State shall use procedures that, to the maximum feasible extent, reduce the burden imposed on the individual of such determination. Such procedures may not require the child's parent, guardian, or custodial relative to provide or verify information that already has been provided to the State agency by an Express Lane agency or another source of information unless the State agency has reason to believe the information is erroneous.

(V) AVAILABILITY OF CHIP MATCHING FUNDS DURING TEMPORARY ENROLLMENT PERIOD.—Medical assistance for items and services that are provided to a child enrolled in title XXI during a temporary enrollment period under this clause shall be treated as child health assistance under such title.

(D) OPTION FOR AUTOMATIC ENROLLMENT.—

(i) IN GENERAL.—The State may initiate and determine eligibility for medical assistance under the State Medicaid plan or for child health assistance under the State CHIP plan without a program application from, or on behalf of, the child based on data obtained from sources other than

the child (or the child's family), but a child can only be automatically enrolled in the State Medicaid plan or the State CHIP plan if the child or the family affirmatively consents to being enrolled through affirmation in writing, by telephone, orally, through electronic signature, or through any other means specified by the Secretary or by signature on an Express Lane agency application, if the requirement of clause (ii) is met.

(ii) INFORMATION REQUIREMENT.—The requirement of this clause is that the State informs the parent, guardian, or custodial relative of the child of the services that will be covered, appropriate methods for using such services, premium or other cost sharing charges (if any) that apply, medical support obligations (under section 1912(a)) created by enrollment (if applicable), and the actions the parent, guardian, or relative must take to maintain enrollment and renew coverage.

(E) CODING; APPLICATION TO ENROLLMENT ERROR RATES.—

(i) IN GENERAL.—For purposes of subparagraph (A)(iv), the requirement of this subparagraph for a State is that the State agrees to—

(I) assign such codes as the Secretary shall require to the children who are enrolled in the State Medicaid plan or the State CHIP plan through reliance on a finding made by an Express Lane agency for the duration of the State's election under this paragraph;

(II) annually provide the Secretary with a statistically valid sample (that is approved by Secretary) of the children enrolled in such plans through reliance on such a finding by conducting a full Medicaid eligibility review of the children identified for such sample for purposes of determining an eligibility error rate (as described in clause (iv)) with respect to the enrollment of such children (and shall not include such children in any data or samples used for purposes of complying with a Medicaid Eligibility Quality Control (MEQC) review or a payment error rate measurement (PERM) requirement);

(III) submit the error rate determined under subclause (II) to the Secretary;

(IV) if such error rate exceeds 3 percent for either of the first 2 fiscal years in which the State elects to apply this paragraph, demonstrate to the satisfaction of the Secretary the specific corrective actions implemented by the State to improve upon such error rate; and

(V) if such error rate exceeds 3 percent for any fiscal year in which the State elects to apply this paragraph, a reduction in the amount otherwise payable to the State under section 1903(a) for quarters for that fiscal year, equal to the total amount of erroneous excess payments determined for the fiscal year only with respect to the children included in the sample for the fiscal year that are in excess of a 3 percent error rate with respect to such children.

(ii) NO PUNITIVE ACTION BASED ON ERROR RATE.—The Secretary shall not apply the error rate derived from the sample under clause (i) to the entire population of children enrolled in the State Medicaid plan or the State CHIP plan through reliance on a finding made by an Express Lane agency, or to the population of children enrolled in such plans on the basis of the State's regular procedures for determining eligibility, or penalize the State on the basis of such error rate in any manner other than the reduction of payments provided for under clause (i)(V).

(iii) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed as relieving a State that elects to apply this paragraph from being subject to a penalty under section 1903(u), for payments made under the State Medicaid plan with respect to ineligible individuals and families that are determined to exceed the error rate permitted under that section (as determined without regard to the error rate determined under clause (i)(II)).

(iv) ERROR RATE DEFINED.—In this subparagraph, the term "error rate" means the rate of erroneous excess payments for medical assistance (as defined in section 1903(u)(1)(D)) for the period involved, except that such payments shall be limited to individuals for which eligibility determinations are made under this paragraph and except that in applying this paragraph under title XXI, there shall be substituted for references to provisions of this title corresponding provisions within title XXI.

(F) EXPRESS LANE AGENCY.—

(i) IN GENERAL.—In this paragraph, the term "Express Lane agency" means a public agency that—

(I) is determined by the State Medicaid agency or the State CHIP agency (as applicable) to be capable of making the determinations of one or more eligibility requirements described in subparagraph (A)(i);

(II) is identified in the State Medicaid plan or the State CHIP plan; and

(III) notifies the child's family—

(aa) of the information which shall be disclosed in accordance with this paragraph;

(bb) that the information disclosed will be used solely for purposes of determining eligibility for medical assistance under the State Medicaid plan or for child health assistance under the State CHIP plan; and

(cc) that the family may elect to not have the information disclosed for such purposes; and

(IV) enters into, or is subject to, an interagency agreement to limit the disclosure and use of the information disclosed.

(ii) INCLUSION OF SPECIFIC PUBLIC AGENCIES AND INDIAN TRIBES AND TRIBAL ORGANIZATIONS.—Such term includes the following:

(I) A public agency that determines eligibility for assistance under any of the following:

(aa) The temporary assistance for needy families program funded under part A of title IV.

(bb) A State program funded under part D of title IV.

(cc) The State Medicaid plan.

(dd) The State CHIP plan.

(ee) The Food and Nutrition Act of 2008 (7 U.S.C. 2011 et seq.).

(ff) The Head Start Act (42 U.S.C. 9801 et seq.).

(gg) The Richard B. Russell National School Lunch Act (42 U.S.C. 1751 et seq.).

(hh) The Child Nutrition Act of 1966 (42 U.S.C. 1771 et seq.).

(ii) The Child Care and Development Block Grant Act of 1990 (42 U.S.C. 9858 et seq.).

(jj) The Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11301 et seq.).

(kk) The United States Housing Act of 1937 (42 U.S.C. 1437 et seq.).

(ll) The Native American Housing Assistance and Self-Determination Act of 1996 (25 U.S.C. 4101 et seq.).

(II) A State-specified governmental agency that has fiscal liability or legal responsibility for the accuracy of the eligibility determination findings relied on by the State.

(III) A public agency that is subject to an interagency agreement limiting the disclosure and use of the information disclosed for purposes of determining eligibility under the State Medicaid plan or the State CHIP plan.

(IV) The Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization (as defined in section 1139(c)).

(iii) EXCLUSIONS.—Such term does not include an agency that determines eligibility for a program established under the Social Services Block Grant established under title XX or a private, for-profit organization.

(iv) RULES OF CONSTRUCTION.—Nothing in this paragraph shall be construed as—

(I) exempting a State Medicaid agency from complying with the requirements of section 1902(a)(4) relating to merit-based personnel standards for employees of the State Medicaid agency and safeguards against conflicts of interest); or

(II) authorizing a State Medicaid agency that elects to use Express Lane agencies under this subparagraph to use the Express Lane option to avoid complying with such requirements for purposes of making eligibility determinations under the State Medicaid plan.

(v) ADDITIONAL DEFINITIONS.—In this paragraph:

(I) STATE.—The term "State" means 1 of the 50 States or the District of Columbia.

(II) STATE CHIP AGENCY.—The term "State CHIP agency" means the State agency responsible for administering the State CHIP plan.

(III) STATE CHIP PLAN.—The term "State CHIP plan" means the State child health plan established under title XXI and includes any waiver of such plan.

(IV) STATE MEDICAID AGENCY.—The term "State Medicaid agency" means the State agency responsible for administering the State Medicaid plan.

(V) STATE MEDICAID PLAN.—The term "State Medicaid plan" means the State plan established under title XIX and includes any waiver of such plan.

(G) CHILD DEFINED.—For purposes of this paragraph, the term "child" means an individual under 19 years of age, or, at the option of a State, such higher age, not to exceed 21 years of age, as the State may elect.

(H) STATE OPTION TO RELY ON STATE INCOME TAX DATA OR RETURN.—At the option of the State, a finding from an Express Lane agency may include gross income or adjusted gross income shown by State income tax records or returns.

(I) APPLICATION.—This paragraph shall not apply with respect to eligibility determinations made after September 30, 2027.

(14) INCOME DETERMINED USING MODIFIED ADJUSTED GROSS INCOME.—

(A) IN GENERAL.—Notwithstanding subsection (r) or any other provision of this title, except as provided in subparagraph (D), for purposes of determining income eligibility for medical assistance under the State plan or under any waiver of such plan and for any other purpose applicable under the plan or waiver for which a determination of income is required, including with respect to the imposition of premiums and cost-sharing, a State shall use the modified adjusted gross income of an individual and, in the case of an individual in a family greater than 1, the household income of such family. A State shall establish income eligibility thresholds for populations to be eligible for medical assistance under the State plan or a waiver of the plan using modified adjusted gross income and household income that are not less than the effective income eligibility levels that applied under the State plan or waiver on the date of enactment of the Patient Protection and Affordable Care Act. For purposes of complying with the maintenance of effort requirements under subsection (gg) during the transition to modified adjusted gross income and household income, a State shall, working with the Secretary, establish an equivalent income test that ensures individuals eligible for medical assistance under the State plan or under a waiver of the plan on the date of enactment of the Patient Protection and Affordable Care Act, do not lose coverage under the State plan or under a waiver of the plan. The Secretary may waive such provisions of this title and title XXI as are necessary to ensure that States establish income and eligibility determination systems that protect beneficiaries.

(B) NO INCOME OR EXPENSE DISREGARDS.—Subject to subparagraph (I), no type of expense, block, or other income disregard shall be applied by a State to determine income eligibility for medical assistance under the State plan or under any waiver of such plan or for any other purpose applicable under the plan or waiver for which a determination of income is required.

(C) NO ASSETS TEST.—A State shall not apply any assets or resources test for purposes of determining eligibility for medical assistance under the State plan or under a waiver of the plan.

(D) EXCEPTIONS.—

(i) INDIVIDUALS ELIGIBLE BECAUSE OF OTHER AID OR ASSISTANCE, ELDERLY INDIVIDUALS, MEDICALLY NEEDY INDIVIDUALS, AND INDIVIDUALS ELIGIBLE FOR MEDICARE COST-SHARING.—Subparagraphs (A), (B), and (C) shall not apply to the determination of eligibility under the State plan or under a waiver for medical assistance for the following:

(I) Individuals who are eligible for medical assistance under the State plan or under a waiver of the plan on a basis that does not require a determination of income by the State agency administering the State plan or waiver, including as a result of eligibility for, or receipt of, other Federal or State aid or assistance, individuals who are eligible on the basis of receiving (or being treated as if receiving) supplemental security income benefits under title XVI, and individuals who are eligible as a result of being or being deemed to be a child in foster care under the responsibility of the State.

(II) Individuals who have attained age 65.

(III) Individuals who qualify for medical assistance under the State plan or under any waiver of such plan on the basis of being blind or disabled (or being treated as being blind or disabled) without regard to whether the individual is eligible for supplemental security income benefits under title XVI on the basis of being blind or disabled and including an individual who is eligible for medical assistance on the basis of section 1902(e)(3).

(IV) Individuals described in subsection (a)(10)(C).

(V) Individuals described in any clause of subsection (a)(10)(E).

(ii) EXPRESS LANE AGENCY FINDINGS.—In the case of a State that elects the Express Lane option under paragraph (13), notwithstanding subparagraphs (A), (B), and (C), the State may rely on a finding made by an Express Lane agency in accordance with that paragraph relating to the income of an individual for purposes of determining the individual's eligibility for medical assistance under the State plan or under a waiver of the plan.

(iii) MEDICARE PRESCRIPTION DRUG SUBSIDIES DETERMINATIONS.—Subparagraphs (A), (B), and (C) shall not apply to any determinations of eligibility for premium and cost-sharing subsidies under and in accordance with section 1860D–14 made by the State pursuant to section 1935(a)(2).

(iv) LONG-TERM CARE.—Subparagraphs (A), (B), and (C) shall not apply to any determinations of eligibility of individuals for purposes of medical assistance for nursing facility services, a level of care in any institution equivalent to that of nursing facility services, home or community-based services furnished under a waiver or State plan amendment under section 1915 or a waiver under section 1115, and services described in section 1917(c)(1)(C)(ii).

(v) GRANDFATHER OF CURRENT ENROLLEES UNTIL DATE OF NEXT REGULAR REDETERMINATION.—An individual who, on January 1, 2014, is enrolled in the State plan or under a waiver of the plan and who would be determined ineligible for medical assistance solely because of the application of the modified adjusted gross income or household income standard described in subparagraph (A), shall remain eligible for medical assistance under the State plan or waiver (and subject to the same premiums and cost-sharing as applied to the individual on that date) through March 31, 2014, or the date on which the individual's next regularly scheduled redetermination of eligibility is to occur, whichever is later.

(E) TRANSITION PLANNING AND OVERSIGHT.—Each State shall submit to the Secretary for the Secretary's approval the income eligibility thresholds proposed to be established using modified adjusted gross income and household income, the methodologies and procedures to be used to determine income eligibility using modified adjusted gross income and household income and, if applicable, a State plan amendment establishing an optional eligibility category under subsection (a)(10)(A)(ii)(XX). To the extent practicable, the State shall use the same methodologies and procedures for purposes of making such determinations as the State used on the date of enactment of the Patient Protection and Affordable Care Act. The Secretary shall ensure that the income eligibility thresholds proposed to be established using modified adjusted gross income and household income, including under the eligibility category established under subsection (a)(10)(A)(ii)(XX), and the methodologies and procedures proposed to be used to determine income eligibility, will not result in children who would have been eligible for medical assistance under the State plan or under a waiver of the plan on the date of enactment of the Patient Protection and Affordable Care Act no longer being eligible for such assistance.

(F) LIMITATION ON SECRETARIAL AUTHORITY.—The Secretary shall not waive compliance with the requirements of this paragraph except to the extent necessary to permit a

State to coordinate eligibility requirements for dual eligible individuals (as defined in section 1915(h)(2)(B)) under the State plan or under a waiver of the plan and under title XVIII and individuals who require the level of care provided in a hospital, a nursing facility, or an intermediate care facility for the mentally retarded.

(G) DEFINITIONS OF MODIFIED ADJUSTED GROSS INCOME AND HOUSEHOLD INCOME.—In this paragraph, the terms "modified adjusted gross income" and "household income" have the meanings given such terms in section 36B(d)(2) of the Internal Revenue Code of 1986.

(H) CONTINUED APPLICATION OF MEDICAID RULES REGARDING POINT-IN-TIME INCOME AND SOURCES OF INCOME.—The requirement under this paragraph for States to use modified adjusted gross income and household income to determine income eligibility for medical assistance under the State plan or under any waiver of such plan and for any other purpose applicable under the plan or waiver for which a determination of income is required shall not be construed as affecting or limiting the application of—

(i) the requirement under this title and under the State plan or a waiver of the plan to determine an individual's income as of the point in time at which an application for medical assistance under the State plan or a waiver of the plan is processed; or

(ii) any rules established under this title or under the State plan or a waiver of the plan regarding sources of countable income.

(I) TREATMENT OF PORTION OF MODIFIED ADJUSTED GROSS INCOME.—For purposes of determining the income eligibility of an individual for medical assistance whose eligibility is determined based on the application of modified adjusted gross income under subparagraph (A), the State shall—

(i) determine the dollar equivalent of the difference between the upper income limit on eligibility for such an individual (expressed as a percentage of the poverty line) and such upper income limit increased by 5 percentage points; and

(ii) notwithstanding the requirement in subparagraph (A) with respect to use of modified adjusted gross income, utilize as the applicable income of such individual, in determining such income eligibility, an amount equal to the modified adjusted gross income applicable to such individual reduced by such dollar equivalent amount.

(J) EXCLUSION OF PARENT MENTOR COMPENSATION FROM INCOME DETERMINATION.—Any nominal amount received by an individual as compensation, including a stipend, for participation as a parent mentor (as defined in paragraph (5) of section 2113(f)) in an activity or program funded through a grant under such section shall be disregarded for purposes of determining the income eligibility of such individual for medical assistance under the State plan or any waiver of such plan.

(K) TREATMENT OF CERTAIN LOTTERY WINNINGS AND INCOME RECEIVED AS A LUMP SUM.—

(i) IN GENERAL.—In the case of an individual who is the recipient of qualified lottery winnings (pursuant to lotteries occurring on or after January 1, 2018) or qualified lump sum income (received on or after such date) and whose eligibility for medical assistance is determined based on the application of modified adjusted gross income under subparagraph (A), a State shall, in determining such eligibility, include such winnings or income (as applicable) as income received—

(I) in the month in which such winnings or income (as applicable) is received if the amount of such winnings or income is less than $80,000;

(II) over a period of 2 months if the amount of such winnings or income (as applicable) is greater than or equal to $80,000 but less than $90,000;

(III) over a period of 3 months if the amount of such winnings or income (as applicable) is greater than or equal to $90,000 but less than $100,000; and

(IV) over a period of 3 months plus 1 additional month for each increment of $10,000 of such winnings or income (as applicable) received, not to exceed a period of 120 months (for winnings or income of $1,260,000 or more), if the amount of such winnings or income is greater than or equal to $100,000.

(ii) COUNTING IN EQUAL INSTALLMENTS.—For purposes of subclauses (II), (III), and (IV) of clause (i), winnings or income to which such subclause applies shall be counted in equal monthly installments over the period of months specified under such subclause.

(iii) HARDSHIP EXEMPTION.—An individual whose income, by application of clause (i), exceeds the applicable eligibility threshold established by the State, shall continue to be eligible for medical assistance to the extent that the State determines, under procedures established by the State (in accordance with standards specified by the Secretary), that the denial of eligibility of the individual would cause an undue medical or financial hardship as determined on the basis of criteria established by the Secretary.

(iv) NOTIFICATIONS AND ASSISTANCE REQUIRED IN CASE OF LOSS OF ELIGIBILITY.—A State shall, with respect to an individual who loses eligibility for medical assistance under the State plan (or a waiver of such plan) by reason of clause (i)—

(I) before the date on which the individual loses such eligibility, inform the individual—

(aa) of the individual's opportunity to enroll in a qualified health plan offered through an Exchange established under title I of the Patient Protection and Affordable Care Act dur-

ing the special enrollment period specified in section 9801(f)(3) of the Internal Revenue Code of 1986 (relating to loss of Medicaid or CHIP coverage); and

(bb) of the date on which the individual would no longer be considered ineligible by reason of clause (i) to receive medical assistance under the State plan or under any waiver of such plan and be eligible to reapply to receive such medical assistance; and

(II) provide technical assistance to the individual seeking to enroll in such a qualified health plan.

(v) QUALIFIED LOTTERY WINNINGS DEFINED.—In this subparagraph, the term "qualified lottery winnings" means winnings from a sweepstakes, lottery, or pool described in paragraph (3) of section 4402 of the Internal Revenue Code of 1986 or a lottery operated by a multistate or multijurisdictional lottery association, including amounts awarded as a lump sum payment.

(vi) QUALIFIED LUMP SUM INCOME DEFINED.—In this subparagraph, the term "qualified lump sum income" means income that is received as a lump sum from monetary winnings from gambling (as defined by the Secretary and including gambling activities described in section 1955(b)(4) of title 18, United States Code).

(15) EXCLUSION OF COMPENSATION FOR PARTICIPATION IN A CLINICAL TRIAL FOR TESTING OF TREATMENTS FOR A RARE DISEASE OR CONDITION.—The first $2,000 received by an individual (who has attained 19 years of age) as compensation for participation in a clinical trial meeting the requirements of section 1612(b)(26) shall be disregarded for purposes of determining the income eligibility of such individual for medical assistance under the State plan or any waiver of such plan.

(f) Notwithstanding any other provision of this title, except as provided in subsection (e) and section 1619(b)(3) and section 1924, except with respect to qualified disabled and working individuals (described in section 1905(s)), and except with respect to qualified medicare beneficiaries, qualified severely impaired individuals, and individuals described in subsection (m)(1), no State not eligible to participate in the State plan program established under title XVI shall be required to provide medical assistance to any aged, blind, or disabled individual (within the meaning of title XVI) for any month unless such State would be (or would have been) required to provide medical assistance to such individual for such month had its plan for medical assistance approved under this title and in effect on January 1, 1972, been in effect in such month, except that for this purpose any such individual shall be deemed eligible for medical assistance under such State plan if (in addition to meeting such other requirements as are or may be imposed under the State plan) the income of any such individual as determined in accordance with section 1903(f) (after deducting any supplemental security income payment and State supplementary payment made with respect to such individual, and incurred expenses for medical care as recognized under State law regardless of whether such ex-

penses are reimbursed under another public program of the State or political subdivision thereof) is not in excess of the standard for medical assistance established under the State plan as in effect on January 1, 1972. In States which provide medical assistance to individuals pursuant to paragraph (10)(C) of subsection (a) of this section, an individual who is eligible for medical assistance by reason of the requirements of this section concerning the deduction of incurred medical expenses from income shall be considered an individual eligible for medical assistance under paragraph (10)(A) of that subsection if that individual is, or is eligible to be (1) an individual with respect to whom there is payable a State supplementary payment on the basis of which similarly situated individuals are eligible to receive medical assistance equal in amount, duration, and scope to that provided to individuals eligible under paragraph (10)(A), or (2) an eligible individual or eligible spouse, as defined in title XVI, with respect to whom supplemental security income benefits are payable; otherwise that individual shall be considered to be an individual eligible for medical assistance under paragraph (10)(C) of that subsection. In States which do not provide medical assistance to individuals pursuant to paragraph (10)(C) of that subsection, an individual who is eligible for medical assistance by reason of the requirements of this section concerning the deduction of incurred medical expenses from income shall be considered an individual eligible for medical assistance under paragraph (10)(A) of that subsection.

(g) In addition to any other sanction available to a State, a State may provide for a reduction of any payment amount otherwise due with respect to a person who furnishes services under the plan in an amount equal to up to three times the amount of any payment sought to be collected by that person in violation of subsection (a)(25)(C).

(h) Nothing in this title (including subsections (a)(13) and (a)(30) of this section) shall be construed as authorizing the Secretary to limit the amount of payment that may be made under a plan under this title for home and community care.

(i)(1) In addition to any other authority under State law, where a State determines that a intermediate care facility for the mentally retarded which is certified for participation under its plan no longer substantially meets the requirements for such a facility under this title and further determines that the facility's deficiencies—

(A) immediately jeopardize the health and safety of its patients, the State shall provide for the termination of the facility's certification for participation under the plan and may provide, or

(B) do not immediately jeopardize the health and safety of its patients, the State may, in lieu of providing for terminating the facility's certification for participation under the plan, establish alternative remedies if the State demonstrates to the Secretary's satisfaction that the alternative remedies are effective in deterring noncompliance and correcting deficiencies, and may provide

that no payment will be made under the State plan with respect to any individual admitted to such facility after a date specified by the State.

(2) The State shall not make such a decision with respect to a facility until the facility has had a reasonable opportunity, following the initial determination that it no longer substantially meets the requirements for such a facility under this title, to correct its deficiencies, and, following this period, has been given reasonable notice and opportunity for a hearing.

(3) The State's decision to deny payment may be made effective only after such notice to the public and to the facility as may be provided for by the State, and its effectiveness shall terminate (A) when the State finds that the facility is in substantial compliance (or is making good faith efforts to achieve substantial compliance) with the requirements for such a facility under this title, or (B) in the case described in paragraph (1)(B), with the end of the eleventh month following the month such decision is made effective, whichever occurs first. If a facility to which clause (B) of the previous sentence applies still fails to substantially meet the provisions of the respective section on the date specified in such clause, the State shall terminate such facility's certification for participation under the plan effective with the first day of the first month following the month specified in such clause.

(j) Notwithstanding any other requirement of this title, the Secretary may waive or modify any requirement of this title with respect to the medical assistance program in American Samoa and the Northern Mariana Islands, other than a waiver of the Federal medical assistance percentage, the limitation in section 1108(f), or the requirement that payment may be made for medical assistance only with respect to amounts expended by American Samoa or the Northern Mariana Islands for care and services described in a numbered paragraph of section 1905(a).

(k)(1) The medical assistance provided to an individual described in subclause (VIII) of subsection (a)(10)(A)(i) shall consist of benchmark coverage described in section 1937(b)(1) or benchmark equivalent coverage described in section 1937(b)(2). Such medical assistance shall be provided subject to the requirements of section 1937, without regard to whether a State otherwise has elected the option to provide medical assistance through coverage under that section, unless an individual described in subclause (VIII) of subsection (a)(10)(A)(i) is also an individual for whom, under subparagraph (B) of section 1937(a)(2), the State may not require enrollment in benchmark coverage described in subsection (b)(1) of section 1937 or benchmark equivalent coverage described in subsection (b)(2) of that section.

(2) Beginning with the first day of any fiscal year quarter that begins on or after April 1, 2010, and before January 1, 2014, a State may elect through a State plan amendment to provide medical assistance to individuals who would be described in subclause (VIII) of subsection (a)(10)(A)(i) if that subclause were effective before January 1, 2014. A State may elect to phase-in the extension of eligibility for medical assistance to such individuals based on income, so long as the State does not extend such eligibility to individuals described in such subclause with higher income before making individuals described in such subclause with lower income eligible for medical assistance.

(3) If an individual described in subclause (VIII) of subsection (a)(10)(A)(i) is the parent of a child who is under 19 years of age

(or such higher age as the State may have elected) who is eligible for medical assistance under the State plan or under a waiver of such plan (under that subclause or under a State plan amendment under paragraph (2), the individual may not be enrolled under the State plan unless the individual's child is enrolled under the State plan or under a waiver of the plan or is enrolled in other health insurance coverage. For purposes of the preceding sentence, the term "parent" includes an individual treated as a caretaker relative for purposes of carrying out section 1931.

(l)(1) Individuals described in this paragraph are—

(A) women during pregnancy (and during the 60-day period beginning on the last day of the pregnancy),

(B) infants under one year of age,

(C) children who have attained one year of age but have not attained 6 years of age, and

(D) children born after September 30, 1983 (or, at the option of a State, after any earlier date), who have attained 6 years of age but have not attained 19 years of age,

who are not described in any of subclauses (I) through (III) of subsection (a)(10)(A)(i) and whose family income does not exceed the income level established by the State under paragraph (2) for a family size equal to the size of the family, including the woman, infant, or child.

(2)(A)(i) For purposes of paragraph (1) with respect to individuals described in subparagraph (A) or (B) of that paragraph, the State shall establish an income level which is a percentage (not less than the percentage provided under clause (ii) and not more than 185 percent) of the income official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved.

(ii) The percentage provided under this clause, with respect to eligibility for medical assistance on or after—

(I) July 1, 1989, is 75 percent, or, if greater, the percentage provided under clause (iii), and

(II) April 1, 1990, 133 percent, or, if greater, the percentage provided under clause (iv).

(iii) In the case of a State which, as of the date of the enactment of this clause, has elected to provide, and provides, medical assistance to individuals described in this subsection or has enacted legislation authorizing, or appropriating funds, to provide such assistance to such individuals before July 1, 1989, the percentage provided under clause (ii)(I) shall not be less than—

(I) the percentage specified by the State in an amendment to its State plan (whether approved or not) as of the date of the enactment of this clause, or

(II) if no such percentage is specified as of the date of the enactment of this clause, the percentage established under the State's authorizing legislation or provided for under the State's appropriations;

but in no case shall this clause require the percentage provided under clause (ii)(I) to exceed 100 percent.

(iv) In the case of a State which, as of the date of the enactment of this clause, has established under clause (i), or has enacted legislation authorizing, or appropriating funds, to provide for, a percent-

age (of the income official poverty line) that is greater than 133 percent, the percentage provided under clause (ii) for medical assistance on or after April 1, 1990, shall not be less than—

(I) the percentage specified by the State in an amendment to its State plan (whether approved or not) as of the date of the enactment of this clause, or

(II) if no such percentage is specified as of the date of the enactment of this clause, the percentage established under the State's authorizing legislation or provided for under the State's appropriations.

(B) For purposes of paragraph (1) with respect to individuals described in subparagraph (C) of such paragraph, the State shall establish an income level which is equal to 133 percent of the income official poverty line described in subparagraph (A) applicable to a family of the size involved.

(C) For purposes of paragraph (1) with respect to individuals described in subparagraph (D) of that paragraph, the State shall establish an income level which is equal to 100 percent (or, beginning January 1, 2014, 133 percent) of the income official poverty line described in subparagraph (A) applicable to a family of the size involved.

(3) Notwithstanding subsection (a)(17), for individuals who are eligible for medical assistance because of subsection (a)(10)(A)(i)(IV), (a)(10)(A)(i)(VI), (a)(10)(A)(i)(VII), or (a)(10)(A)(ii)(IX)—

(A) application of a resource standard shall be at the option of the State;

(B) any resource standard or methodology that is applied with respect to an individual described in subparagraph (A) of paragraph (1) may not be more restrictive than the resource standard or methodology that is applied under title XVI;

(C) any resource standard or methodology that is applied with respect to an individual described in subparagraph (B), (C), or (D) of paragraph (1) may not be more restrictive than the corresponding methodology that is applied under the State plan under part A of title IV;

(D) the income standard to be applied is the appropriate income standard established under paragraph (2); and

(E) family income shall be determined in accordance with the methodology employed under the State plan under part A or E of title IV (except to the extent such methodology is inconsistent with clause (D) of subsection (a)(17)), and costs incurred for medical care or for any other type of remedial care shall not be taken into account.

Any different treatment provided under this paragraph for such individuals shall not, because of subsection (a)(17), require or permit such treatment for other individuals.

(4)(A) In the case of any State which is providing medical assistance to its residents under a waiver granted under section 1115, the Secretary shall require the State to provide medical assistance for pregnant women and infants under age 1 described in subsection (a)(10)(A)(i)(IV) and for children described in subsection (a)(10)(A)(i)(VI) or subsection (a)(10)(A)(i)(VII) in the same manner as the State would be required to provide such assistance for such

individuals if the State had in effect a plan approved under this title.

(B) In the case of a State which is not one of the 50 States or the District of Columbia, the State need not meet the requirement of subsection (a)(10)(A)(i)(IV), (a)(10)(A)(i)(VI), or (a)(10)(A)(i)(VII) and, for purposes of paragraph (2)(A), the State may substitute for the percentage provided under clause (ii) of such paragraph any percentage.

(m)(1) Individuals described in this paragraph are individuals—

(A) who are 65 years of age or older or are disabled individuals (as determined under section 1614(a)(3)),

(B) whose income (as determined under section 1612 for purposes of the supplemental security income program, except as provided in paragraph (2)(C)) does not exceed an income level established by the State consistent with paragraph (2)(A), and

(C) whose resources (as determined under section 1613 for purposes of the supplemental security income program) do not exceed (except as provided in paragraph (2)(B)) the maximum amount of resources that an individual may have and obtain benefits under that program.

(2)(A) The income level established under paragraph (1)(B) may not exceed a percentage (not more than 100 percent) of the official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved.

(B) In the case of a State that provides medical assistance to individuals not described in subsection (a)(10)(A) and at the State's option, the State may use under paragraph (1)(C) such resource level (which is higher than the level described in that paragraph) as may be applicable with respect to individuals described in paragraph (1)(A) who are not described in subsection (a)(10)(A).

(C) The provisions of section 1905(p)(2)(D) shall apply to determinations of income under this subsection in the same manner as they apply to determinations of income under section 1905(p).

(3) Notwithstanding subsection (a)(17), for individuals described in paragraph (1) who are covered under the State plan by virtue of subsection (a)(10)(A)(ii)(X)—

(A) the income standard to be applied is the income standard described in paragraph (1)(B), and

(B) except as provided in section 1612(b)(4)(B)(ii), costs incurred for medical care or for any other type of remedial care shall not be taken into account in determining income.

Any different treatment provided under this paragraph for such individuals shall not, because of subsection (a)(17), require or permit such treatment for other individuals.

(4) Notwithstanding subsection (a)(17), for qualified medicare beneficiaries described in section 1905(p)(1)—

(A) the income standard to be applied is the income standard described in section 1905(p)(1)(B), and

(B) except as provided in section 1612(b)(4)(B)(ii), costs incurred for medical care or for any other type of remedial care shall not be taken into account in determining income.

Any different treatment provided under this paragraph for such individuals shall not, because of subsection (a)(17), require or permit such treatment for other individuals.

(n)(1) In the case of medical assistance furnished under this title for medicare cost-sharing respecting the furnishing of a service or item to a qualified medicare beneficiary, the State plan may provide payment in an amount with respect to the service or item that results in the sum of such payment amount and any amount of payment made under title XVIII with respect to the service or item exceeding the amount that is otherwise payable under the State plan for the item or service for eligible individuals who are not qualified medicare beneficiaries.

(2) In carrying out paragraph (1), a State is not required to provide any payment for any expenses incurred relating to payment for deductibles, coinsurance, or copayments for medicare cost-sharing to the extent that payment under title XVIII for the service would exceed the payment amount that otherwise would be made under the State plan under this title for such service if provided to an eligible recipient other than a medicare beneficiary.

(3) In the case in which a State's payment for medicare cost-sharing for a qualified medicare beneficiary with respect to an item or service is reduced or eliminated through the application of paragraph (2)—

(A) for purposes of applying any limitation under title XVIII on the amount that the beneficiary may be billed or charged for the service, the amount of payment made under title XVIII plus the amount of payment (if any) under the State plan shall be considered to be payment in full for the service;

(B) the beneficiary shall not have any legal liability to make payment to a provider or to an organization described in section 1903(m)(1)(A) for the service; and

(C) any lawful sanction that may be imposed upon a provider or such an organization for excess charges under this title or title XVIII shall apply to the imposition of any charge imposed upon the individual in such case.

This paragraph shall not be construed as preventing payment of any medicare cost-sharing by a medicare supplemental policy or an employer retiree health plan on behalf of an individual.

(o) Notwithstanding any provision of subsection (a) to the contrary, a State plan under this title shall provide that any supplemental security income benefits paid by reason of subparagraph (E) or (G) of section 1611(e)(1) to an individual who—

(1) is eligible for medical assistance under the plan, and

(2) is in a hospital, skilled nursing facility, or intermediate care facility at the time such benefits are paid,

will be disregarded for purposes of determining the amount of any post-eligibility contribution by the individual to the cost of the care and services provided by the hospital, skilled nursing facility, or intermediate care facility.

(p)(1) In addition to any other authority, a State may exclude any individual or entity for purposes of participating under the State plan under this title for any reason for which the Secretary could exclude the individual or entity from participation in a program under title XVIII under section 1128, 1128A, or 1866(b)(2).

(2) In order for a State to receive payments for medical assistance under section 1903(a), with respect to payments the State makes to a medicaid managed care organization (as defined in section 1903(m)) or to an entity furnishing services under a waiver approved under section 1915(b)(1), the State must provide that it will exclude from participation, as such an organization or entity, any organization or entity that—

(A) could be excluded under section 1128(b)(8) (relating to owners and managing employees who have been convicted of certain crimes or received other sanctions),

(B) has, directly or indirectly, a substantial contractual relationship (as defined by the Secretary) with an individual or entity that is described in section 1128(b)(8)(B), or

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

(3) As used in this subsection, the term "exclude" includes the refusal to enter into or renew a participation agreement or the termination of such an agreement.

(q)(1)(A) In order to meet the requirement of subsection (a)(50), the State plan must provide that, in the case of an institutionalized individual or couple described in subparagraph (B), in determining the amount of the individual's or couple's income to be applied monthly to payment for the cost of care in an institution, there shall be deducted from the monthly income (in addition to other allowances otherwise provided under the State plan) a monthly personal needs allowance—

(i) which is reasonable in amount for clothing and other personal needs of the individual (or couple) while in an institution, and

(ii) which is not less (and may be greater) than the minimum monthly personal needs allowance described in paragraph (2).

(B) In this subsection, the term "institutionalized individual or couple" means an individual or married couple—

(i) who is an inpatient (or who are inpatients) in a medical institution or nursing facility for which payments are made under this title throughout a month, and

(ii) who is or are determined to be eligible for medical assistance under the State plan.

(2) The minimum monthly personal needs allowance described in this paragraph is $30 for an institutionalized individual and $60 for an institutionalized couple (if both are aged, blind, or disabled, and their incomes are considered available to each other in determining eligibility).

(r)(1)(A) For purposes of sections 1902(a)(17) and 1924(d)(1)(D) and for purposes of a waiver under section 1915, with respect to the post-eligibility treatment of income of individuals who are institutionalized or receiving home or community-based services under such a waiver, the treatment described in subparagraph (B) shall apply, there shall be disregarded reparation payments made by the Federal Republic of Germany, and there shall be taken into ac-

count amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) medicare and other health insurance premiums, deductibles, or coinsurance, and

(ii) necessary medical or remedial care recognized under State law but not covered under the State plan under this title, subject to reasonable limits the State may establish on the amount of these expenses.

(B)(i) In the case of a veteran who does not have a spouse or a child, if the veteran—

(I) receives, after the veteran has been determined to be eligible for medical assistance under the State plan under this title, a veteran's pension in excess of $90 per month, and

(II) resides in a State veterans home with respect to which the Secretary of Veterans Affairs makes per diem payments for nursing home care pursuant to section 1741(a) of title 38, United States Code,

any such pension payment, including any payment made due to the need for aid and attendance, or for unreimbursed medical expenses, that is in excess of $90 per month shall be counted as income only for the purpose of applying such excess payment to the State veterans home's cost of providing nursing home care to the veteran.

(ii) The provisions of clause (i) shall apply with respect to a surviving spouse of a veteran who does not have a child in the same manner as they apply to a veteran described in such clause.

(2)(A) The methodology to be employed in determining income and resource eligibility for individuals under subsection (a)(10)(A)(i)(III), (a)(10)(A)(i)(IV), (a)(10)(A)(i)(VI), (a)(10)(A)(i)(VII), (a)(10)(A)(ii), (a)(10)(C)(i)(III), or (f) or under section 1905(p) may be less restrictive, and shall be no more restrictive, than the methodology—

(i) in the case of groups consisting of aged, blind, or disabled individuals, under the supplemental security income program under title XVI, or

(ii) in the case of other groups, under the State plan most closely categorically related.

(B) For purposes of this subsection and subsection (a)(10), methodology is considered to be "no more restrictive" if, using the methodology, additional individuals may be eligible for medical assistance and no individuals who are otherwise eligible are made ineligible for such assistance.

(s) In order to meet the requirements of subsection (a)(55), the State plan must provide that payments to hospitals under the plan for inpatient hospital services furnished to infants who have not attained the age of 1 year, and to children who have not attained the age of 6 years and who receive such services in a disproportionate share hospital described in section 1923(b)(1), shall—

(1) if made on a prospective basis (whether per diem, per case, or otherwise) provide for an outlier adjustment in payment amounts for medically necessary inpatient hospital services involving exceptionally high costs or exceptionally long lengths of stay,

(2) not be limited by the imposition of day limits with respect to the delivery of such services to such individuals, and

(3) not be limited by the imposition of dollar limits (other than such limits resulting from prospective payments as adjusted pursuant to paragraph (1)) with respect to the delivery of such services to any such individual who has not attained their first birthday (or in the case of such an individual who is an inpatient on his first birthday until such individual is discharged).

(t) Nothing in this title (including sections 1903(a) and 1905(a)) shall be construed as authorizing the Secretary to deny or limit payments to a State for expenditures, for medical assistance for items or services, attributable to taxes of general applicability imposed with respect to the provision of such items or services.

(u)(1) Individuals described in this paragraph are individuals—

(A) who are entitled to elect COBRA continuation coverage (as defined in paragraph (3)),

(B) whose income (as determined under section 1612 for purposes of the supplemental security income program) does not exceed 100 percent of the official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved,

(C) whose resources (as determined under section 1613 for purposes of the supplemental security income program) do not exceed twice the maximum amount of resources that an individual may have and obtain benefits under that program, and

(D) with respect to whose enrollment for COBRA continuation coverage the State has determined that the savings in expenditures under this title resulting from such enrollment is likely to exceed the amount of payments for COBRA premiums made.

(2) For purposes of subsection (a)(10)(F) and this subsection, the term "COBRA premiums" means the applicable premium imposed with respect to COBRA continuation coverage.

(3) In this subsection, the term "COBRA continuation coverage" means coverage under a group health plan provided by an employer with 75 or more employees provided pursuant to title XXII of the Public Health Service Act, section 4980B of the Internal Revenue Code of 1986, or title VI of the Employee Retirement Income Security Act of 1974.

(4) Notwithstanding subsection (a)(17), for individuals described in paragraph (1) who are covered under the State plan by virtue of subsection (a)(10)(A)(ii)(XI)—

(A) the income standard to be applied is the income standard described in paragraph (1)(B), and

(B) except as provided in section 1612(b)(4)(B)(ii), costs incurred for medical care or for any other type of remedial care shall not be taken into account in determining income.

Any different treatment provided under this paragraph for such individuals shall not, because of subsection (a)(10)(B) or (a)(17), require or permit such treatment for other individuals.

(v) A State plan may provide for the making of determinations of disability or blindness for the purpose of determining eligibility for medical assistance under the State plan by the single State agency or its designee, and make medical assistance available to

individuals whom it finds to be blind or disabled and who are determined otherwise eligible for such assistance during the period of time prior to which a final determination of disability or blindness is made by the Social Security Administration with respect to such an individual. In making such determinations, the State must apply the definitions of disability and blindness found in section 1614(a) of the Social Security Act.

(w)(1) For purposes of subsection (a)(57) and sections 1903(m)(1)(A) and 1919(c)(2)(E), the requirement of this subsection is that a provider or organization (as the case may be) maintain written policies and procedures with respect to all adult individuals receiving medical care by or through the provider or organization—

(A) to provide written information to each such individual concerning—

(i) an individual's rights under State law (whether statutory or as recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives (as defined in paragraph (3)), and

(ii) the provider's or organization's written policies respecting the implementation of such rights;

(B) to document in the individual's medical record whether or not the individual has executed an advance directive;

(C) not to condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

(D) to ensure compliance with requirements of State law (whether statutory or as recognized by the courts of the State) respecting advance directives; and

(E) to provide (individually or with others) for education for staff and the community on issues concerning advance directives.

Subparagraph (C) shall not be construed as requiring the provision of care which conflicts with an advance directive.

(2) The written information described in paragraph (1)(A) shall be provided to an adult individual—

(A) in the case of a hospital, at the time of the individual's admission as an inpatient,

(B) in the case of a nursing facility, at the time of the individual's admission as a resident,

(C) in the case of a provider of home health care or personal care services, in advance of the individual coming under the care of the provider,

(D) in the case of a hospice program, at the time of initial receipt of hospice care by the individual from the program, and

(E) in the case of a medicaid managed care organization, at the time of enrollment of the individual with the organization.

(3) Nothing in this section shall be construed to prohibit the application of a State law which allows for an objection on the basis of conscience for any health care provider or any agent of such provider which as a matter of conscience cannot implement an advance directive.

(4) In this subsection, the term "advance directive" means a written instruction, such as a living will or durable power of attorney

for health care, recognized under State law (whether statutory or as recognized by the courts of the State) and relating to the provision of such care when the individual is incapacitated.

(5) For construction relating to this subsection, see section 7 of the Assisted Suicide Funding Restriction Act of 1997 (relating to clarification respecting assisted suicide, euthanasia, and mercy killing).

(x) The Secretary shall establish a system, for implementation by not later than July 1, 1991, which provides for a unique identifier for each physician who furnishes services for which payment may be made under a State plan approved under this title.

(y)(1) In addition to any other authority under State law, where a State determines that a psychiatric hospital which is certified for participation under its plan no longer meets the requirements for a psychiatric hospital (referred to in section 1905(h)) and further finds that the hospital's deficiencies—

(A) immediately jeopardize the health and safety of its patients, the State shall terminate the hospital's participation under the State plan; or

(B) do not immediately jeopardize the health and safety of its patients, the State may terminate the hospital's participation under the State plan, or provide that no payment will be made under the State plan with respect to any individual admitted to such hospital after the effective date of the finding, or both.

(2) Except as provided in paragraph (3), if a psychiatric hospital described in paragraph (1)(B) has not complied with the requirements for a psychiatric hospital under this title—

(A) within 3 months after the date the hospital is found to be out of compliance with such requirements, the State shall provide that no payment will be made under the State plan with respect to any individual admitted to such hospital after the end of such 3-month period, or

(B) within 6 months after the date the hospital is found to be out of compliance with such requirements, no Federal financial participation shall be provided under section 1903(a) with respect to further services provided in the hospital until the State finds that the hospital is in compliance with the requirements of this title.

(3) The Secretary may continue payments, over a period of not longer than 6 months from the date the hospital is found to be out of compliance with such requirements, if—

(A) the State finds that it is more appropriate to take alternative action to assure compliance of the hospital with the requirements than to terminate the certification of the hospital,

(B) the State has submitted a plan and timetable for corrective action to the Secretary for approval and the Secretary approves the plan of corrective action, and

(C) the State agrees to repay to the Federal Government payments received under this paragraph if the corrective action is not taken in accordance with the approved plan and timetable.

(z)(1) Individuals described in this paragraph are individuals not described in subsection (a)(10)(A)(i)—

(A) who are infected with tuberculosis;

(B) whose income (as determined under the State plan under this title with respect to disabled individuals) does not exceed the maximum amount of income a disabled individual described in subsection (a)(10)(A)(i) may have and obtain medical assistance under the plan; and

(C) whose resources (as determined under the State plan under this title with respect to disabled individuals) do not exceed the maximum amount of resources a disabled individual described in subsection (a)(10)(A)(i) may have and obtain medical assistance under the plan.

(2) For purposes of subsection (a)(10), the term "TB-related services" means each of the following services relating to treatment of infection with tuberculosis:

(A) Prescribed drugs.

(B) Physicians' services and services described in section 1905(a)(2).

(C) Laboratory and X-ray services (including services to confirm the presence of infection).

(D) Clinic services and Federally-qualified health center services.

(E) Case management services (as defined in section 1915(g)(2)).

(F) Services (other than room and board) designed to encourage completion of regimens of prescribed drugs by outpatients, including services to observe directly the intake of prescribed drugs.

(aa) Individuals described in this subsection are individuals who—

(1) are not described in subsection (a)(10)(A)(i);

(2) have not attained age 65;

(3) have been screened for breast and cervical cancer under the Centers for Disease Control and Prevention breast and cervical cancer early detection program established under title XV of the Public Health Service Act (42 U.S.C. 300k et seq.) in accordance with the requirements of section 1504 of that Act (42 U.S.C. 300n) and need treatment for breast or cervical cancer; and

(4) are not otherwise covered under creditable coverage, as defined in section 2701(c) of the Public Health Service Act (42 U.S.C. 300gg(c)), but applied without regard to paragraph (1)(F) of such section.

(bb) PAYMENT FOR SERVICES PROVIDED BY FEDERALLY-QUALIFIED HEALTH CENTERS AND RURAL HEALTH CLINICS.—

(1) IN GENERAL.—Beginning with fiscal year 2001 with respect to services furnished on or after January 1, 2001, and each succeeding fiscal year, the State plan shall provide for payment for services described in section 1905(a)(2)(C) furnished by a Federally-qualified health center and services described in section 1905(a)(2)(B) furnished by a rural health clinic in accordance with the provisions of this subsection.

(2) FISCAL YEAR 2001.—Subject to paragraph (4), for services furnished on and after January 1, 2001, during fiscal year 2001, the State plan shall provide for payment for such services in an amount (calculated on a per visit basis) that is equal to 100 percent of the average of the costs of the center or clinic

of furnishing such services during fiscal years 1999 and 2000 which are reasonable and related to the cost of furnishing such services, or based on such other tests of reasonableness as the Secretary prescribes in regulations under section 1833(a)(3), or, in the case of services to which such regulations do not apply, the same methodology used under section 1833(a)(3), adjusted to take into account any increase or decrease in the scope of such services furnished by the center or clinic during fiscal year 2001.

(3) FISCAL YEAR 2002 AND SUCCEEDING FISCAL YEARS.—Subject to paragraph (4), for services furnished during fiscal year 2002 or a succeeding fiscal year, the State plan shall provide for payment for such services in an amount (calculated on a per visit basis) that is equal to the amount calculated for such services under this subsection for the preceding fiscal year—

(A) increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) applicable to primary care services (as defined in section 1842(i)(4)) for that fiscal year; and

(B) adjusted to take into account any increase or decrease in the scope of such services furnished by the center or clinic during that fiscal year.

(4) ESTABLISHMENT OF INITIAL YEAR PAYMENT AMOUNT FOR NEW CENTERS OR CLINICS.—In any case in which an entity first qualifies as a Federally-qualified health center or rural health clinic after fiscal year 2000, the State plan shall provide for payment for services described in section 1905(a)(2)(C) furnished by the center or services described in section 1905(a)(2)(B) furnished by the clinic in the first fiscal year in which the center or clinic so qualifies in an amount (calculated on a per visit basis) that is equal to 100 percent of the costs of furnishing such services during such fiscal year based on the rates established under this subsection for the fiscal year for other such centers or clinics located in the same or adjacent area with a similar case load or, in the absence of such a center or clinic, in accordance with the regulations and methodology referred to in paragraph (2) or based on such other tests of reasonableness as the Secretary may specify. For each fiscal year following the fiscal year in which the entity first qualifies as a Federally-qualified health center or rural health clinic, the State plan shall provide for the payment amount to be calculated in accordance with paragraph (3).

(5) ADMINISTRATION IN THE CASE OF MANAGED CARE.—

(A) IN GENERAL.—In the case of services furnished by a Federally-qualified health center or rural health clinic pursuant to a contract between the center or clinic and a managed care entity (as defined in section 1932(a)(1)(B)), the State plan shall provide for payment to the center or clinic by the State of a supplemental payment equal to the amount (if any) by which the amount determined under paragraphs (2), (3), and (4) of this subsection exceeds the amount of the payments provided under the contract.

(B) PAYMENT SCHEDULE.—The supplemental payment required under subparagraph (A) shall be made pursuant to a payment schedule agreed to by the State and the Feder-

ally-qualified health center or rural health clinic, but in no case less frequently than every 4 months.

(6) ALTERNATIVE PAYMENT METHODOLOGIES.—Notwithstanding any other provision of this section, the State plan may provide for payment in any fiscal year to a Federally-qualified health center for services described in section 1905(a)(2)(C) or to a rural health clinic for services described in section 1905(a)(2)(B) in an amount which is determined under an alternative payment methodology that—

(A) is agreed to by the State and the center or clinic; and

(B) results in payment to the center or clinic of an amount which is at least equal to the amount otherwise required to be paid to the center or clinic under this section.

(cc)(1) Individuals described in this paragraph are individuals—

(A) who are children who have not attained 19 years of age and are born—

(i) on or after January 1, 2001 (or, at the option of a State, on or after an earlier date), in the case of the second, third, and fourth quarters of fiscal year 2007;

(ii) on or after October 1, 1995 (or, at the option of a State, on or after an earlier date), in the case of each quarter of fiscal year 2008; and

(iii) after October 1, 1989, in the case of each quarter of fiscal year 2009 and each quarter of any fiscal year thereafter;

(B) who would be considered disabled under section 1614(a)(3)(C) (as determined under title XVI for children but without regard to any income or asset eligibility requirements that apply under such title with respect to children); and

(C) whose family income does not exceed such income level as the State establishes and does not exceed—

(i) 300 percent of the poverty line (as defined in section 2110(c)(5)) applicable to a family of the size involved; or

(ii) such higher percent of such poverty line as a State may establish, except that—

(I) any medical assistance provided to an individual whose family income exceeds 300 percent of such poverty line may only be provided with State funds; and

(II) no Federal financial participation shall be provided under section 1903(a) for any medical assistance provided to such an individual.

(2)(A) If an employer of a parent of an individual described in paragraph (1) offers family coverage under a group health plan (as defined in section 2791(a) of the Public Health Service Act), the State shall—

(i) notwithstanding section 1906, require such parent to apply for, enroll in, and pay premiums for such coverage as a condition of such parent's child being or remaining eligible for medical assistance under subsection (a)(10)(A)(ii)(XIX) if the parent is determined eligible for such coverage and the employer contributes at least 50 percent of the total cost of annual premiums for such coverage; and

(ii) if such coverage is obtained—

(I) subject to paragraph (2) of section 1916(h), reduce the premium imposed by the State under that section in an amount that reasonably reflects the premium contribution made by the parent for private coverage on behalf of a child with a disability; and

(II) treat such coverage as a third party liability under subsection (a)(25).

(B) In the case of a parent to which subparagraph (A) applies, a State, notwithstanding section 1906 but subject to paragraph (1)(C)(ii), may provide for payment of any portion of the annual premium for such family coverage that the parent is required to pay. Any payments made by the State under this subparagraph shall be considered, for purposes of section 1903(a), to be payments for medical assistance.

(dd) ELECTRONIC TRANSMISSION OF INFORMATION.—If the State agency determining eligibility for medical assistance under this title or child health assistance under title XXI verifies an element of eligibility based on information from an Express Lane Agency (as defined in subsection (e)(13)(F)), or from another public agency, then the applicant's signature under penalty of perjury shall not be required as to such element. Any signature requirement for an application for medical assistance may be satisfied through an electronic signature, as defined in section 1710(1) of the Government Paperwork Elimination Act (44 U.S.C. 3504 note). The requirements of subparagraphs (A) and (B) of section 1137(d)(2) may be met through evidence in digital or electronic form.

(ee)(1) For purposes of subsection (a)(46)(B)(ii), the requirements of this subsection with respect to an individual declaring to be a citizen or national of the United States for purposes of establishing eligibility under this title, are, in lieu of requiring the individual to present satisfactory documentary evidence of citizenship or nationality under section 1903(x) (if the individual is not described in paragraph (2) of that section), as follows:

(A) The State submits the name and social security number of the individual to the Commissioner of Social Security as part of the program established under paragraph (2).

(B) If the State receives notice from the Commissioner of Social Security that the name or social security number, or the declaration of citizenship or nationality, of the individual is inconsistent with information in the records maintained by the Commissioner—

(i) the State makes a reasonable effort to identify and address the causes of such inconsistency, including through typographical or other clerical errors, by contacting the individual to confirm the accuracy of the name or social security number submitted or declaration of citizenship or nationality and by taking such additional actions as the Secretary, through regulation or other guidance, or the State may identify, and continues to provide the individual with medical assistance while making such effort; and

(ii) in the case such inconsistency is not resolved under clause (i), the State—

(I) notifies the individual of such fact;

(II) provides the individual with a period of 90 days from the date on which the notice required under subclause (I) is received by the individual to either present satisfactory documentary evidence of citizenship or nationality (as defined in section 1903(x)(3)) or resolve the inconsistency with the Commissioner of Social Security (and continues to provide the individual with medical assistance during such 90-day period); and

(III) disenrolls the individual from the State plan under this title within 30 days after the end of such 90-day period if no such documentary evidence is presented or if such inconsistency is not resolved.

(2)(A) Each State electing to satisfy the requirements of this subsection for purposes of section 1902(a)(46)(B) shall establish a program under which the State submits at least monthly to the Commissioner of Social Security for comparison of the name and social security number, of each individual newly enrolled in the State plan under this title that month who is not described in section 1903(x)(2) and who declares to be a United States citizen or national, with information in records maintained by the Commissioner.

(B) In establishing the State program under this paragraph, the State may enter into an agreement with the Commissioner of Social Security—

(i) to provide, through an on-line system or otherwise, for the electronic submission of, and response to, the information submitted under subparagraph (A) for an individual enrolled in the State plan under this title who declares to be citizen or national on at least a monthly basis; or

(ii) to provide for a determination of the consistency of the information submitted with the information maintained in the records of the Commissioner through such other method as agreed to by the State and the Commissioner and approved by the Secretary, provided that such method is no more burdensome for individuals to comply with than any burdens that may apply under a method described in clause (i).

(C) The program established under this paragraph shall provide that, in the case of any individual who is required to submit a social security number to the State under subparagraph (A) and who is unable to provide the State with such number, shall be provided with at least the reasonable opportunity to present satisfactory documentary evidence of citizenship or nationality (as defined in section 1903(x)(3)) 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.

(3)(A) The State agency implementing the plan approved under this title shall, at such times and in such form as the Secretary may specify, provide information on the percentage each month that the inconsistent submissions bears to the total submissions made for comparison for such month. For purposes of this subparagraph, a name, social security number, or declaration of citizenship or nationality of an individual shall be treated as inconsistent and included in the determination of such percentage only if—

(i) the information submitted by the individual is not consistent with information in records maintained by the Commissioner of Social Security;

(ii) the inconsistency is not resolved by the State;

(iii) the individual was provided with a reasonable period of time to resolve the inconsistency with the Commissioner of Social Security or provide satisfactory documentation of citizenship status and did not successfully resolve such inconsistency; and

(iv) payment has been made for an item or service furnished to the individual under this title.

(B) If, for any fiscal year, the average monthly percentage determined under subparagraph (A) is greater than 3 percent—

(i) the State shall develop and adopt a corrective plan to review its procedures for verifying the identities of individuals seeking to enroll in the State plan under this title and to identify and implement changes in such procedures to improve their accuracy; and

(ii) pay to the Secretary an amount equal to the amount which bears the same ratio to the total payments under the State plan for the fiscal year for providing medical assistance to individuals who provided inconsistent information as the number of individuals with inconsistent information in excess of 3 percent of such total submitted bears to the total number of individuals with inconsistent information.

(C) The Secretary may waive, in certain limited cases, all or part of the payment under subparagraph (B)(ii) if the State is unable to reach the allowable error rate despite a good faith effort by such State.

(D) Subparagraphs (A) and (B) shall not apply to a State for a fiscal year if there is an agreement described in paragraph (2)(B) in effect as of the close of the fiscal year that provides for the submission on a real-time basis of the information described in such paragraph.

(4) Nothing in this subsection shall affect the rights of any individual under this title to appeal any disenrollment from a State plan.

(ff) Notwithstanding any other requirement of this title or any other provision of Federal or State law, a State shall disregard the following property from resources for purposes of determining the eligibility of an individual who is an Indian for medical assistance under this title:

(1) Property, including real property and improvements, that is held in trust, subject to Federal restrictions, or otherwise under the supervision of the Secretary of the Interior, located on a reservation, including any federally recognized Indian Tribe's reservation, pueblo, or colony, including former reservations in Oklahoma, Alaska Native regions established by the Alaska Native Claims Settlement Act, and Indian allotments on or near a reservation as designated and approved by the Bureau of Indian Affairs of the Department of the Interior.

(2) For any federally recognized Tribe not described in paragraph (1), property located within the most recent boundaries of a prior Federal reservation.

(3) Ownership interests in rents, leases, royalties, or usage rights related to natural resources (including extraction of natural resources or harvesting of timber, other plants and plant products, animals, fish, and shellfish) resulting from the exercise of federally protected rights.

(4) Ownership interests in or usage rights to items not covered by paragraphs (1) through (3) that have unique religious, spiritual, traditional, or cultural significance or rights that support subsistence or a traditional lifestyle according to applicable tribal law or custom.

(gg) MAINTENANCE OF EFFORT.—

(1) GENERAL REQUIREMENT TO MAINTAIN ELIGIBILITY STANDARDS UNTIL STATE EXCHANGE IS FULLY OPERATIONAL.—Subject to the succeeding paragraphs of this subsection, during the period that begins on the date of enactment of the Patient Protection and Affordable Care Act and ends on the date on which the Secretary determines that an Exchange established by the State under section 1311 of the Patient Protection and Affordable Care Act is fully operational, as a condition for receiving any Federal payments under section 1903(a) for calendar quarters occurring during such period, a State shall not have in effect eligibility standards, methodologies, or procedures under the State plan under this title or under any waiver of such plan that is in effect during that period, that are more restrictive than the eligibility standards, methodologies, or procedures, respectively, under the plan or waiver that are in effect on the date of enactment of the Patient Protection and Affordable Care Act.

(2) CONTINUATION OF ELIGIBILITY STANDARDS FOR CHILDREN THROUGH SEPTEMBER 30, 2027.—The requirement under paragraph (1) shall continue to apply to a State through September 30, 2027 (but during the period that begins on October 1, 2019, and ends on September 30, 2027 only with respect to children in families whose income does not exceed 300 percent of the poverty line (as defined in section 2110(c)(5)) applicable to a family of the size involved) with respect to the eligibility standards, methodologies, and procedures under the State plan under this title or under any waiver of such plan that are applicable to determining the eligibility for medical assistance of any child who is under 19 years of age (or such higher age as the State may have elected).

(3) NONAPPLICATION.—During the period that begins on January 1, 2011, and ends on December 31, 2013, the requirement under paragraph (1) shall not apply to a State with respect to nonpregnant, nondisabled adults who are eligible for medical assistance under the State plan or under a waiver of the plan at the option of the State and whose income exceeds 133 percent of the poverty line (as defined in section 2110(c)(5)) applicable to a family of the size involved if, on or after December 31, 2010, the State certifies to the Secretary that, with respect to the State fiscal year during which the certification is made, the State has a budget deficit, or with respect to the succeeding State fiscal year, the State is projected to have a budget deficit. Upon submission of such a certification to the Secretary, the requirement under paragraph (1) shall not apply to

the State with respect to any remaining portion of the period described in the preceding sentence.

(4) DETERMINATION OF COMPLIANCE.—

(A) STATES SHALL APPLY MODIFIED ADJUSTED GROSS INCOME.—A State's determination of income in accordance with subsection (e)(14) shall not be considered to be eligibility standards, methodologies, or procedures that are more restrictive than the standards, methodologies, or procedures in effect under the State plan or under a waiver of the plan on the date of enactment of the Patient Protection and Affordable Care Act for purposes of determining compliance with the requirements of paragraph (1), (2), or (3).

(B) STATES MAY EXPAND ELIGIBILITY OR MOVE WAIVERED POPULATIONS INTO COVERAGE UNDER THE STATE PLAN.—With respect to any period applicable under paragraph (1), (2), or (3), a State that applies eligibility standards, methodologies, or procedures under the State plan under this title or under any waiver of the plan that are less restrictive than the eligibility standards, methodologies, or procedures, applied under the State plan or under a waiver of the plan on the date of enactment of the Patient Protection and Affordable Care Act, or that makes individuals who, on such date of enactment, are eligible for medical assistance under a waiver of the State plan, after such date of enactment eligible for medical assistance through a State plan amendment with an income eligibility level that is not less than the income eligibility level that applied under the waiver, or as a result of the application of subclause (VIII) of section 1902(a)(10)(A)(i), shall not be considered to have in effect eligibility standards, methodologies, or procedures that are more restrictive than the standards, methodologies, or procedures in effect under the State plan or under a waiver of the plan on the date of enactment of the Patient Protection and Affordable Care Act for purposes of determining compliance with the requirements of paragraph (1), (2), or (3).

(hh)(1) A State may elect to phase-in the extension of eligibility for medical assistance to individuals described in subclause (XX) of subsection (a)(10)(A)(ii) based on the categorical group (including nonpregnant childless adults) or income, so long as the State does not extend such eligibility to individuals described in such subclause with higher income before making individuals described in such subclause with lower income eligible for medical assistance.

(2) If an individual described in subclause (XX) of subsection (a)(10)(A)(ii) is the parent of a child who is under 19 years of age (or such higher age as the State may have elected) who is eligible for medical assistance under the State plan or under a waiver of such plan, the individual may not be enrolled under the State plan unless the individual's child is enrolled under the State plan or under a waiver of the plan or is enrolled in other health insurance coverage. For purposes of the preceding sentence, the term "parent" includes an individual treated as a caretaker relative for purposes of carrying out section 1931.

(ii)(1) Individuals described in this subsection are individuals—

(A) whose income does not exceed an income eligibility level established by the State that does not exceed the highest income eligibility level established under the State plan under this title (or under its State child health plan under title XXI) for pregnant women; and

(B) who are not pregnant.

(2) At the option of a State, individuals described in this subsection may include individuals who, had individuals applied on or before January 1, 2007, would have been made eligible pursuant to the standards and processes imposed by that State for benefits described in clause (XVI) of the matter following subparagraph (G) of section subsection (a)(10) pursuant to a waiver granted under section 1115.

(3) At the option of a State, for purposes of subsection (a)(17)(B), in determining eligibility for services under this subsection, the State may consider only the income of the applicant or recipient.

(jj) PRIMARY CARE SERVICES DEFINED.—For purposes of subsection (a)(13)(C), the term "primary care services" means—

(1) evaluation and management services that are procedure codes (for services covered under title XVIII) for services in the category designated Evaluation and Management in the Healthcare Common Procedure Coding System (established by the Secretary under section 1848(c)(5) as of December 31, 2009, and as subsequently modified); and

(2) services related to immunization administration for vaccines and toxoids for which CPT codes 90465, 90466, 90467, 90468, 90471, 90472, 90473, or 90474 (as subsequently modified) apply under such System.

(kk) PROVIDER AND SUPPLIER SCREENING, OVERSIGHT, AND REPORTING REQUIREMENTS.—For purposes of subsection (a)(77), the requirements of this subsection are the following:

(1) SCREENING.—The State complies with the process for screening providers and suppliers under this title, as established by the Secretary under section 1866(j)(2).

(2) PROVISIONAL PERIOD OF ENHANCED OVERSIGHT FOR NEW PROVIDERS AND SUPPLIERS.—The State complies with procedures to provide for a provisional period of enhanced oversight for new providers and suppliers under this title, as established by the Secretary under section 1866(j)(3).

(3) DISCLOSURE REQUIREMENTS.—The State requires providers and suppliers under the State plan or under a waiver of the plan to comply with the disclosure requirements established by the Secretary under section 1866(j)(5).

(4) TEMPORARY MORATORIUM ON ENROLLMENT OF NEW PROVIDERS OR SUPPLIERS.—

(A) TEMPORARY MORATORIUM IMPOSED BY THE SECRETARY.—

(i) IN GENERAL.—Subject to clause (ii), the State complies with any temporary moratorium on the enrollment of new providers or suppliers imposed by the Secretary under section 1866(j)(7).

(ii) EXCEPTIONS.—

(I) COMPLIANCE WITH MORATORIUM.—A State shall not be required to comply with a temporary

moratorium described in clause (i) if the State determines that the imposition of such temporary moratorium would adversely impact beneficiaries' access to medical assistance.

(II) FFP AVAILABLE.—Notwithstanding section 1903(i)(2)(E), payment may be made to a State under this title with respect to amounts expended for items and services described in such section if the Secretary, in consultation with the State agency administering the State plan under this title (or a waiver of the plan), determines that denying payment to the State pursuant to such section would adversely impact beneficiaries' access to medical assistance.

(iii) LIMITATION ON CHARGES TO BENEFICIARIES.—With respect to any amount expended for items or services furnished during calendar quarters beginning on or after October 1, 2017, the State prohibits, during the period of a temporary moratorium described in clause (i), a provider meeting the requirements specified in subparagraph (C)(iii) of section 1866(j)(7) from charging an individual or other person eligible to receive medical assistance under the State plan under this title (or a waiver of the plan) for an item or service described in section 1903(i)(2)(E) furnished to such an individual.

(B) MORATORIUM ON ENROLLMENT OF PROVIDERS AND SUPPLIERS.—At the option of the State, the State imposes, for purposes of entering into participation agreements with providers or suppliers under the State plan or under a waiver of the plan, periods of enrollment moratoria, or numerical caps or other limits, for providers or suppliers identified by the Secretary as being at high-risk for fraud, waste, or abuse as necessary to combat fraud, waste, or abuse, but only if the State determines that the imposition of any such period, cap, or other limits would not adversely impact beneficiaries' access to medical assistance.

(5) COMPLIANCE PROGRAMS.—The State requires providers and suppliers under the State plan or under a waiver of the plan to establish, in accordance with the requirements of section 1866(j)(7), a compliance program that contains the core elements established under subparagraph (B) of that section 1866(j)(7) for providers or suppliers within a particular industry or category.

(6) REPORTING OF ADVERSE PROVIDER ACTIONS.—The State complies with the national system for reporting criminal and civil convictions, sanctions, negative licensure actions, and other adverse provider actions to the Secretary, through the Administrator of the Centers for Medicare & Medicaid Services, in accordance with regulations of the Secretary.

(7) ENROLLMENT AND NPI OF ORDERING OR REFERRING PROVIDERS.—The State requires—

(A) all ordering or referring physicians or other professionals to be enrolled under the State plan or under a waiver of the plan as a participating provider; and

(B) the national provider identifier of any ordering or referring physician or other professional to be specified on any claim for payment that is based on an order or referral of the physician or other professional.

(8) PROVIDER TERMINATIONS.—

(A) IN GENERAL.—Beginning on July 1, 2018, in the case of a notification under subsection (a)(41) with respect to a termination for a reason specified in section 455.101 of title 42, Code of Federal Regulations (as in effect on November 1, 2015) or for any other reason specified by the Secretary, of the participation of a provider of services or any other person under the State plan (or under a waiver of the plan), the State, not later than 30 days after the effective date of such termination, submits to the Secretary with respect to any such provider or person, as appropriate—

(i) the name of such provider or person;

(ii) the provider type of such provider or person;

(iii) the specialty of such provider's or person's practice;

(iv) the date of birth, Social Security number, national provider identifier (if applicable), Federal taxpayer identification number, and the State license or certification number of such provider or person (if applicable);

(v) the reason for the termination;

(vi) a copy of the notice of termination sent to the provider or person;

(vii) the date on which such termination is effective, as specified in the notice; and

(viii) any other information required by the Secretary.

(B) EFFECTIVE DATE DEFINED.—For purposes of this paragraph, the term "effective date" means, with respect to a termination described in subparagraph (A), the later of—

(i) the date on which such termination is effective, as specified in the notice of such termination; or

(ii) the date on which all appeal rights applicable to such termination have been exhausted or the timeline for any such appeal has expired.

(9) OTHER STATE OVERSIGHT.—Nothing in this subsection shall be interpreted to preclude or limit the ability of a State to engage in provider and supplier screening or enhanced provider and supplier oversight activities beyond those required by the Secretary.

(ll) TERMINATION NOTIFICATION DATABASE.—In the case of a provider of services or any other person whose participation under this title or title XXI is terminated (as described in subsection (kk)(8)), the Secretary shall, not later than 30 days after the date on which the Secretary is notified of such termination under subsection (a)(41) (as applicable), review such termination and, if the Secretary determines appropriate, include such termination in any database or similar system developed pursuant to section 6401(b)(2) of the Patient Protection and Affordable Care Act (42 U.S.C. 1395cc note; Public Law 111–148).

(mm) DIRECTORY PHYSICIAN OR PROVIDER DESCRIBED.—A physician or provider described in this subsection is—

(1) in the case of a physician or provider of a provider type for which the State agency, as a condition on receiving payment for items and services furnished by the physician or provider to individuals eligible to receive medical assistance under the State plan, requires the enrollment of the physician or provider with the State agency, a physician or a provider that—

(A) is enrolled with the agency as of the date on which the directory is published or updated (as applicable) under subsection (a)(83); and

(B) received payment under the State plan in the 12-month period preceding such date; and

(2) in the case of a physician or provider of a provider type for which the State agency does not require such enrollment, a physician or provider that received payment under the State plan (or a waiver of the plan) in the 12-month period preceding the date on which the directory is published or updated (as applicable) under subsection (a)(83).

(nn) DRUG REVIEW AND UTILIZATION REQUIREMENTS.—

(1) IN GENERAL.—For purposes of subsection (a)(84), the drug review and utilization requirements under this subsection are, subject to paragraph (3) and beginning October 1, 2019, the following:

(A) CLAIMS REVIEW LIMITATIONS.—

(i) IN GENERAL.—The State has in place—

(I) safety edits (as specified by the State) for subsequent fills for opioids and a claims review automated process (as designed and implemented by the State) that indicates when an individual enrolled under the State plan (or under a waiver of the State plan) is prescribed a subsequent fill of opioids in excess of any limitation that may be identified by the State;

(II) safety edits (as specified by the State) on the maximum daily morphine equivalent that can be prescribed to an individual enrolled under the State plan (or under a waiver of the State plan) for treatment of chronic pain and a claims review automated process (as designed and implemented by the State) that indicates when an individual enrolled under the plan (or waiver) is prescribed the morphine equivalent for such treatment in excess of any limitation that may be identified by the State; and

(III) a claims review automated process (as designed and implemented by the State) that monitors when an individual enrolled under the State plan (or under a waiver of the State plan) is concurrently prescribed opioids and—

(aa) benzodiazepines; or

(bb) antipsychotics.

(ii) MANAGED CARE ENTITIES.—The State requires each managed care entity (as defined in section 1932(a)(1)(B)) with respect to which the State has a

contract under section 1903(m) or under section 1905(t)(3) to have in place, subject to paragraph (3), with respect to individuals who are eligible for medical assistance under the State plan (or under a waiver of the State plan) and who are enrolled with the entity, the limitations described in subclauses (I) and (II) of clause (i) and a claims review automated process described in subclause (III) of such clause.

(iii) RULES OF CONSTRUCTION.—Nothing in this subparagraph may be construed as prohibiting a State or managed care entity from designing and implementing a claims review automated process under this subparagraph that provides for prospective or retrospective reviews of claims. Nothing in this subparagraph shall be understood as prohibiting the exercise of clinical judgment from a provider enrolled as a participating provider in a State plan (or waiver of the State plan) or contracting with a managed care entity regarding the best items and services for an individual enrolled under such State plan (or waiver).

(B) PROGRAM TO MONITOR ANTIPSYCHOTIC MEDICATIONS BY CHILDREN.—The State has in place a program (as designed and implemented by the State), including such a program that the State had in place before the date of the enactment of this subsection, to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the State plan (or under a waiver of the State plan) and submits annually to the Secretary such information as the Secretary may require on activities carried out under such program for individuals not more than the age of 18 years generally and children in foster care specifically.

(C) FRAUD AND ABUSE IDENTIFICATION.—The State has in place a process (as designed and implemented by the State), including such a process that the State had in place before the date of the enactment of this subsection, that identifies potential fraud or abuse of controlled substances by individuals enrolled under the State plan (or under a waiver of the State plan), health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled.

(D) REPORTS.—The State shall include in the annual report submitted to the Secretary under section 1927(g)(3)(D) information on the limitations, requirement, program, and processes applied by the State under subparagraphs (A) through (C) in accordance with such manner and time as specified by the Secretary.

(2) ANNUAL REPORT BY SECRETARY.—For each fiscal year beginning with fiscal year 2020, the Secretary shall submit to Congress a report on the most recent information submitted by States under paragraph (1)(D).

(3) EXCEPTIONS.—

(A) CERTAIN INDIVIDUALS EXEMPTED.—The drug review and utilization requirements under this subsection shall not apply with respect to an individual who—

(i) is receiving—

(I) hospice or palliative care; or

(II) treatment for cancer;

(ii) is a resident of a long-term care facility, of a facility described in section 1905(d), or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or

(iii) the State elects to treat as exempted from such requirements.

(B) EXCEPTION RELATING TO ENSURING ACCESS.—In order to ensure reasonable access to health care, the Secretary may waive the drug review and utilization requirements under this subsection, with respect to a State, in the case of natural disasters and similar situations, and in the case of the provision of emergency services (as defined for purposes of section 1860D–4(c)(5)(D)(ii)(II)).

* * * * * * *

PAYMENT FOR COVERED OUTPATIENT DRUGS

SEC. 1927. (a) REQUIREMENT FOR REBATE AGREEMENT.—

(1) IN GENERAL.—In order for payment to be available under section 1903(a) or under part B of title XVIII for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of title VI of the Veterans Health Care Act of 1992) and paragraph (6). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter on or before the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(2) EFFECTIVE DATE.—Paragraph (1) shall first apply to drugs dispensed under this title on or after January 1, 1991.

(3) AUTHORIZING PAYMENT FOR DRUGS NOT COVERED UNDER REBATE AGREEMENTS.—Paragraph (1), and section 1903(i)(10)(A), shall not apply to the dispensing of a single source drug or innovator multiple source drug if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1-A by the Food and Drug Administration; and (iii)(I) the

physician has obtained approval for use of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d), or (II) the Secretary has reviewed and approved the State's determination under subparagraph (A); or (B) the Secretary determines that in the first calendar quarter of 1991, there were extenuating circumstances.

(4) EFFECT ON EXISTING AGREEMENTS.—In the case of a rebate agreement in effect between a State and a manufacturer on the date of the enactment of this section, such agreement, for the initial agreement period specified therein, shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State agrees to report to the Secretary any rebates paid pursuant to the agreement and such agreement provides for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs under this title. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement in effect on the date of the enactment of this section provides for rebates that are at least as large as the rebates otherwise required under this section, and the State agrees to report any rebates under the agreement to the Secretary, the agreement shall be considered to be a rebate agreement in compliance with the section for the renewal periods of such agreement.

(5) LIMITATION ON PRICES OF DRUGS PURCHASED BY COVERED ENTITIES.—

(A) AGREEMENT WITH SECRETARY.—A manufacturer meets the requirements of this paragraph if the manufacturer has entered into an agreement with the Secretary that meets the requirements of section 340B of the Public Health Service Act with respect to covered outpatient drugs purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of this paragraph.

(B) COVERED ENTITY DEFINED.—In this subsection, the term "covered entity" means an entity described in section 340B(a)(4) of the Public Health Service Act.

(C) ESTABLISHMENT OF ALTERNATIVE MECHANISM TO ENSURE AGAINST DUPLICATE DISCOUNTS OR REBATES.—If the Secretary does not establish a mechanism under section 340B(a)(5)(A) of the Public Health Service Act within 12 months of the date of the enactment of such section, the following requirements shall apply:

(i) ENTITIES.—Each covered entity shall inform the single State agency under section 1902(a)(5) when it is seeking reimbursement from the State plan for medical assistance described in section 1905(a)(12) with respect to a unit of any covered outpatient drug which is subject to an agreement under section 340B(a) of such Act.

(ii) STATE AGENCY.—Each such single State agency shall provide a means by which a covered entity shall indicate on any drug reimbursement claims form (or format, where electronic claims management is used) that a unit of the drug that is the subject of the form

is subject to an agreement under section 340B of such Act, and not submit to any manufacturer a claim for a rebate payment under subsection (b) with respect to such a drug.

(D) EFFECT OF SUBSEQUENT AMENDMENTS.—In determining whether an agreement under subparagraph (A) meets the requirements of section 340B of the Public Health Service Act, the Secretary shall not take into account any amendments to such section that are enacted after the enactment of title VI of the Veterans Health Care Act of 1992.

(E) DETERMINATION OF COMPLIANCE.—A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 340B of the Public Health Service Act (as in effect immediately after the enactment of this paragraph, and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after the date of the enactment of this paragraph.

(6) REQUIREMENTS RELATING TO MASTER AGREEMENTS FOR DRUGS PROCURED BY DEPARTMENT OF VETERANS AFFAIRS AND CERTAIN OTHER FEDERAL AGENCIES.—

(A) IN GENERAL.—A manufacturer meets the requirements of this paragraph if the manufacturer complies with the provisions of section 8126 of title 38, United States Code, including the requirement of entering into a master agreement with the Secretary of Veterans Affairs under such section.

(B) EFFECT OF SUBSEQUENT AMENDMENTS.—In determining whether a master agreement described in subparagraph (A) meets the requirements of section 8126 of title 38, United States Code, the Secretary shall not take into account any amendments to such section that are enacted after the enactment of title VI of the Veterans Health Care Act of 1992.

(C) DETERMINATION OF COMPLIANCE.—A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 8126 of title 38, United States Code (as in effect immediately after the enactment of this paragraph) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after the date of the enactment of this paragraph.

(7) REQUIREMENT FOR SUBMISSION OF UTILIZATION DATA FOR CERTAIN PHYSICIAN ADMINISTERED DRUGS.—

(A) SINGLE SOURCE DRUGS.—In order for payment to be available under section 1903(a) for a covered outpatient drug that is a single source drug that is physician administered under this title (as determined by the Secretary), and that is administered on or after January 1, 2006, the

State shall provide for the collection and submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section for drugs administered for which payment is made under this title.

(B) MULTIPLE SOURCE DRUGS.—

(i) IDENTIFICATION OF MOST FREQUENTLY PHYSICIAN ADMINISTERED MULTIPLE SOURCE DRUGS.—Not later than January 1, 2007, the Secretary shall publish a list of the 20 physician administered multiple source drugs that the Secretary determines have the highest dollar volume of physician administered drugs dispensed under this title. The Secretary may modify such list from year to year to reflect changes in such volume.

(ii) REQUIREMENT.—In order for payment to be available under section 1903(a) for a covered outpatient drug that is a multiple source drug that is physician administered (as determined by the Secretary), that is on the list published under clause (i), and that is administered on or after January 1, 2008, the State shall provide for the submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section.

(C) USE OF NDC CODES.—Not later than January 1, 2007, the information shall be submitted under subparagraphs (A) and (B)(ii) using National Drug Code codes unless the Secretary specifies that an alternative coding system should be used.

(D) HARDSHIP WAIVER.—The Secretary may delay the application of subparagraph (A) or (B)(ii), or both, in the case of a State to prevent hardship to States which require additional time to implement the reporting system required under the respective subparagraph.

(b) TERMS OF REBATE AGREEMENT.—

(1) PERIODIC REBATES.—

(A) IN GENERAL.—A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this title, a rebate for a rebate period in an amount specified in subsection (c) for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period, including such drugs dispensed to individuals enrolled with a medicaid managed care organization if the organization is responsible for coverage of such drugs. Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

(B) OFFSET AGAINST MEDICAL ASSISTANCE.—Amounts received by a State under this section (or under an agree-

ment authorized by the Secretary under subsection (a)(1) or an agreement described in subsection (a)(4)) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1903(a)(1).

(C) SPECIAL RULE FOR INCREASED MINIMUM REBATE PERCENTAGE.—

(i) IN GENERAL.—In addition to the amounts applied as a reduction under subparagraph (B), for rebate periods beginning on or after January 1, 2010, during a fiscal year, the Secretary shall reduce payments to a State under section 1903(a) in the manner specified in clause (ii), in an amount equal to the product of—

(I) 100 percent minus the Federal medical assistance percentage applicable to the rebate period for the State; and

(II) the amounts received by the State under such subparagraph that are attributable (as estimated by the Secretary based on utilization and other data) to the increase in the minimum rebate percentage effected by the amendments made by subsections (a)(1), (b), and (d) of section 2501 of the Patient Protection and Affordable Care Act, taking into account the additional drugs included under the amendments made by subsection (c) of section 2501 of such Act.

The Secretary shall adjust such payment reduction for a calendar quarter to the extent the Secretary determines, based upon subsequent utilization and other data, that the reduction for such quarter was greater or less than the amount of payment reduction that should have been made.

(ii) MANNER OF PAYMENT REDUCTION.—The amount of the payment reduction under clause (i) for a State for a quarter shall be deemed an overpayment to the State under this title to be disallowed against the State's regular quarterly draw for all Medicaid spending under section 1903(d)(2). Such a disallowance is not subject to a reconsideration under section 1116(d).

(2) STATE PROVISION OF INFORMATION.—

(A) STATE RESPONSIBILITY.—Each State agency under this title shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, including such information reported by each medicaid managed care organization, and shall promptly transmit a copy of such report to the Secretary.

(B) AUDITS.—A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent

that information indicates that utilization was greater or less than the amount previously specified.

(3) MANUFACTURER PROVISION OF PRICE INFORMATION.—

(A) IN GENERAL.—Each manufacturer with an agreement in effect under this section shall report to the Secretary—

(i) not later than 30 days after the last day of each rebate period under the agreement—

(I) on the average manufacturer price (as defined in subsection (k)(1)) for covered outpatient drugs for the rebate period under the agreement (including for all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act); and

(II) for single source drugs and innovator multiple source drugs (including all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), on the manufacturer's best price (as defined in subsection (c)(1)(C)) for such drugs for the rebate period under the agreement;

(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1)) as of October 1, 1990 for each of the manufacturer's covered outpatient drugs (including for such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act); and

(iii) for calendar quarters beginning on or after January 1, 2004, in conjunction with reporting required under clause (i) and by National Drug Code (including package size)—

(I) the manufacturer's average sales price (as defined in section 1847A(c)) and the total number of units specified under section 1847A(b)(2)(A);

(II) if required to make payment under section 1847A, the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and

(III) information on those sales that were made at a nominal price or otherwise described in section 1847A(c)(2)(B);

for a drug or biological described in subparagraph (C), (D), (E), or (G) of section 1842(o)(1) or section 1881(b)(13)(A)(ii), and, for calendar quarters beginning on or after January 1, 2007 and only with respect to the information described in subclause (III), for covered outpatient drugs.

(iv) not later than 30 days after the last day of each month of a rebate period under the agreement, on the manufacturer's total number of units that are used to calculate the monthly average manufacturer price for each covered outpatient drug;

Information reported under this subparagraph is subject to audit by the Inspector General of the Department of

Health and Human Services. Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States under subparagraph (D)(iv) the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website under subparagraph (D)(v) (relating to the weighted average of the most recently reported monthly average manufacturer prices).

(B) VERIFICATION SURVEYS OF AVERAGE MANUFACTURER PRICE AND MANUFACTURER'S AVERAGE SALES PRICE.—The Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(C) PENALTIES.—

(i) FAILURE TO PROVIDE TIMELY INFORMATION.—In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) on a timely basis, the amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of such 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).

(ii) FALSE INFORMATION.—Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(D) CONFIDENTIALITY OF INFORMATION.—Notwithstanding any other provision of law, information disclosed

by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) (other than the wholesale acquisition cost for purposes of carrying out section 1847A) is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except—

(i) as the Secretary determines to be necessary to carry out this section, to carry out section 1847A (including the determination and implementation of the payment amount), or to carry out section 1847B,

(ii) to permit the Comptroller General to review the information provided,

(iii) to permit the Director of the Congressional Budget Office to review the information provided,

(iv) to States to carry out this title, and

(v) to the Secretary to disclose (through a website accessible to the public) the weighted average of the most recently reported monthly average manufacturer prices and the average retail survey price determined for each multiple source drug in accordance with subsection (f).

The previous sentence shall also apply to information disclosed under section 1860D–2(d)(2) or 1860D–4(c)(2)(E) and drug pricing data reported under the first sentence of section 1860D–31(i)(1).

(4) LENGTH OF AGREEMENT.—

(A) IN GENERAL.—A rebate agreement shall be effective for an initial period of not less than 1 year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

(B) TERMINATION.—

(i) BY THE SECRETARY.—The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(ii) BY A MANUFACTURER.—A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until the calendar quarter beginning at least 60 days after the date the manufacturer provides notice to the Secretary.

(iii) EFFECTIVENESS OF TERMINATION.—Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

(iv) NOTICE TO STATES.—In the case of a termination under this subparagraph, the Secretary shall provide notice of such termination to the States within not less than 30 days before the effective date of such termination.

(v) APPLICATION TO TERMINATIONS OF OTHER AGREEMENTS.—The provisions of this subparagraph shall apply to the terminations of agreements described in section 340B(a)(1) of the Public Health Service Act and master agreements described in section 8126(a) of title 38, United States Code.

(C) DELAY BEFORE REENTRY.—In the case of any rebate agreement with a manufacturer under this section which is terminated, another such agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed since the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

(c) DETERMINATION OF AMOUNT OF REBATE.—

(1) BASIC REBATE FOR SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS.—

(A) IN GENERAL.—Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8)) with respect to each dosage form and strength of a single source drug or an innovator multiple source drug shall be equal to the product of—

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of—

(I) the difference between the average manufacturer price and the best price (as defined in subparagraph (C)) for the dosage form and strength of the drug, or

(II) the minimum rebate percentage (specified in subparagraph (B)(i)) of such average manufacturer price,

of or the rebate period.

(B) RANGE OF REBATES REQUIRED.—

(i) MINIMUM REBATE PERCENTAGE.—For purposes of subparagraph (A)(ii)(II), the "minimum rebate percentage" for rebate periods beginning—

(I) after December 31, 1990, and before October 1, 1992, is 12.5 percent;

(II) after September 30, 1992, and before January 1, 1994, is 15.7 percent;

(III) after December 31, 1993, and before January 1, 1995, is 15.4 percent;

(IV) after December 31, 1994, and before January 1, 1996, is 15.2 percent;

(V) after December 31, 1995, and before January 1, 2010 is 15.1 percent;and

(VI) except as provided in clause (iii), after December 31, 2009, 23.1 percent.

(ii) TEMPORARY LIMITATION ON MAXIMUM REBATE AMOUNT.—In no case shall the amount applied under subparagraph (A)(ii) for a rebate period beginning—

(I) before January 1, 1992, exceed 25 percent of the average manufacturer price; or

(II) after December 31, 1991, and before January 1, 1993, exceed 50 percent of the average manufacturer price.

(iii) MINIMUM REBATE PERCENTAGE FOR CERTAIN DRUGS.—

(I) IN GENERAL.—In the case of a single source drug or an innovator multiple source drug described in subclause (II), the minimum rebate percentage for rebate periods specified in clause (i)(VI) is 17.1 percent.

(II) DRUG DESCRIBED.—For purposes of subclause (I), a single source drug or an innovator multiple source drug described in this subclause is any of the following drugs:

(aa) A clotting factor for which a separate furnishing payment is made under section 1842(o)(5) and which is included on a list of such factors specified and updated regularly by the Secretary.

(bb) A drug approved by the Food and Drug Administration exclusively for pediatric indications.

(C) BEST PRICE DEFINED.—For purposes of this section—

(i) IN GENERAL.—The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding—

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, United States Code, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the Public Health Service Act);

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State pharmaceutical assistance program;

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(V) the prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under section 1860D–31; and

(VI) any prices charged which are negotiated by a prescription drug plan under part D of title XVIII, by an MA–PD plan under part C of such title with respect to covered part D drugs or by a qualified retiree prescription drug plan (as defined in section 1860D–22(a)(2)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D–14A.

(ii) SPECIAL RULES.—The term "best price"—

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package;

(III) shall not take into account prices that are merely nominal in amount; and

(IV) in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding those prices described in subclauses (I) through (IV) of clause (i).

(iii) APPLICATION OF AUDITING AND RECORDKEEPING REQUIREMENTS.—With respect to a covered entity described in section 340B(a)(4)(L) of the Public Health Service Act, any drug purchased for inpatient use shall be subject to the auditing and recordkeeping requirements described in section 340B(a)(5)(C) of the Public Health Service Act.

(D) LIMITATION ON SALES AT A NOMINAL PRICE.—

(i) IN GENERAL.—For purposes of subparagraph (C)(ii)(III) and subsection (b)(3)(A)(iii)(III), only sales by a manufacturer of covered outpatient drugs at nominal prices to the following shall be considered to be sales at a nominal price or merely nominal in amount:

(I) A covered entity described in section 340B(a)(4) of the Public Health Service Act.

(II) An intermediate care facility for the mentally retarded.

(III) A State-owned or operated nursing facility.

(IV) An entity that—

(aa) is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Act or is State-owned or operated; and

(bb) would be a covered entity described in section 340(B)(a)(4) of the Public Health Service Act insofar as the entity provides the same type of services to the same type of populations as a covered entity described in such section provides, but does not receive funding under a provision of law referred to in such section;

(V) A public or nonprofit entity, or an entity based at an institution of higher learning whose primary purpose is to provide health care services to students of that institution, that provides a service or services described under section 1001(a) of the Public Health Service Act, 42 U.S.C. 300.

(VI) Any other facility or entity that the Secretary determines is a safety net provider to which sales of such drugs at a nominal price would be appropriate based on the factors described in clause (ii).

(ii) FACTORS.—The factors described in this clause with respect to a facility or entity are the following:

(I) The type of facility or entity.

(II) The services provided by the facility or entity.

(III) The patient population served by the facility or entity.

(IV) The number of other facilities or entities eligible to purchase at nominal prices in the same service area.

(iii) NONAPPLICATION.—Clause (i) shall not apply with respect to sales by a manufacturer at a nominal price of covered outpatient drugs pursuant to a master agreement under section 8126 of title 38, United States Code.

(iv) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed to alter any existing statutory or regulatory prohibition on services with respect to an entity described in clause (i)(IV), including the prohibition set forth in section 1008 of the Public Health Service Act.

(2) ADDITIONAL REBATE FOR SINGLE SOURCE AND INNOVATOR MULTIPLE SOURCE DRUGS.—

(A) IN GENERAL.—The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of—

(i) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period; and

(ii) the amount (if any) by which—

(I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds

(II) the average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

(B) TREATMENT OF SUBSEQUENTLY APPROVED DRUGS.—In the case of a covered outpatient drug approved by the Food and Drug Administration after October 1, 1990, clause (ii)(II) of subparagraph (A) shall be applied by substituting "the first full calendar quarter after the day on which the drug was first marketed" for "the calendar quarter beginning July 1, 1990" and "the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed" for "September 1990".

(C) TREATMENT OF NEW FORMULATIONS.—

(i) IN GENERAL.—In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation for a rebate period with respect to such drug under this subsection shall be the greater of the amount described in clause (ii) for such drug or the amount described in clause (iii) for such drug.

(ii) AMOUNT 1.—For purposes of clause (i), the amount described in this clause with respect to a drug described in clause (i) and rebate period is the amount computed under paragraph (1) for such drug, increased by the amount computed under subparagraph (A) and, as applicable, subparagraph (B) for such drug and rebate period.

(iii) AMOUNT 2.—For purposes of clause (i), the amount described in this clause with respect to a drug described in clause (i) and rebate period is the amount computed under paragraph (1) for such drug, increased by the product of—

(I) the average manufacturer price for the rebate period of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form;

(II) the highest additional rebate (calculated as a percentage of average manufacturer price) under this paragraph for the rebate period for any

strength of the original single source drug or innovator multiple source drug; and

(III) the total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

In this subparagraph, the term "line extension" means, with respect to a drug, a new formulation of the drug, such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation.

(D) MAXIMUM REBATE AMOUNT.—In no case shall the sum of the amounts applied under paragraph (1)(A)(ii) and this paragraph with respect to each dosage form and strength of a single source drug or an innovator multiple source drug for a rebate period beginning after December 31, 2009, exceed 100 percent of the average manufacturer price of the drug.

(3) REBATE FOR OTHER DRUGS.—

(A) IN GENERAL.—Except as provided in subparagraph (C), the amount of the rebate paid to a State for a rebate period with respect to each dosage form and strength of covered outpatient drugs (other than single source drugs and innovator multiple source drugs) shall be equal to the product of—

(i) the applicable percentage (as described in subparagraph (B)) of the average manufacturer price for the dosage form and strength for the rebate period, and

(ii) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period.

(B) APPLICABLE PERCENTAGE DEFINED.—For purposes of subparagraph (A)(i), the "applicable percentage" for rebate periods beginning—

(i) before January 1, 1994, is 10 percent,

(ii) after December 31, 1993, and before January 1, 2010, is 11 percent; and

(iii) after December 31, 2009, is 13 percent.

(C) ADDITIONAL REBATE.—

(i) IN GENERAL.—The amount of the rebate specified in this paragraph for a rebate period, with respect to each dosage form and strength of a covered outpatient drug other than a single source drug or an innovator multiple source drug of a manufacturer, shall be increased in the manner that the rebate for a dosage form and strength of a single source drug or an innovator multiple source drug is increased under subparagraphs (A) and (D) of paragraph (2), except as provided in clause (ii).

(ii) SPECIAL RULES FOR APPLICATION OF PROVISION.—In applying subparagraphs (A) and (D) of paragraph (2) under clause (i)—

(I) the reference in subparagraph (A)(i) of such paragraph to "1990" shall be deemed a reference to "2014";

(II) subject to clause (iii), the reference in subparagraph (A)(ii) of such paragraph to "the calendar quarter beginning July 1, 1990" shall be deemed a reference to "the calendar quarter beginning July 1, 2014"; and

(III) subject to clause (iii), the reference in subparagraph (A)(ii) of such paragraph to "September 1990" shall be deemed a reference to "September 2014";

(IV) the references in subparagraph (D) of such paragraph to "paragraph (1)(A)(ii)", "this paragraph", and "December 31, 2009" shall be deemed references to "subparagraph (A)", "this subparagraph", and "December 31, 2014", respectively; and

(V) any reference in such paragraph to a "single source drug or an innovator multiple source drug" shall be deemed to be a reference to a drug to which clause (i) applies.

(iii) SPECIAL RULE FOR CERTAIN NONINNOVATOR MULTIPLE SOURCE DRUGS.—In applying paragraph (2)(A)(ii)(II) under clause (i) with respect to a covered outpatient drug that is first marketed as a drug other than a single source drug or an innovator multiple source drug after April 1, 2013, such paragraph shall be applied—

(I) by substituting "the applicable quarter" for "the calendar quarter beginning July 1, 1990"; and

(II) by substituting "the last month in such applicable quarter" for "September 1990".

(iv) APPLICABLE QUARTER DEFINED.—In this subsection, the term "applicable quarter" means, with respect to a drug described in clause (iii), the fifth full calendar quarter after which the drug is marketed as a drug other than a single source drug or an innovator multiple source drug.

(d) LIMITATIONS ON COVERAGE OF DRUGS.—

(1) PERMISSIBLE RESTRICTIONS.—(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if—

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6));

(ii) the drug is contained in the list referred to in paragraph (2);

(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4); or

(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

(2) LIST OF DRUGS SUBJECT TO RESTRICTION.—The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(F) Nonprescription drugs, except, in the case of pregnant women when recommended in accordance with the Guideline referred to in section 1905(bb)(2)(A), agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

(G) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(H) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

(3) UPDATE OF DRUG LISTINGS.—The Secretary shall, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

(4) REQUIREMENTS FOR FORMULARIES.—A State may establish a formulary if the formulary meets the following requirements:

(A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3)).

(B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug,

and Cosmetic Act but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6)), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) REQUIREMENTS OF PRIOR AUTHORIZATION PROGRAMS.—A State plan under this title may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) only if the system providing for such approval—

(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(6) OTHER PERMISSIBLE RESTRICTIONS.—A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this Act.

(7) NON-EXCLUDABLE DRUGS.—The following drugs or classes of drugs, or their medical uses, shall not be excluded from coverage:

(A) Agents when used to promote smoking cessation, including agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

(B) Barbiturates.

(C) Benzodiazepines.

(e) TREATMENT OF PHARMACY REIMBURSEMENT LIMITS.—

(1) IN GENERAL.—During the period beginning on January 1, 1991, and ending on December 31, 1994—

(A) a State may not reduce the payment limits established by regulation under this title or any limitation described in paragraph (3) with respect to the ingredient cost of a covered outpatient drug or the dispensing fee for such a drug below the limits in effect as of January 1, 1991, and

(B) except as provided in paragraph (2), the Secretary may not modify by regulation the formula established under sections 447.331 through 447.334 of title 42, Code of Federal Regulations, in effect on November 5, 1990, to reduce the limits described in subparagraph (A).

(2) SPECIAL RULE.—If a State is not in compliance with the regulations described in paragraph (1)(B), paragraph (1)(A) shall not apply to such State until such State is in compliance with such regulations.

(3) EFFECT ON STATE MAXIMUM ALLOWABLE COST LIMITATIONS.—This section shall not supersede or affect provisions in effect prior to January 1, 1991, or after December 31, 1994, relating to any maximum allowable cost limitation established by a State for payment by the State for covered outpatient drugs, and rebates shall be made under this section without regard to whether or not payment by the State for such drugs is subject to such a limitation or the amount of such a limitation.

(4) ESTABLISHMENT OF UPPER PAYMENT LIMITS.—Subject to paragraph (5), the Secretary shall establish a Federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such and shall use only such formulations when determining any such upper limit.

(5) USE OF AMP IN UPPER PAYMENT LIMITS.—The Secretary shall calculate the Federal upper reimbursement limit established under paragraph (4) as no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly average manufacturer prices for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. The Secretary shall implement a smoothing process for average manufacturer prices. Such process shall be similar to the smoothing process used in determining the average sales price of a drug or biological under section 1847A.

(f) SURVEY OF RETAIL PRICES; STATE PAYMENT AND UTILIZATION RATES; AND PERFORMANCE RANKINGS.—

(1) SURVEY OF RETAIL PRICES.—

(A) USE OF VENDOR.—The Secretary may contract services for—

(i) with respect to a retail community pharmacy, the determination on a monthly basis of retail survey prices for covered outpatient drugs that represent a nationwide average of consumer purchase prices for such drugs, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available); and

(ii) the notification of the Secretary when a drug product that is therapeutically and pharmaceutically

equivalent and bioequivalent becomes generally available.

(B) SECRETARY RESPONSE TO NOTIFICATION OF AVAILABILITY OF MULTIPLE SOURCE PRODUCTS.—If contractor notifies the Secretary under subparagraph (A)(ii) that a drug product described in such subparagraph has become generally available, the Secretary shall make a determination, within 7 days after receiving such notification, as to whether the product is now described in subsection (e)(4).

(C) USE OF COMPETITIVE BIDDING.—In contracting for such services, the Secretary shall competitively bid for an outside vendor that has a demonstrated history in—

(i) surveying and determining, on a representative nationwide basis, retail prices for ingredient costs of prescription drugs;

(ii) working with retail community pharmacies, commercial payers, and States in obtaining and disseminating such price information; and

(iii) collecting and reporting such price information on at least a monthly basis.

In contracting for such services, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this subsection, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(D) ADDITIONAL PROVISIONS.—A contract with a vendor under this paragraph shall include such terms and conditions as the Secretary shall specify, including the following:

(i) The vendor must monitor the marketplace and report to the Secretary each time there is a new covered outpatient drug generally available.

(ii) The vendor must update the Secretary no less often than monthly on the retail survey prices for covered outpatient drugs.

(iii) The contract shall be effective for a term of 2 years.

(E) AVAILABILITY OF INFORMATION TO STATES.—Information on retail survey prices obtained under this paragraph, including applicable information on single source drugs, shall be provided to States on at least a monthly basis. The Secretary shall devise and implement a means for providing access to each State agency designated under section 1902(a)(5) with responsibility for the administration or supervision of the administration of the State plan under this title of the retail survey price determined under this paragraph.

(2) ANNUAL STATE REPORT.—Each State shall annually report to the Secretary information on—

(A) the payment rates under the State plan under this title for covered outpatient drugs;

(B) the dispensing fees paid under such plan for such drugs; and

(C) utilization rates for noninnovator multiple source drugs under such plan.

(3) ANNUAL STATE PERFORMANCE RANKINGS.—

(A) COMPARATIVE ANALYSIS.—The Secretary annually shall compare, for the 50 most widely prescribed drugs identified by the Secretary, the national retail sales price data (collected under paragraph (1)) for such drugs with data on prices under this title for each such drug for each State.

(B) AVAILABILITY OF INFORMATION.—The Secretary shall submit to Congress and the States full information regarding the annual rankings made under subparagraph (A).

(4) APPROPRIATION.—Out of any funds in the Treasury not otherwise appropriated, there is appropriated to the Secretary of Health and Human Services $5,000,000 for each of fiscal years 2006 through 2010 to carry out this subsection.

(g) DRUG USE REVIEW.—

(1) IN GENERAL.—

(A) In order to meet the requirement [of section 1903(i)(10)(B)] *of section 1902(a)(54)* , a State shall provide[, by not later than January 1, 1993,] for a drug use review program described in paragraph (2) for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, *excessive utilization,* [or inappropriate or medically unnecessary care] *inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization* , among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

(i) compendia which shall consist of the following:

(I) American Hospital Formulary Service Drug Information;

(II) United States Pharmacopeia-Drug Information (or its successor publications); and

(III) the DRUGDEX Information System; and

(ii) the peer-reviewed medical literature.

(C) The Secretary, under the procedures established in section 1903, shall pay to each State an amount equal to 75 per centum of so much of the sums expended by the State plan during calendar years 1991 through 1993 as the Secretary determines is attributable to the statewide adop-

tion of a drug use review program which conforms to the requirements of this subsection.

(D) States shall not be required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with the drug regimen review procedures prescribed by the Secretary for such facilities in regulations implementing section 1919, currently at section 483.60 of title 42, Code of Federal Regulations.

(2) DESCRIPTION OF PROGRAM.—Each drug use review program shall meet the following requirements for covered outpatient drugs:

(A) PROSPECTIVE DRUG REVIEW.—(i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this title, typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

(ii) As part of the State's prospective drug use review program under this subparagraph applicable State law shall establish standards for counseling of individuals receiving benefits under this title by pharmacists which includes at least the following:

(I) The pharmacist must offer to discuss with each individual receiving benefits under this title or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:

(aa) The name and description of the medication.

(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

(cc) Special directions and precautions for preparation, administration and use by the patient.

(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(ee) Techniques for self-monitoring drug therapy.

(ff) Proper storage.

(gg) Prescription refill information.

(hh) Action to be taken in the event of a missed dose.

(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this title:

(aa) Name, address, telephone number, date of birth (or age) and gender.

(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

(cc) Pharmacist comments relevant to the individual's drug therapy.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual receiving benefits under this title or caregiver of such individual refuses such consultation, or to require verification of the offer to provide consultation or a refusal of such offer.

(B) RETROSPECTIVE DRUG USE REVIEW.—The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1903(r)) or otherwise, for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, *excessive utilization,* ⟦or inappropriate or medically unnecessary care⟧ *inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization* , among physicians, pharmacists and individuals receiving benefits under this title, or associated with specific drugs or groups of drugs. *In the case that the program identifies a pattern described in the previous sentence, the State shall take such remedial actions as determined necessary to address such pattern.*

(C) APPLICATION OF STANDARDS.—The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using the compendia and literature referred to in subsection (1)(B) as the source of standards for such assessment) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

(D) EDUCATIONAL PROGRAM.—The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies or other organizations as specified by the State, and using data provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities de-

scribed in paragraph (3)(C)(iii) of this subsection) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

(3) STATE DRUG USE REVIEW BOARD.—

(A) ESTABLISHMENT.—Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the "DUR Board") either directly or through a contract with a private organization.

(B) MEMBERSHIP.—The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

(i) The clinically appropriate prescribing of covered outpatient drugs.

(ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.

(iii) Drug use review, evaluation, and intervention.

(iv) Medical quality assurance.

The membership of the DUR Board shall be made up at least ⅓ but no more than 51 percent licensed and actively practicing physicians and at least ⅓ licensed and actively practicing pharmacists.

(C) ACTIVITIES.—The activities of the DUR Board shall include but not be limited to the following:

(i) Retrospective DUR as defined in section (2)(B).

(ii) Application of standards as defined in section (2)(C).

(iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:

(I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of information concerning its duties, powers, and basis for its standards;

(II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;

(III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and

(IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention im-

proved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

(D) ANNUAL REPORT.—Each State shall require the DUR Board to prepare a report on an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

(h) ELECTRONIC CLAIMS MANAGEMENT.—

(1) IN GENERAL.—In accordance with chapter 35 of title 44, United States Code (relating to coordination of Federal information policy), the Secretary shall encourage each State agency to establish, as its principal means of processing claims for covered outpatient drugs under this title, a point-of-sale electronic claims management system, for the purpose of performing on-line, real time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment.

(2) ENCOURAGEMENT.—In order to carry out paragraph (1)—

(A) for calendar quarters during fiscal years 1991 and 1992, expenditures under the State plan attributable to development of a system described in paragraph (1) shall receive Federal financial participation under section 1903(a)(3)(A)(i) (at a matching rate of 90 percent) if the State acquires, through applicable competitive procurement process in the State, the most cost-effective telecommunications network and automatic data processing services and equipment; and

(B) the Secretary may permit, in the procurement described in subparagraph (A) in the application of part 433 of title 42, Code of Federal Regulations, and parts 95, 205, and 307 of title 45, Code of Federal Regulations, the substitution of the State's request for proposal in competitive procurement for advance planning and implementation documents otherwise required.

(i) ANNUAL REPORT.—

(1) IN GENERAL.—Not later than May 1 of each year the Secretary shall transmit to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives a report on the operation of this section in the preceding fiscal year.

(2) DETAILS.—Each report shall include information on—

(A) ingredient costs paid under this title for single source drugs, multiple source drugs, and nonprescription covered outpatient drugs;

(B) the total value of rebates received and number of manufacturers providing such rebates;

(C) how the size of such rebates compare with the size or rebates offered to other purchasers of covered outpatient drugs;

(D) the effect of inflation on the value of rebates required under this section;

(E) trends in prices paid under this title for covered outpatient drugs; and

(F) Federal and State administrative costs associated with compliance with the provisions of this title.

(j) EXEMPTION OF ORGANIZED HEALTH CARE SETTINGS.—

(1) Covered outpatient drugs are not subject to the requirements of this section if such drugs are—

(A) dispensed by health maintenance organizations, including Medicaid managed care organizations that contract under section 1903(m); and

(B) subject to discounts under section 340B of the Public Health Service Act.

(2) The State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject to the requirements of this section.

(3) Nothing in this subsection shall be construed as providing that amounts for covered outpatient drugs paid by the institutions described in this subsection should not be taken into account for purposes of determining the best price as described in subsection (c).

(k) DEFINITIONS.—In the section—

(1) AVERAGE MANUFACTURER PRICE.—

(A) IN GENERAL.—Subject to subparagraph (B), the term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by—

(i) wholesalers for drugs distributed to retail community pharmacies; and

(ii) retail community pharmacies that purchase drugs directly from the manufacturer.

(B) EXCLUSION OF CUSTOMARY PROMPT PAY DISCOUNTS AND OTHER PAYMENTS.—

(i) IN GENERAL.—The average manufacturer price for a covered outpatient drug shall exclude—

(I) customary prompt pay discounts extended to wholesalers;

(II) bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);

(III) reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable

returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction;

(IV) payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy, unless the drug is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy; and

(V) discounts provided by manufacturers under section 1860D–14A.

(ii) INCLUSION OF OTHER DISCOUNTS AND PAYMENTS.—Notwithstanding clause (i), any other discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies shall be included in the average manufacturer price for a covered outpatient drug.

(C) INCLUSION OF SECTION 505(c) DRUGS.—In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, such term shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies.

(2) COVERED OUTPATIENT DRUG.—Subject to the exceptions in paragraph (3), the term "covered outpatient drug" means—

(A) of those drugs which are treated as prescribed drugs for purposes of section 1905(a)(12), a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and—

(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act;

(ii)(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or

(iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

(B) a biological product, other than a vaccine which—

(i) may only be dispensed upon prescription,

(ii) is licensed under section 351 of the Public Health Service Act, and

(iii) is produced at an establishment licensed under such section to produce such product; and

(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.

(3) LIMITING DEFINITION.—The term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug):

(A) Inpatient hospital services.

(B) Hospice services.

(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

(D) Physicians' services.

(E) Outpatient hospital services.

(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

(G) Other laboratory and x-ray services.

(H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological used for a medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C)) for such drug, biological product, or insulin.

(4) NONPRESCRIPTION DRUGS.—If a State plan for medical assistance under this title includes coverage of prescribed drugs as described in section 1905(a)(12) and permits coverage of drugs which may be sold without a prescription (commonly referred to as "over-the-counter" drugs), if they are prescribed by a physician (or other person authorized to prescribe under

State law), such a drug shall be regarded as a covered outpatient drug.

(5) MANUFACTURER.—The term "manufacturer" means any entity which is engaged in—

(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(6) MEDICALLY ACCEPTED INDICATION.—The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).

(7) MULTIPLE SOURCE DRUG; INNOVATOR MULTIPLE SOURCE DRUG; NONINNOVATOR MULTIPLE SOURCE DRUG; SINGLE SOURCE DRUG.—

(A) DEFINED.—

(i) MULTIPLE SOURCE DRUG.—The term "multiple source drug" means, with respect to a rebate period, a covered outpatient drug (not including any drug described in paragraph (5)) for which there at least 1 other drug product which—

(I) is rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations"),

(II) except as provided in subparagraph (B), is pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

(III) is sold or marketed in the United States during the period.

(ii) INNOVATOR MULTIPLE SOURCE DRUG.—The term "innovator multiple source drug" means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

(iii) NONINNOVATOR MULTIPLE SOURCE DRUG.—The term "noninnovator multiple source drug" means a multiple source drug that is not an innovator multiple source drug.

(iv) SINGLE SOURCE DRUG.—The term "single source drug" means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(B) EXCEPTION.—Subparagraph (A)(i)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (A)(i)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

(C) DEFINITIONS.—For purposes of this paragraph—

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

(8) REBATE PERIOD.—The term "rebate period" means, with respect to an agreement under subsection (a), a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under such agreement.

(9) STATE AGENCY.—The term "State agency" means the agency designated under section 1902(a)(5) to administer or supervise the administration of the State plan for medical assistance.

(10) RETAIL COMMUNITY PHARMACY.—The term "retail community pharmacy" means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

(11) WHOLESALER.—The term "wholesaler" means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including (but not limited to) manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer's and distributor's warehouses, chain drug warehouses, and wholesale drug warehouses) independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

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PROVISIONS RELATING TO MANAGED CARE

SEC. 1932. (a) STATE OPTION TO USE MANAGED CARE.—

(1) USE OF MEDICAID MANAGED CARE ORGANIZATIONS AND PRIMARY CARE CASE MANAGERS.—

(A) IN GENERAL.—Subject to the succeeding provisions of this section, and notwithstanding paragraph (1), (10)(B), or (23)(A) of section 1902(a), a State—

(i) may require an individual who is eligible for medical assistance under the State plan under this title to enroll with a managed care entity as a condition of receiving such assistance (and, with respect to assistance furnished by or under arrangements with such entity, to receive such assistance through the entity), if—

(I) the entity and the contract with the State meet the applicable requirements of this section and section 1903(m) or section 1905(t), and

(II) the requirements described in the succeeding paragraphs of this subsection are met; and

(ii) may restrict the number of provider agreements with managed care entities under the State plan if such restriction does not substantially impair access to services.

(B) DEFINITION OF MANAGED CARE ENTITY.—In this section, the term "managed care entity" means—

(i) a medicaid managed care organization, as defined in section 1903(m)(1)(A), that provides or arranges for services for enrollees under a contract pursuant to section 1903(m); and

(ii) a primary care case manager, as defined in section 1905(t)(2).

(2) SPECIAL RULES.—

(A) EXEMPTION OF CERTAIN CHILDREN WITH SPECIAL NEEDS.—A State may not require under paragraph (1) the enrollment in a managed care entity of an individual under 19 years of age who—

(i) is eligible for supplemental security income under title XVI;

(ii) is described in section 501(a)(1)(D);

(iii) is described in section 1902(e)(3);

(iv) is receiving foster care or adoption assistance under part E of title IV; or

(v) is in foster care or otherwise in an out-of-home placement.

(B) EXEMPTION OF MEDICARE BENEFICIARIES.—A State may not require under paragraph (1) the enrollment in a managed care entity of an individual who is a qualified medicare beneficiary (as defined in section 1905(p)(1)) or an individual otherwise eligible for benefits under title XVIII.

(C) INDIAN ENROLLMENT.—A State may not require under paragraph (1) the enrollment in a managed care entity of an individual who is an Indian (as defined in section 4(c) of the Indian Health Care Improvement Act of 1976 (25 U.S.C. 1603(c)) unless the entity is one of the following (and only if such entity is participating under the plan):

(i) The Indian Health Service.

(ii) An Indian health program operated by an Indian tribe or tribal organization pursuant to a contract, grant, cooperative agreement, or compact with the In-

dian Health Service pursuant to the Indian Self-Determination Act (25 U.S.C. 450 et seq.).

(iii) An urban Indian health program operated by an urban Indian organization pursuant to a grant or contract with the Indian Health Service pursuant to title V of the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

(3) CHOICE OF COVERAGE.—

(A) IN GENERAL.—A State must permit an individual to choose a managed care entity from not less than two such entities that meet the applicable requirements of this section, and of section 1903(m) or section 1905(t).

(B) STATE OPTION.—At the option of the State, a State shall be considered to meet the requirements of subparagraph (A) in the case of an individual residing in a rural area, if the State requires the individual to enroll with a managed care entity if such entity—

(i) permits the individual to receive such assistance through not less than two physicians or case managers (to the extent that at least two physicians or case managers are available to provide such assistance in the area), and

(ii) permits the individual to obtain such assistance from any other provider in appropriate circumstances (as established by the State under regulations of the Secretary).

(C) TREATMENT OF CERTAIN COUNTY-OPERATED HEALTH INSURING ORGANIZATIONS.—A State shall be considered to meet the requirement of subparagraph (A) if—

(i) the managed care entity in which the individual is enrolled is a health-insuring organization which—

(I) first became operational prior to January 1, 1986, or

(II) is described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as added by section 4734(2) of the Omnibus Budget Reconciliation Act of 1990), and

(ii) the individual is given a choice between at least two providers within such entity.

(4) PROCESS FOR ENROLLMENT AND TERMINATION AND CHANGE OF ENROLLMENT.—As conditions under paragraph (1)(A)—

(A) IN GENERAL.—The State, enrollment broker (if any), and managed care entity shall permit an individual eligible for medical assistance under the State plan under this title who is enrolled with the entity under this title to terminate (or change) such enrollment—

(i) for cause at any time (consistent with section 1903(m)(2)(A)(vi)), and

(ii) without cause—

(I) during the 90-day period beginning on the date the individual receives notice of such enrollment, and

(II) at least every 12 months thereafter.

(B) NOTICE OF TERMINATION RIGHTS.—The State shall provide for notice to each such individual of the opportunity to terminate (or change) enrollment under such conditions. Such notice shall be provided at least 60 days before each annual enrollment opportunity described in subparagraph (A)(ii)(II).

(C) ENROLLMENT PRIORITIES.—In carrying out paragraph (1)(A), the State shall establish a method for establishing enrollment priorities in the case of a managed care entity that does not have sufficient capacity to enroll all such individuals seeking enrollment under which individuals already enrolled with the entity are given priority in continuing enrollment with the entity.

(D) DEFAULT ENROLLMENT PROCESS.—In carrying out paragraph (1)(A), the State shall establish a default enrollment process—

(i) under which any such individual who does not enroll with a managed care entity during the enrollment period specified by the State shall be enrolled by the State with such an entity which has not been found to be out of substantial compliance with the applicable requirements of this section and of section 1903(m) or section 1905(t); and

(ii) that takes into consideration—

(I) maintaining existing provider-individual relationships or relationships with providers that have traditionally served beneficiaries under this title; and

(II) if maintaining such provider relationships is not possible, the equitable distribution of such individuals among qualified managed care entities available to enroll such individuals, consistent with the enrollment capacities of the entities.

(5) PROVISION OF INFORMATION.—

(A) INFORMATION IN EASILY UNDERSTOOD FORM.—Each State, enrollment broker, or managed care entity shall provide all enrollment notices and informational and instructional materials relating to such an entity under this title in a manner and form which may be easily understood by enrollees and potential enrollees of the entity who are eligible for medical assistance under the State plan under this title.

(B) INFORMATION TO ENROLLEES AND POTENTIAL ENROLLEES.—Each managed care entity that is a medicaid managed care organization shall, upon request, make available to enrollees and potential enrollees in the organization's service area information concerning the following:

(i) PROVIDERS.—The identity, locations, qualifications, and availability of health care providers that participate with the organization.

(ii) ENROLLEE RIGHTS AND RESPONSIBILITIES.—The rights and responsibilities of enrollees.

(iii) GRIEVANCE AND APPEAL PROCEDURES.—The procedures available to an enrollee and a health care pro-

vider to challenge or appeal the failure of the organization to cover a service.

(iv) INFORMATION ON COVERED ITEMS AND SERVICES.—All items and services that are available to enrollees under the contract between the State and the organization that are covered either directly or through a method of referral and prior authorization. Each managed care entity that is a primary care case manager shall, upon request, make available to enrollees and potential enrollees in the organization's service area the information described in clause (iii).

(C) COMPARATIVE INFORMATION.—A State that requires individuals to enroll with managed care entities under paragraph (1)(A) shall annually (and upon request) provide, directly or through the managed care entity, to such individuals a list identifying the managed care entities that are (or will be) available and information (presented in a comparative, chart-like form) relating to the following for each such entity offered:

(i) BENEFITS AND COST-SHARING.—The benefits covered and cost-sharing imposed by the entity.

(ii) SERVICE AREA.—The service area of the entity.

(iii) QUALITY AND PERFORMANCE.—To the extent available, quality and performance indicators for the benefits under the entity.

(D) INFORMATION ON BENEFITS NOT COVERED UNDER MANAGED CARE ARRANGEMENT.—A State, directly or through managed care entities, shall, on or before an individual enrolls with such an entity under this title, inform the enrollee in a written and prominent manner of any benefits to which the enrollee may be entitled to under this title but which are not made available to the enrollee through the entity. Such information shall include information on where and how such enrollees may access benefits not made available to the enrollee through the entity.

(b) BENEFICIARY PROTECTIONS.—

(1) SPECIFICATION OF BENEFITS.—Each contract with a managed care entity under section 1903(m) or under section 1905(t)(3) shall specify the benefits the provision (or arrangement) for which the entity is responsible.

(2) ASSURING COVERAGE TO EMERGENCY SERVICES.—

(A) IN GENERAL.—Each contract with a medicaid managed care organization under section 1903(m) and each contract with a primary care case manager under section 1905(t)(3) shall require the organization or manager—

(i) to provide coverage for emergency services (as defined in subparagraph (B)) without regard to prior authorization or the emergency care provider's contractual relationship with the organization or manager, and

(ii) to comply with guidelines established under section 1852(d)(2) (respecting coordination of post-stabilization care) in the same manner as such guidelines apply to Medicare+Choice plans offered under part C of title XVIII.

The requirement under clause (ii) shall first apply 30 days after the date of promulgation of the guidelines referred to in such clause.

(B) EMERGENCY SERVICES DEFINED.—In subparagraph (A)(i), the term "emergency services" means, with respect to an individual enrolled with an organization, covered inpatient and outpatient services that—

(i) are furnished by a provider that is qualified to furnish such services under this title, and

(ii) are needed to evaluate or stabilize an emergency medical condition (as defined in subparagraph (C)).

(C) EMERGENCY MEDICAL CONDITION DEFINED.—In subparagraph (B)(ii), the term "emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

(i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

(ii) serious impairment to bodily functions, or

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

(D) EMERGENCY SERVICES FURNISHED BY NON-CONTRACT PROVIDERS.—Any provider of emergency services that does not have in effect a contract with a Medicaid managed care entity that establishes payment amounts for services furnished to a beneficiary enrolled in the entity's Medicaid managed care plan must accept as payment in full no more than the amounts (less any payments for indirect costs of medical education and direct costs of graduate medical education) that it could collect if the beneficiary received medical assistance under this title other than through enrollment in such an entity. In a State where rates paid to hospitals under the State plan are negotiated by contract and not publicly released, the payment amount applicable under this subparagraph shall be the average contract rate that would apply under the State plan for general acute care hospitals or the average contract rate that would apply under such plan for tertiary hospitals.

(3) PROTECTION OF ENROLLEE-PROVIDER COMMUNICATIONS.—

(A) IN GENERAL.—Subject to subparagraphs (B) and (C), under a contract under section 1903(m) a medicaid managed care organization (in relation to an individual enrolled under the contract) shall not prohibit or otherwise restrict a covered health care professional (as defined in subparagraph (D)) from advising such an individual who is a patient of the professional about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under the contract, if the professional is acting within the lawful scope of practice.

(B) CONSTRUCTION.—Subparagraph (A) shall not be construed as requiring a medicaid managed care organization

to provide, reimburse for, or provide coverage of, a counseling or referral service if the organization—

(i) objects to the provision of such service on moral or religious grounds; and

(ii) in the manner and through the written instrumentalities such organization deems appropriate, makes available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization adopts a change in policy regarding such a counseling or referral service.

Nothing in this subparagraph shall be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974.

(C) HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this paragraph, the term "health care professional" means a physician (as defined in section 1861(r)) or other health care professional if coverage for the professional's services is provided under the contract referred to in subparagraph (A) for the services of the professional. Such term includes a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

(4) GRIEVANCE PROCEDURES.—Each medicaid managed care organization shall establish an internal grievance procedure under which an enrollee who is eligible for medical assistance under the State plan under this title, or a provider on behalf of such an enrollee, may challenge the denial of coverage of or payment for such assistance.

(5) DEMONSTRATION OF ADEQUATE CAPACITY AND SERVICES.—Each medicaid managed care organization shall provide the State and the Secretary with adequate assurances (in a time and manner determined by the Secretary) that the organization, with respect to a service area, has the capacity to serve the expected enrollment in such service area, including assurances that the organization—

(A) offers an appropriate range of services and access to preventive and primary care services for the population expected to be enrolled in such service area, and

(B) maintains a sufficient number, mix, and geographic distribution of providers of services.

(6) PROTECTING ENROLLEES AGAINST LIABILITY FOR PAYMENT.—Each medicaid managed care organization shall provide that an individual eligible for medical assistance under the State plan under this title who is enrolled with the organization may not be held liable—

(A) for the debts of the organization, in the event of the organization's insolvency,

(B) for services provided to the individual—

(i) in the event of the organization failing to receive payment from the State for such services; or

(ii) in the event of a health care provider with a contractual, referral, or other arrangement with the organization failing to receive payment from the State or the organization for such services, or

(C) for payments to a provider that furnishes covered services under a contractual, referral, or other arrangement with the organization in excess of the amount that would be owed by the individual if the organization had directly provided the services.

(7) ANTIDISCRIMINATION.—A medicaid managed care organization shall not discriminate with respect to participation, reimbursement, or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification. This paragraph shall not be construed to prohibit an organization from including providers only to the extent necessary to meet the needs of the organization's enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the organization.

(8) COMPLIANCE WITH CERTAIN MATERNITY AND MENTAL HEALTH REQUIREMENTS.—Each medicaid managed care organization shall comply with the requirements of subpart 2 of part A of title XXVII of the Public Health Service Act insofar as such requirements apply and are effective with respect to a health insurance issuer that offers group health insurance coverage.

(c) QUALITY ASSURANCE STANDARDS.—

(1) QUALITY ASSESSMENT AND IMPROVEMENT STRATEGY.—

(A) IN GENERAL.—If a State provides for contracts with medicaid managed care organizations under section 1903(m), the State shall develop and implement a quality assessment and improvement strategy consistent with this paragraph. Such strategy shall include the following:

(i) ACCESS STANDARDS.—Standards for access to care so that covered services are available within reasonable timeframes and in a manner that ensures continuity of care and adequate primary care and specialized services capacity.

(ii) OTHER MEASURES.—Examination of other aspects of care and service directly related to the improvement of quality of care (including grievance procedures and marketing and information standards).

(iii) MONITORING PROCEDURES.—Procedures for monitoring and evaluating the quality and appropriateness of care and services to enrollees that reflect the full spectrum of populations enrolled under the contract and that includes requirements for provision of quality assurance data to the State using the data and information set that the Secretary has specified for use under part C of title XVIII or such alternative data as the Secretary approves, in consultation with the State.

(iv) PERIODIC REVIEW.—Regular, periodic examinations of the scope and content of the strategy.

(B) STANDARDS.—The strategy developed under subparagraph (A) shall be consistent with standards that the Secretary first establishes within 1 year after the date of the enactment of this section. Such standards shall not preempt any State standards that are more stringent than such standards. Guidelines relating to quality assurance that are applied under section 1915(b)(1) shall apply under this subsection until the effective date of standards for quality assurance established under this subparagraph.

(C) MONITORING.—The Secretary shall monitor the development and implementation of strategies under subparagraph (A).

(D) CONSULTATION.—The Secretary shall conduct activities under subparagraphs (B) and (C) in consultation with the States.

(2) EXTERNAL INDEPENDENT REVIEW OF MANAGED CARE ACTIVITIES.—

(A) REVIEW OF CONTRACTS.—

(i) IN GENERAL.—Each contract under section 1903(m) with a medicaid managed care organization shall provide for an annual (as appropriate) external independent review conducted by a qualified independent entity of the quality outcomes and timeliness of, and access to, the items and services for which the organization is responsible under the contract. The requirement for such a review shall not apply until after the date that the Secretary establishes the identification method described in clause (ii).

(ii) QUALIFICATIONS OF REVIEWER.—The Secretary, in consultation with the States, shall establish a method for the identification of entities that are qualified to conduct reviews under clause (i).

(iii) USE OF PROTOCOLS.—The Secretary, in coordination with the National Governors' Association, shall contract with an independent quality review organization (such as the National Committee for Quality Assurance) to develop the protocols to be used in external independent reviews conducted under this paragraph on and after January 1, 1999.

(iv) AVAILABILITY OF RESULTS.—The results of each external independent review conducted under this subparagraph shall be available to participating health care providers, enrollees, and potential enrollees of the organization, except that the results may not be made available in a manner that discloses the identity of any individual patient.

(B) NONDUPLICATION OF ACCREDITATION.—A State may provide that, in the case of a medicaid managed care organization that is accredited by a private independent entity (such as those described in section 1852(e)(4)) or that has an external review conducted under section 1852(e)(3), the external review activities conducted under subparagraph (A) with respect to the organization shall not be duplica-

tive of review activities conducted as part of the accreditation process or the external review conducted under such section.

(C) DEEMED COMPLIANCE FOR MEDICARE MANAGED CARE ORGANIZATIONS.—At the option of a State, the requirements of subparagraph (A) shall not apply with respect to a medicaid managed care organization if the organization is an eligible organization with a contract in effect under section 1876 or a Medicare+Choice organization with a contract in effect under part C of title XVIII and the organization has had a contract in effect under section 1903(m) at least during the previous 2-year period.

(d) PROTECTIONS AGAINST FRAUD AND ABUSE.—

(1) PROHIBITING AFFILIATIONS WITH INDIVIDUALS DEBARRED BY FEDERAL AGENCIES.—

(A) IN GENERAL.—A managed care entity may not knowingly—

(i) have a person described in subparagraph (C) as a director, officer, partner, or person with beneficial ownership of more than 5 percent of the entity's equity, or

(ii) have an employment, consulting, or other agreement with a person described in such subparagraph for the provision of items and services that are significant and material to the entity's obligations under its contract with the State.

(B) EFFECT OF NONCOMPLIANCE.—If a State finds that a managed care entity is not in compliance with clause (i) or (ii) of subparagraph (A), the State—

(i) shall notify the Secretary of such noncompliance;

(ii) may continue an existing agreement with the entity unless the Secretary (in consultation with the Inspector General of the Department of Health and Human Services) directs otherwise; and

(iii) may not renew or otherwise extend the duration of an existing agreement with the entity unless the Secretary (in consultation with the Inspector General of the Department of Health and Human Services) provides to the State and to Congress a written statement describing compelling reasons that exist for renewing or extending the agreement.

(C) PERSONS DESCRIBED.—A person is described in this subparagraph if such person—

(i) is debarred, suspended, or otherwise excluded from participating in procurement activities under the Federal Acquisition Regulation or from participating in nonprocurement activities under regulations issued pursuant to Executive Order No. 12549 or under guidelines implementing such order; or

(ii) is an affiliate (as defined in such Regulation) of a person described in clause (i).

(2) RESTRICTIONS ON MARKETING.—

(A) DISTRIBUTION OF MATERIALS.—

(i) IN GENERAL.—A managed care entity, with respect to activities under this title, may not distribute

directly or through any agent or independent contractor marketing materials within any State—

(I) without the prior approval of the State, and

(II) that contain false or materially misleading information.

The requirement of subclause (I) shall not apply with respect to a State until such date as the Secretary specifies in consultation with such State.

(ii) CONSULTATION IN REVIEW OF MARKET MATERIALS.—In the process of reviewing and approving such materials, the State shall provide for consultation with a medical care advisory committee.

(B) SERVICE MARKET.—A managed care entity shall distribute marketing materials to the entire service area of such entity covered under the contract under section 1903(m) or section 1905(t)(3).

(C) PROHIBITION OF TIE-INS.—A managed care entity, or any agency of such entity, may not seek to influence an individual's enrollment with the entity in conjunction with the sale of any other insurance.

(D) PROHIBITING MARKETING FRAUD.—Each managed care entity shall comply with such procedures and conditions as the Secretary prescribes in order to ensure that, before an individual is enrolled with the entity, the individual is provided accurate oral and written information sufficient to make an informed decision whether or not to enroll.

(E) PROHIBITION OF "COLD-CALL" MARKETING .—Each managed care entity shall not, directly or indirectly, conduct door-to-door, telephonic, or other "cold-call" marketing of enrollment under this title.

(3) STATE CONFLICT-OF-INTEREST SAFEGUARDS IN MEDICAID RISK CONTRACTING.—A medicaid managed care organization may not enter into a contract with any State under section 1903(m) unless the State has in effect conflict-of-interest safeguards with respect to officers and employees of the State with responsibilities relating to contracts with such organizations or to the default enrollment process described in subsection (a)(4)(C)(ii) that are at least as effective as the Federal safeguards provided under section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423), against conflicts of interest that apply with respect to Federal procurement officials with comparable responsibilities with respect to such contracts.

(4) USE OF UNIQUE PHYSICIAN IDENTIFIER FOR PARTICIPATING PHYSICIANS.—Each medicaid managed care organization shall require each physician providing services to enrollees eligible for medical assistance under the State plan under this title to have a unique identifier in accordance with the system established under section 1173(b).

(5) CONTRACT REQUIREMENT FOR MANAGED CARE ENTITIES.—With respect to any contract with a managed care entity under section 1903(m) or 1905(t)(3) (as applicable), no later than July 1, 2018, such contract shall include a provision that providers of services or persons terminated (as described in section 1902(kk)(8)) from participation under this title, title XVIII, or

title XXI shall be terminated from participating under this title as a provider in any network of such entity that serves individuals eligible to receive medical assistance under this title.

(6) ENROLLMENT OF PARTICIPATING PROVIDERS.—

(A) IN GENERAL.—Beginning not later than January 1, 2018, a State shall require that, in order to participate as a provider in the network of a managed care entity that provides services to, or orders, prescribes, refers, or certifies eligibility for services for, individuals who are eligible for medical assistance under the State plan under this title (or under a waiver of the plan) and who are enrolled with the entity, the provider is enrolled consistent with section 1902(kk) with the State agency administering the State plan under this title. Such enrollment shall include providing to the State agency the provider's identifying information, including the name, specialty, date of birth, Social Security number, national provider identifier, Federal taxpayer identification number, and the State license or certification number of the provider.

(B) RULE OF CONSTRUCTION.—Nothing in subparagraph (A) shall be construed as requiring a provider described in such subparagraph to provide services to individuals who are not enrolled with a managed care entity under this title.

(e) SANCTIONS FOR NONCOMPLIANCE.—

(1) USE OF INTERMEDIATE SANCTIONS BY THE STATE TO ENFORCE REQUIREMENTS.—

(A) IN GENERAL.—A State may not enter into or renew a contract under section 1903(m) unless the State has established intermediate sanctions, which may include any of the types described in paragraph (2), other than the termination of a contract with a medicaid managed care organization, which the State may impose against a medicaid managed care organization with such a contract, if the organization—

(i) fails substantially to provide medically necessary items and services that are required (under law or under such organization's contract with the State) to be provided to an enrollee covered under the contract;

(ii) imposes premiums or charges on enrollees in excess of the premiums or charges permitted under this title;

(iii) acts to discriminate among enrollees on the basis of their health status or requirements for health care services, including expulsion or refusal to reenroll an individual, except as permitted by this title, or engaging in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment with the organization by eligible individuals 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 title; or

(II) to an enrollee, potential enrollee, or a health care provider under such title; or

(v) fails to comply with the applicable requirements of section 1903(m)(2)(A)(x).

The State may also impose such intermediate sanction against a managed care entity if the State determines that the entity distributed directly or through any agent or independent contractor marketing materials in violation of subsection (d)(2)(A)(i)(II).

(B) RULE OF CONSTRUCTION.—Clause (i) of subparagraph (A) shall not apply to the provision of abortion services, except that a State may impose a sanction on any medicaid managed care organization that has a contract to provide abortion services if the organization does not provide such services as provided for under the contract.

(2) INTERMEDIATE SANCTIONS.—The sanctions described in this paragraph are as follows:

(A) Civil money penalties as follows:

(i) Except as provided in clause (ii), (iii), or (iv), not more than $25,000 for each determination under paragraph (1)(A).

(ii) With respect to a determination under clause (iii) or (iv)(I) of paragraph (1)(A), not more than $100,000 for each such determination.

(iii) With respect to a determination under paragraph (1)(A)(ii), double the excess amount charged in violation of such subsection (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned).

(iv) Subject to clause (ii), with respect to a determination under paragraph (1)(A)(iii), $15,000 for each individual not enrolled as a result of a practice described in such subsection.

(B) The appointment of temporary management—

(i) to oversee the operation of the medicaid managed care organization upon a finding by the State that there is continued egregious behavior by the organization or there is a substantial risk to the health of enrollees; or

(ii) to assure the health of the organization's enrollees, if there is a need for temporary management while—

(I) there is an orderly termination or reorganization of the organization; or

(II) improvements are made to remedy the violations found under paragraph (1),

except that temporary management under this subparagraph may not be terminated until the State has determined that the medicaid managed care organization has the capability to ensure that the violations shall not recur.

(C) Permitting individuals enrolled with the managed care entity to terminate enrollment without cause, and notifying such individuals of such right to terminate enrollment.

(D) Suspension or default of all enrollment of individuals under this title after the date the Secretary or the State notifies the entity of a determination of a violation of any requirement of section 1903(m) or this section.

(E) Suspension of payment to the entity under this title for individuals enrolled after the date the Secretary or State notifies the entity of such a determination and until the Secretary or State is satisfied that the basis for such determination has been corrected and is not likely to recur.

(3) TREATMENT OF CHRONIC SUBSTANDARD ENTITIES.—In the case of a medicaid managed care organization which has repeatedly failed to meet the requirements of section 1903(m) and this section, the State shall (regardless of what other sanctions are provided) impose the sanctions described in subparagraphs (B) and (C) of paragraph (2).

(4) AUTHORITY TO TERMINATE CONTRACT.—

(A) IN GENERAL.—In the case of a managed care entity which has failed to meet the requirements of this part or a contract under section 1903(m) or 1905(t)(3), the State shall have the authority to terminate such contract with the entity and to enroll such entity's enrollees with other managed care entities (or to permit such enrollees to receive medical assistance under the State plan under this title other than through a managed care entity).

(B) AVAILABILITY OF HEARING PRIOR TO TERMINATION OF CONTRACT.—A State may not terminate a contract with a managed care entity under subparagraph (A) unless the entity is provided with a hearing prior to the termination.

(C) NOTICE AND RIGHT TO DISENROLL IN CASES OF TERMINATION HEARING.—A State may—

(i) notify individuals enrolled with a managed care entity which is the subject of a hearing to terminate the entity's contract with the State of the hearing, and

(ii) in the case of such an entity, permit such enrollees to disenroll immediately with the entity without cause.

(5) OTHER PROTECTIONS FOR MANAGED CARE ENTITIES AGAINST SANCTIONS IMPOSED BY STATE.—Before imposing any sanction against a managed care entity other than termination of the entity's contract, the State shall provide the entity with notice and such other due process protections as the State may provide, except that a State may not provide a managed care entity with a pre-termination hearing before imposing the sanction described in paragraph (2)(B).

(f) TIMELINESS OF PAYMENT; ADEQUACY OF PAYMENT FOR PRIMARY CARE SERVICES.—A contract under section 1903(m) with a medicaid managed care organization shall provide that the organization shall make payment to health care providers for items and services which are subject to the contract and that are furnished to individuals eligible for medical assistance under the State plan under this title who are enrolled with the organization on a timely basis consistent with the claims payment procedures described in section 1902(a)(37)(A), unless the health care provider and the organization agree to an alternate payment schedule and, in the case of primary care services described in section 1902(a)(13)(C), con-

sistent with the minimum payment rates specified in such section (regardless of the manner in which such payments are made, including in the form of capitation or partial capitation).

(g) IDENTIFICATION OF PATIENTS FOR PURPOSES OF MAKING DSH PAYMENTS.—Each contract with a managed care entity under section 1903(m) or under section 1905(t)(3) shall require the entity either—

(1) to report to the State information necessary to determine the hospital services provided under the contract (and the identity of hospitals providing such services) for purposes of applying sections 1886(d)(5)(F) and 1923; or

(2) to include a sponsorship code in the identification card issued to individuals covered under this title in order that a hospital may identify a patient as being entitled to benefits under this title.

(h) SPECIAL RULES WITH RESPECT TO INDIAN ENROLLEES, INDIAN HEALTH CARE PROVIDERS, AND INDIAN MANAGED CARE ENTITIES.—

(1) ENROLLEE OPTION TO SELECT AN INDIAN HEALTH CARE PROVIDER AS PRIMARY CARE PROVIDER.—In the case of a non-Indian Medicaid managed care entity that—

(A) has an Indian enrolled with the entity; and

(B) has an Indian health care provider that is participating as a primary care provider within the network of the entity,

insofar as the Indian is otherwise eligible to receive services from such Indian health care provider and the Indian health care provider has the capacity to provide primary care services to such Indian, the contract with the entity under section 1903(m) or under section 1905(t)(3) shall require, as a condition of receiving payment under such contract, that the Indian shall be allowed to choose such Indian health care provider as the Indian's primary care provider under the entity.

(2) ASSURANCE OF PAYMENT TO INDIAN HEALTH CARE PROVIDERS FOR PROVISION OF COVERED SERVICES.—Each contract with a managed care entity under section 1903(m) or under section 1905(t)(3) shall require any such entity, as a condition of receiving payment under such contract, to satisfy the following requirements:

(A) DEMONSTRATION OF ACCESS TO INDIAN HEALTH CARE PROVIDERS AND APPLICATION OF ALTERNATIVE PAYMENT ARRANGEMENTS.—Subject to subparagraph (C), to—

(i) demonstrate that the number of Indian health care providers that are participating providers with respect to such entity are sufficient to ensure timely access to covered Medicaid managed care services for those Indian enrollees who are eligible to receive services from such providers; and

(ii) agree to pay Indian health care providers, whether such providers are participating or non-participating providers with respect to the entity, for covered Medicaid managed care services provided to those Indian enrollees who are eligible to receive services from such providers at a rate equal to the rate negotiated between such entity and the provider involved

or, if such a rate has not been negotiated, at a rate 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 participating provider which is not an Indian health care provider.

The Secretary shall establish procedures for applying the requirements of clause (i) in States where there are no or few Indian health providers.

(B) PROMPT PAYMENT.—To agree to make prompt payment (consistent with rule for prompt payment of providers under section 1932(f)) to Indian health care providers that are participating providers with respect to such entity or, in the case of an entity to which subparagraph (A)(ii) or (C) applies, that the entity is required to pay in accordance with that subparagraph.

(C) APPLICATION OF SPECIAL PAYMENT REQUIREMENTS FOR FEDERALLY-QUALIFIED HEALTH CENTERS AND FOR SERVICES PROVIDED BY CERTAIN INDIAN HEALTH CARE PROVIDERS.—

(i) FEDERALLY-QUALIFIED HEALTH CENTERS.—

(I) MANAGED CARE ENTITY PAYMENT REQUIREMENT.—To agree to pay any Indian health care provider that is a federally-qualified health center under this title but not a participating provider with respect to the entity, for the provision of covered Medicaid managed care services by such provider to an Indian enrollee of the entity at a rate equal to the amount of payment that the entity would pay a federally-qualified health center that is a participating provider with respect to the entity but is not an Indian health care provider for such services.

(II) CONTINUED APPLICATION OF STATE REQUIREMENT TO MAKE SUPPLEMENTAL PAYMENT.—Nothing in subclause (I) or subparagraph (A) or (B) shall be construed as waiving the application of section 1902(bb)(5) regarding the State plan requirement to make any supplemental payment due under such section to a federally-qualified health center for services furnished by such center to an enrollee of a managed care entity (regardless of whether the federally-qualified health center is or is not a participating provider with the entity).

(ii) PAYMENT RATE FOR SERVICES PROVIDED BY CERTAIN INDIAN HEALTH CARE PROVIDERS.—If the amount paid by a managed care entity to an Indian health care provider that is not a federally-qualified health center for services provided by the provider to an Indian enrollee with the managed care entity is less than the rate that applies to the provision of such services by the provider under the State plan, the plan shall provide for payment to the Indian health care provider, whether the provider is a participating or nonparticipating provider with respect to the entity, of the difference between such applicable rate and the

amount paid by the managed care entity to the provider for such services.

(D) CONSTRUCTION.—Nothing in this paragraph shall be construed as waiving the application of section 1902(a)(30)(A) (relating to application of standards to assure that payments are consistent with efficiency, economy, and quality of care).

(3) SPECIAL RULE FOR ENROLLMENT FOR INDIAN MANAGED CARE ENTITIES.—Regarding the application of a Medicaid managed care program to Indian Medicaid managed care entities, an Indian Medicaid managed care entity may restrict enrollment under such program to Indians in the same manner as Indian Health Programs may restrict the delivery of services to Indians.

(4) DEFINITIONS.—For purposes of this subsection:

(A) INDIAN HEALTH CARE PROVIDER.—The term "Indian health care provider" means an Indian Health Program or an Urban Indian Organization.

(B) INDIAN MEDICAID MANAGED CARE ENTITY.—The term "Indian Medicaid managed care entity" means a managed care entity that is controlled (within the meaning of the last sentence of section 1903(m)(1)(C)) by the Indian Health Service, a Tribe, Tribal Organization, or Urban Indian Organization, or a consortium, which may be composed of 1 or more Tribes, Tribal Organizations, or Urban Indian Organizations, and which also may include the Service.

(C) NON-INDIAN MEDICAID MANAGED CARE ENTITY.—The term "non-Indian Medicaid managed care entity" means a managed care entity that is not an Indian Medicaid managed care entity.

(D) COVERED MEDICAID MANAGED CARE SERVICES.—The term "covered Medicaid managed care services" means, with respect to an individual enrolled with a managed care entity, items and services for which benefits are available with respect to the individual under the contract between the entity and the State involved.

(E) MEDICAID MANAGED CARE PROGRAM.—The term "Medicaid managed care program" means a program under sections 1903(m), 1905(t), and 1932 and includes a managed care program operating under a waiver under section 1915(b) or 1115 or otherwise.

(i) DRUG UTILIZATION REVIEW ACTIVITIES AND REQUIREMENTS.—Beginning not later than October 1, 2019, each contract under a State plan with a managed care entity (other than a primary care case manager) under section 1903(m) shall provide that the entity is in compliance with the applicable provisions of section 438.3(s)(2) of title 42 of the Code of Federal Regulations, section 483.3(s)(4)) of such title, and section 483.3(s)(5) of such title, as such provisions were in effect on March 31, 2018.

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