

NURTURING AND SUPPORTING HEALTHY BABIES ACT

MAY 10, 2016.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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

R E P O R T

[To accompany H.R. 4978]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 4978) to require the Government Accountability Office to submit to Congress a report on neonatal abstinence syndrome (NAS) in the United States and its treatment under Medicaid, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

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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 “Nurturing And Supporting Healthy Babies Act” or as the “NAS Healthy Babies Act”.

**SEC. 2. GAO REPORT ON NEONATAL ABSTINENCE SYNDROME (NAS).**

(a) **IN GENERAL.**—Not later than one year after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance and the Committee on Health, Education, Labor and Pensions of the Senate a report on neonatal abstinence syndrome (in this section referred to as “NAS”) in the United States.

(b) **INFORMATION TO BE INCLUDED IN REPORT.**—Such report shall include information on the following:

(1) The prevalence of NAS in the United States, including the proportion of children born in the United States with NAS who are eligible for medical assistance under State Medicaid programs under title XIX of the Social Security Act at birth and the costs associated with NAS through such programs.

(2) The services for which coverage is available under State Medicaid programs for treatment of infants with NAS.

(3) The settings (including inpatient, outpatient, hospital-based, and other settings) for the treatment of infants with NAS and the reimbursement methodologies and costs associated with such treatment in such settings.

(4) The prevalence of utilization of various care settings under State Medicaid programs for treatment of infants with NAS and any Federal barriers to treating such infants under such programs, particularly in non-hospital-based settings.

(c) **RECOMMENDATIONS.**—Such report also shall include such recommendations as the Comptroller General determines appropriate for improvements that will ensure access to treatment for infants with NAS under State Medicaid programs.

**SEC. 3. EXCLUDING ABUSE-DETERRENT FORMULATIONS OF PRESCRIPTION DRUGS FROM THE MEDICAID ADDITIONAL REBATE REQUIREMENT FOR NEW FORMULATIONS OF PRESCRIPTION DRUGS.**

(a) **IN GENERAL.**—The last sentence of section 1927(c)(2)(C) of the Social Security Act (42 U.S.C. 1396r–8(c)(2)(C)) is amended by inserting before the period at the end the following: “, 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”.

(b) **EFFECTIVE DATE.**—The amendment made by subsection (a) shall apply to drugs that are paid for by a State in calendar quarters beginning on or after the date of the enactment of this Act.

**SEC. 4. LIMITING DISCLOSURE OF PREDICTIVE MODELING AND OTHER ANALYTICS TECHNOLOGIES TO IDENTIFY AND PREVENT WASTE, FRAUD, AND ABUSE.**

(a) **IN GENERAL.**—Title XI of the Social Security Act is amended by inserting after section 1128J (42 U.S.C. 1320a–7k) the following new section:

**“SEC. 1128K. DISCLOSURE OF PREDICTIVE MODELING AND OTHER ANALYTICS TECHNOLOGIES TO IDENTIFY AND PREVENT WASTE, FRAUD, AND ABUSE.**

“(a) **REFERENCE TO PREDICTIVE MODELING TECHNOLOGIES REQUIREMENTS.**—For provisions relating to the use of predictive modeling and other analytics technologies to identify and prevent waste, fraud, and abuse with respect to the Medicare program under title XVIII, the Medicaid program under title XIX, and the Children’s Health Insurance Program under title XXI, see section 4241 of the Small Business Jobs Act of 2010 (42 U.S.C. 1320a–7m).

“(b) **LIMITING DISCLOSURE OF PREDICTIVE MODELING TECHNOLOGIES.**—In implementing such provisions under such section 4241 with respect to covered algorithms (as defined in subsection (c)), the following shall apply:

“(1) **NONAPPLICATION OF FOIA.**—The covered algorithms used or developed for purposes of such section (including by the Secretary or a State (or an entity operating under a contract with a State)) shall be exempt from disclosure under section 552(b)(3) of title 5, United States Code.

“(2) **LIMITATION WITH RESPECT TO USE AND DISCLOSURE OF INFORMATION BY STATE AGENCIES.**—

“(A) **IN GENERAL.**—A State agency may not use or disclose covered algorithms used or developed for purposes of such section except for purposes of administering the State plan (or a waiver of the plan) under the Medicaid program under title XIX or the State child health plan (or a waiver of the plan) under the Children’s Health Insurance Program under title XXI, including by enabling an entity operating under a contract with a

State to assist the State to identify or prevent waste, fraud and abuse with respect to such programs.

“(B) INFORMATION SECURITY.—A State agency shall have in effect data security and control policies that the Secretary finds adequate to ensure the security of covered algorithms used or developed for purposes of such section 4241 and to ensure that access to such information is restricted to authorized persons for purposes of authorized uses and disclosures described in subparagraph (A).

“(C) PROCEDURAL REQUIREMENTS.—State agencies to which information is disclosed pursuant to such section 4241 shall adhere to uniform procedures established by the Secretary.

“(c) COVERED ALGORITHM DEFINED.—In this section, the term ‘covered algorithm’—

“(1) means a predictive modeling or other analytics technology, as used for purposes of section 4241(a) of the Small Business Jobs Act of 2010 (42 U.S.C. 1320a–7m(a)) to identify and prevent waste, fraud, and abuse with respect to the Medicare program under title XVIII, the Medicaid program under title XIX, and the Children’s Health Insurance Program under title XXI; and

“(2) includes the mathematical expressions utilized in the application of such technology and the means by which such technology is developed.”.

(b) CONFORMING AMENDMENTS.—

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

(A) in paragraph (80), by striking “and” at the end;

(B) in paragraph (81), by striking the period at the end and inserting “; and”; and

(C) by inserting after paragraph (81) the following new paragraph:

“(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).”.

(2) STATE CHILD HEALTH PLAN REQUIREMENT.—Section 2102(a)(7) of the Social Security Act (42 U.S.C. 1397bb(a)(7)) is amended—

(A) in subparagraph (A), by striking “, and” at the end and inserting a semicolon;

(B) in subparagraph (B), by striking the period at the end and inserting “; and”; and

(C) by adding at the end the following new subparagraph:

“(C) to ensure that the State agency involved is in compliance with subparagraphs (A), (B), and (C) of section 1128K(b)(2).”.

#### SEC. 5. MEDICAID IMPROVEMENT FUND.

Section 1941(b)(1) of the Social Security Act (42 U.S.C. 1396w–1(b)(1)) is amended to read as follows:

“(1) IN GENERAL.—There shall be available to the Fund, for expenditures from the Fund for fiscal year 2021 and thereafter, \$5,000,000.”.

Amend the long title so as to read: A bill to require the Government Accountability Office to submit to Congress a report on neonatal abstinence syndrome (NAS) in the United States and its treatment under Medicaid, and for other purposes.

#### PURPOSE AND SUMMARY

H.R. 4978, the “Nurturing and Supporting Healthy Babies Act,” would require the Comptroller General of the United States to issue a report one year after enactment on neonatal abstinence syndrome (NAS), including information on the treatment for infants with NAS under Medicaid. The bill would also correct an unintended consequence in current law by exempting abuse-deterrent formulations (ADF) of prescription drugs from the definition of “line extension” when calculating Medicaid rebates—thus helping to incentivize the development of ADF to combat opioid abuse. In addition, the bill would prevent the public disclosure of program integrity algorithms used to identify and predict waste, fraud, and abuse in Medicare, Medicaid, and the Children’s Health Insurance

Program (CHIP) and place savings in the Medicaid Improvement Fund.

#### BACKGROUND AND NEED FOR LEGISLATION

The Centers for Disease Control and Prevention (CDC) has estimated that prescription opioid abuse costs the U.S. economy tens of billions of dollars each year in lost productivity and health care costs. Sadly, the human cost is much higher—more than 4 million Americans misuse or abuse prescription painkillers, and more than 16,000 individuals die from prescription painkiller overdoses each year. Deaths from drug overdose are now the leading cause of injury-related death in the country—more than from car accidents.

Even infants are suffering as a result of the drug abuse crisis, as opioid use by pregnant women can lead to infants being born with NAS, a group of problems that occur in a newborn who was exposed to addictive opiate drugs while in the mother's womb. There has been a significant increase in the national prevalence of NAS. A 2012 article in the *Journal of the American Medical Association* found the diagnosis of NAS increased from 1.20 per 1,000 hospital births in 2000 to 3.39 per 1,000 hospital births in 2009.<sup>1</sup>

Since Medicaid covers nearly 50 percent of births nationwide, many infants born with NAS will be covered by Medicaid. To make effective policy regarding treatment of NAS, Congress needs better information on the prevalence of NAS nationwide and among children covered by Medicaid, the services available under Medicaid for the treatment of infants with NAS, and the settings in which such care is provided.

One promising method to try to address the nation's drug abuse crisis is the development of ADFs of drugs. In its Opioids Action Plan, the Food and Drug Administration (FDA) said its goal is to "expand access to abuse deterrent formulations to discourage abuse." And in its ADF guidance to manufacturers, the agency has said it "considers the development of these products a high public health priority." However, due to an unintended consequence in current law, ADFs are subject to a higher rebate under the Medicaid program, thus disincentivizing their development. H.R. 4978 would remove this disincentive by ensuring that ADFs are not considered a line extension of a drug and thus are not subject to increased rebates. This policy was included in the President's fiscal year 2017 budget.

The cost of the ADF policy is being offset by a common sense policy from the President's budget to protect tools used to identify and prevent fraud, waste, and abuse in Medicare, Medicaid, and CHIP. The Centers for Medicare and Medicaid Services (CMS) uses mathematical algorithms and predictive technologies to uncover fraud, waste, and abuse. However, if various aspects of these algorithms were to become publicly known, fraudsters could utilize the information to re-direct their schemes to other areas of the Medicare, Medicaid, and CHIP programs or adjust their schemes to avoid detection. H.R. 4978 would allow CMS and state Medicaid and CHIP programs to freely share algorithms and other predictive analytic tools, while protecting these anti-fraud tools from public disclosure.

<sup>1</sup>Patrick S. Schumacher R, Benneyworth B, et al. "Neonatal abstinence syndrome and associated health care expenditures: United States, 2000–2009." *JAMA*. 2012. 307(18):1934–40.

## HEARINGS

The Subcommittee on Health held no hearings on H.R. 4978.

## COMMITTEE CONSIDERATION

On April 20, 2016, the Subcommittee on Health met in open markup session and forwarded H.R. 4978, without amendment, to the full Committee by a voice vote. On April 26, 27, and 28, 2016, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 4978 reported to the House, as amended, by a voice vote.

## COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 4978 reported.

## COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has not held hearings on this legislation.

## STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The objective of H.R. 4978 is to provide Congress with more information about Medicaid treatment for infants with NAS; incentivize the development of ADF of drugs to combat opioid abuse; and prevent waste, fraud, and abuse in Medicare, Medicaid, and CHIP.

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

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 4978 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

## EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that H.R. 4978 contains no earmarks, limited tax benefits, or limited tariff benefits.

## COMMITTEE COST ESTIMATE

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.

## CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, 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, May 9, 2016.*

Hon. FRED UPTON,  
*Chairman, Committee on Energy and Commerce,  
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 4978, the Nurturing and Supporting Healthy Babies Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Andrea Noda, Lara Robillard, and Zoë Williams.

Sincerely,

KEITH HALL.

Enclosure.

*H.R. 4978—Nurturing and Supporting Healthy Babies Act*

Summary: H.R. 4978 would exclude formulations of prescription drugs that include abuse deterrents from Medicaid’s requirement that new drug formulations pay additional rebates. The bill also would prevent the disclosure of algorithms used to detect fraud, provide additional funding to the Medicaid Improvement Fund, and require the Government Accountability Office to submit a report to the Congress on neonatal abstinence syndrome in the United States.

CBO estimates that enacting H.R. 4978 would not, on net, change direct spending over the 2017–2026 period. Some provisions of the bill would increase direct spending by \$80 million over that period while other provisions would decrease direct spending by the same amount. In addition, CBO estimates that implementing H.R. 4978 would have a discretionary cost of less than \$500,000; any such spending would be subject to the availability of appropriated funds. Pay-as-you-go procedures apply because enacting the legislation would affect direct spending. Enacting the legislation would not affect revenues.

CBO estimates that enacting the legislation would not increase net direct spending or on-budget deficits by more than \$5 billion in any of the four consecutive 10-year periods beginning in 2027.

H.R. 4978 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

Estimated cost to the Federal Government: The estimated budgetary effect of H.R. 4978 is shown in the following table. The budgetary effects of this legislation fall within budget functions 550 (health) and 570 (Medicare).

|  | By fiscal year, in millions of dollars— |      |      |      |      |      |      |      |      |      |           |           |  |
|--|---|------|------|------|------|------|------|------|------|------|-----------|-----------|--|
|  | 2017                                    | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2017–2021 | 2017–2026 |  |
| CHANGES IN DIRECT SPENDING   |   |      |      |      |      |      |      |      |      |      |           |           |  |
| Exclusion from Medicaid Re-<br>bate Requirements:<br>Estimated Budget Au-<br>thority ..... | 1                                       | 3    | 5    | 8    | 8    | 9    | 9    | 10   | 10   | 11   | 26        | 75        |  |

|  | By fiscal year, in millions of dollars— |      |      |      |      |      |      |      |      |      |           |           |
|--|---|------|------|------|------|------|------|------|------|------|-----------|-----------|
|  | 2017                                    | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2017–2021 | 2017–2026 |
| Estimated Outlays .....                      | 1                                       | 3    | 5    | 8    | 8    | 9    | 9    | 10   | 10   | 11   | 26        | 75        |
| Disclosure of Predictive Modeling:           |   |      |      |      |      |      |      |      |      |      |           |           |
| Estimated Budget Authority .....             | -8                                      | -8   | -8   | -8   | -8   | -8   | -8   | -8   | -8   | -8   | -40       | -80       |
| Estimated Outlays .....                      | -8                                      | -8   | -8   | -8   | -8   | -8   | -8   | -8   | -8   | -8   | -40       | -80       |
| Medicaid Improvement Fund:                   |   |      |      |      |      |      |      |      |      |      |           |           |
| Budget Authority .....                       | 0                                       | 0    | 0    | 0    | 5    | 0    | 0    | 0    | 0    | 0    | 5         | 5         |
| Estimated Outlays .....                      | 0                                       | 0    | 0    | 0    | 5    | 0    | 0    | 0    | 0    | 0    | 5         | 5         |
| Total Changes:                               |   |      |      |      |      |      |      |      |      |      |           |           |
| Estimated Budget Authority .....             | -7                                      | -5   | -3   | 0    | 5    | 1    | 1    | 2    | 2    | 3    | -9        | 0         |
| Estimated Outlays .....                      | -7                                      | -5   | -3   | 0    | 5    | 1    | 1    | 2    | 2    | 3    | -9        | 0         |
| CHANGES IN SPENDING SUBJECT TO APPROPRIATION |   |      |      |      |      |      |      |      |      |      |           |           |
| GAO Report:                                  |   |      |      |      |      |      |      |      |      |      |           |           |
| Estimated Authorization Level .....          | *                                       | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | *         | *         |
| Estimated Outlays .....                      | *                                       | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | *         | *         |

Notes: \* = Less than \$500,000; Components may not add to totals because of rounding.

**Basis of estimate:** For this estimate, CBO assumes that H.R. 4978 will be enacted near the end of fiscal year 2016.

### *Changes in direct spending*

CBO estimates that enacting H.R. 4978 would not have a net effect on direct spending over the 2017–2026 period.

**Exclusion from Medicaid Rebate Requirements.** Section 3 of H.R. 4978 would reduce the Medicaid rebate amount paid by some manufacturers of brand-name drugs that contain abuse-deterrent formulations (ADFs). ADFs are designed to make it more difficult to intentionally use prescription drugs for non-therapeutic purposes. For example, some ADFs make it more difficult for an individual to crush, break, or dissolve a drug to inappropriately extract and use its active ingredient.

Under current law, pharmaceutical manufacturers are required to pay rebates to states for prescription drugs provided through Medicaid. Based on administrative data from the Centers for Medicare and Medicaid Services (CMS), manufacturers paid more than \$20 billion in rebates to the Medicaid program in FY 2015. The formula which determines rebate amounts in the Medicaid program has several components. Some components generate rebates that are paid to states and shared with the federal government and others generate rebates that are paid to states and subsequently transferred in their entirety to the federal government. Under the bill, the component of the rebate formula that would no longer apply to ADFs of brand-name drugs is one that is paid to states and transferred in full to the federal government. Therefore, states would not be directly affected by this section of the bill.

CBO estimates that this section would increase federal Medicaid costs by about \$75 million over the 2017–2026 period by reducing rebates. CBO anticipates that an increasing number of ADFs of brand name drugs will launch over time; therefore, the component of the rebate affected by H.R. 4978 would also grow over time. This estimate is based on a review of potential classes of drugs where ADFs may be introduced over the next 10 years and on rebate cal-

culations generated from Medicaid data obtained from the Centers for Medicare and Medicaid Services and Red Book data available from Truven Health Analytics.

Disclosure of Predictive Modeling. CMS currently uses the Fraud Prevention System (FPS) to detect questionable and fraudulent activity within the fee-for-service Medicare program. The FPS uses sophisticated computer algorithms—similar to those used by credit-card issuers—to review millions of claims to look for evidence of inappropriate utilization or problematic billing. Originally authorized by the Small Business Jobs Act of 2010, the FPS is currently used to review Medicare claims. In the future, use of the FPS may expand to Medicaid and the Children’s Health Insurance Program (CHIP), which are administered by the states.

Section 4 of H.R. 4978 would prevent disclosure of the FPS algorithms through requests under the Freedom of Information Act. The bill also would forbid disclosure of that information by state agencies unless such disclosure is necessary to administer their Medicaid and CHIP programs. Permitting public access to the algorithms would facilitate fraudulent schemes to circumvent the FPS. Because H.R. 4978 prevents public access to the FPS algorithms and discourages fraud, CBO estimates that enacting Section 4 of H.R. 4978 would reduce direct spending in the Medicare, Medicaid, and CHIP programs by about \$80 million over the 2017–2026 period.

Medicaid Improvement Fund. Section 5 of H.R. 4978 would provide \$5 million in mandatory funding to the Medicaid Improvement Fund (MIF) in 2021, which would be available to the Secretary of Health and Human Services to improve federal management of the Medicaid program. Activities that could be funded by the MIF include oversight of contracts and contractors, and evaluation of demonstration programs. CBO estimates that Section 5 would increase spending by \$5 million over the 2017–2026 period.

*Changes in spending subject to appropriation*

Section 2 of H.R. 4978 would require the Government Accountability Office to submit a report to the Congress on neonatal abstinence syndrome in the United States. CBO estimates that implementing section 2 would cost less than \$500,000 over the 2017–2026 period; any such spending would be subject to the availability of appropriated funds.

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. The net changes in outlays that are subject to those pay-as-you-go procedures are shown in the following table.



CBO ESTIMATE OF PAY-AS-YOU-GO EFFECTS FOR H.R. 4978, THE NURTURING AND SUPPORTING HEALTHY BABIES ACT, AS ORDERED REPORTED BY THE HOUSE COMMITTEE ON ENERGY AND COMMERCE ON APRIL 27, 2016

|   | By fiscal year, in millions of dollars— |      |      |      |      |      |      |      |      |      |      |           |           |  |
|---|---|------|------|------|------|------|------|------|------|------|------|-----------|-----------|--|
|   | 2016                                    | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2016–2021 | 2016–2026 |  |
| NET INCREASE OR DECREASE (–) IN THE DEFICIT |   |      |      |      |      |      |      |      |      |      |      |           |           |  |
| Statutory Pay-As-You-Go Impact ...          | 0                                       | –7   | –5   | –3   | 0    | 5    | 1    | 1    | 2    | 2    | 3    | –9        | 0         |  |

Increase in long-term direct spending and deficits: CBO estimates that enacting the legislation would not increase net direct spending or on-budget deficits by more than \$5 billion in any of the four consecutive 10-year periods beginning in 2026.

Intergovernmental and private-sector impact: H.R. 4978 contains no intergovernmental or private-sector mandate as defined in UMRA and would impose no costs on state, local, or tribal governments.

Estimate prepared by: Federal costs: Andrea Noda, Lara Robillard, and Zoë Williams; Impact on state, local, and tribal governments: J'Nell Blanco Suchy; Impact on the Private Sector: Amy Petz.

Estimate approved by: Holly Harvey, Deputy 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.

#### DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 4978 establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

#### DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 4978 specifically directs to be completed no rule making within the meaning of 5 U.S.C. 551.

#### 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*

This section provides the short title of the “Nurturing and Supporting Healthy Babies Act” or the “NAS Healthy Babies Act”.

*Section 2. GAO report on Neonatal Abstinence Syndrome (NAS)*

Subsection (a) requires the Comptroller General of the United States to submit a report, one year after enactment, on NAS to the congressional committees of jurisdiction.

Subsection (b) specifies that the report shall, among other things, include information on the prevalence of NAS among children covered by Medicaid, NAS treatment services covered by Medicaid and the costs associated with that treatment, the settings in which Medicaid covered treatment for infants with NAS are provided, and any Federal barriers for treating infants with NAS.

Subsection (c) specifies that the report shall include recommendations, as the Comptroller General determines appropriate, for improving access to treatment for infants with NAS under Medicaid.

*Section 3. Excluding abuse-deterrent formulations of prescription drugs from the Medicaid additional rebate requirement for new formulations of prescription drugs.*

Subsection (a) specifies that an ADF of a drug is not included as a line-extension of a drug, even if such ADF is an extended release formulation.

Subsection (b) specifies that the amendment made by subsection (a) is effective for drugs paid for by States in calendar quarters beginning on or after the date of enactment.

*Section 4. Limiting disclosure of predictive modeling and other analytics technologies to identify and prevent waste, fraud, and abuse*

Subsection (a) inserts a new section in Title XI of the Social Security Act. This section limits the disclosure of predictive modeling and other analytics technologies to identify and prevent waste, fraud, and abuse in Medicare, Medicaid, and CHIP. Specifically, the section exempts the algorithms used in such technology from disclosure under the Freedom of Information Act. It also restricts states from using or disclosing such algorithms except for purposes of administering their Medicaid or CHIP programs and specifies that states must have data security and procedures in place that the Secretary of Health and Human Services finds appropriate to ensure that the algorithms are protected.

Subsection (b) makes conforming amendments to the Medicaid and CHIP statute.

*Section 5. Medicaid Improvement Fund*

This section places \$5,000,000 in the Medicaid Improvement Fund to be available for fiscal year 2021 or later.

## 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 XI—GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

#### PART A—GENERAL PROVISIONS

\* \* \* \* \*

**SEC. 1128K. DISCLOSURE OF PREDICTIVE MODELING AND OTHER ANALYTICS TECHNOLOGIES TO IDENTIFY AND PREVENT WASTE, FRAUD, AND ABUSE.**

(a) *REFERENCE TO PREDICTIVE MODELING TECHNOLOGIES REQUIREMENTS.*—For provisions relating to the use of predictive modeling and other analytics technologies to identify and prevent waste, fraud, and abuse with respect to the Medicare program under title XVIII, the Medicaid program under title XIX, and the Children’s Health Insurance Program under title XXI, see section 4241 of the Small Business Jobs Act of 2010 (42 U.S.C. 1320a–7m).

(b) *LIMITING DISCLOSURE OF PREDICTIVE MODELING TECHNOLOGIES.*—In implementing such provisions under such section 4241 with respect to covered algorithms (as defined in subsection (c)), the following shall apply:

(1) *NONAPPLICATION OF FOIA.*—The covered algorithms used or developed for purposes of such section (including by the Secretary or a State (or an entity operating under a contract with a State)) shall be exempt from disclosure under section 552(b)(3) of title 5, United States Code.

(2) *LIMITATION WITH RESPECT TO USE AND DISCLOSURE OF INFORMATION BY STATE AGENCIES.*—

(A) *IN GENERAL.*—A State agency may not use or disclose covered algorithms used or developed for purposes of such section except for purposes of administering the State plan (or a waiver of the plan) under the Medicaid program under title XIX or the State child health plan (or a waiver of the plan) under the Children’s Health Insurance Program under title XXI, including by enabling an entity operating under a contract with a State to assist the State to identify or prevent waste, fraud and abuse with respect to such programs.

(B) *INFORMATION SECURITY.*—A State agency shall have in effect data security and control policies that the Secretary finds adequate to ensure the security of covered algorithms used or developed for purposes of such section 4241 and to ensure that access to such information is restricted to authorized persons for purposes of authorized uses and disclosures described in subparagraph (A).

(C) *PROCEDURAL REQUIREMENTS.*—State agencies to which information is disclosed pursuant to such section

*4241 shall adhere to uniform procedures established by the Secretary.*

*(c) COVERED ALGORITHM DEFINED.—In this section, the term “covered algorithm”—*

*(1) means a predictive modeling or other analytics technology, as used for purposes of section 4241(a) of the Small Business Jobs Act of 2010 (42 U.S.C. 1320a–7m(a)) to identify and prevent waste, fraud, and abuse with respect to the Medicare program under title XVIII, the Medicaid program under title XIX, and the Children’s Health Insurance Program under title XXI; and*

*(2) includes the mathematical expressions utilized in the application of such technology and the means by which such technology is developed.*

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TITLE XIX—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

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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 utilization 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 (1)(1) and whose family income does not exceed the minimum income level the State is required to establish under subsection (1)(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 (1)(1) and whose family income does not exceed the income level the State is required to establish under subsection (1)(2)(B) for such a family,

(VII) who are described in subparagraph (D) of subsection (1)(1) and whose family income does not exceed the income level the State is required to establish under subsection (1)(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 subsection (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 (1)(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)(14), (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 (disregarding 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 prenatal or 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 agree-

ment, 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 the State plan under this title (and, at State option, 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 or any other State plan under this title, 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 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 In-

spector 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 mentally 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 men-

tally 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);

(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; **[and]**

(81) provide for implementation of the payment models specified by the Secretary under section 1115A(c) for implementation 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**[.]**; *and*

*(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).*

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 supervised 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 (1)(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 inter-agency 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, 2017.

(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 in-

come 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.

(14) 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 expenses 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 effec-



tive 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 indi-

viduals 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.

(1)(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 percentage (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 account 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 Federally-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 the 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 UNTIL OCTOBER 1, 2019.—The requirement under paragraph (1) shall continue to apply to a State through September 30, 2019, 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 1886(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 1886(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 1886(j)(4).

(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 1886(j)(6).

(ii) EXCEPTION.—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.

(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) 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.

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#### 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 agreement 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 avail-

able 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 340B(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.—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 with respect to such drug under this section shall be the amount computed under this section for such new drug or, if greater, the product of—



(i) the average manufacturer price 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 section 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 subpara-

graphs (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 ex-

cluded 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), 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, or inappropriate or medically unnecessary care, 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 adoption 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, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits under this title, or associated with specific drugs or groups of drugs.

(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 described 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  $\frac{1}{3}$  but no more than 51 percent licensed and actively practicing physicians and at least  $\frac{1}{3}$  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 improved 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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MEDICAID IMPROVEMENT FUND

SEC. 1941. (a) ESTABLISHMENT.—The Secretary shall establish under this title a Medicaid Improvement Fund (in this section referred to as the “Fund”) which shall be available to the Secretary to improve the management of the Medicaid program by the Centers for Medicare & Medicaid Services, including oversight of contracts and contractors and evaluation of demonstration projects.



Payments made for activities under this subsection shall be in addition to payments that would otherwise be made for such activities.

(b) FUNDING.—

[(1) IN GENERAL.—There shall be available to the Fund, for expenditures from the Fund—

[(A) for fiscal year 2014, \$10,000,000; and

[(B) for each of fiscal years 2015 through 2018, \$0.]

(1) *IN GENERAL.—There shall be available to the Fund, for expenditures from the Fund for fiscal year 2021 and thereafter, \$5,000,000.*

(2) FUNDING LIMITATION.—Amounts in the Fund shall be available in advance of appropriations but only if the total amount obligated from the Fund does not exceed the amount available to the Fund under paragraph (1). The Secretary may obligate funds from the Fund only if the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services and the appropriate budget officer certify) that there are available in the Fund sufficient amounts to cover all such obligations incurred consistent with the previous sentence.

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TITLE XXI—STATE CHILDREN’S HEALTH INSURANCE PROGRAM

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**SEC. 2102. GENERAL CONTENTS OF STATE CHILD HEALTH PLAN; ELIGIBILITY; OUTREACH.**

(a) GENERAL BACKGROUND AND DESCRIPTION.—A State child health plan shall include a description, consistent with the requirements of this title, of—

(1) the extent to which, and manner in which, children in the State, including targeted low-income children and other classes of children classified by income and other relevant factors, currently have creditable health coverage (as defined in section 2110(c)(2));

(2) current State efforts to provide or obtain creditable health coverage for uncovered children, including the steps the State is taking to identify and enroll all uncovered children who are eligible to participate in public health insurance programs and health insurance programs that involve public-private partnerships;

(3) how the plan is designed to be coordinated with such efforts to increase coverage of children under creditable health coverage;

(4) the child health assistance provided under the plan for targeted low-income children, including the proposed methods of delivery, and utilization control systems;

(5) eligibility standards consistent with subsection (b);

(6) outreach activities consistent with subsection (c); and

(7) methods (including monitoring) used—

(A) to assure the quality and appropriateness of care, particularly with respect to well-baby care, well-child care, and immunizations provided under the plan[, and];

(B) to assure access to covered services, including emergency services and services described in section 2103(c)(5)【.】; and

(C) to ensure that the State agency involved is in compliance with subparagraphs (A), (B), and (C) of section 1128K(b)(2).

(b) GENERAL DESCRIPTION OF ELIGIBILITY STANDARDS AND METHODOLOGY.—

(1) ELIGIBILITY STANDARDS.—

(A) IN GENERAL.—The plan shall include a description of the standards used to determine the eligibility of targeted low-income children for child health assistance under the plan. Such standards may include (to the extent consistent with this title) those relating to the geographic areas to be served by the plan, age, income and resources (including any standards relating to spenddowns and disposition of resources), residency, disability status (so long as any standard relating to such status does not restrict eligibility), access to or coverage under other health coverage, and duration of eligibility. Such standards may not discriminate on the basis of diagnosis.

(B) LIMITATIONS ON ELIGIBILITY STANDARDS.—Such eligibility standards—

(i) shall, within any defined group of covered targeted low-income children, not cover such children with higher family income without covering children with a lower family income;

(ii) may not deny eligibility based on a child having a preexisting medical condition;

(iii) may not apply a waiting period (including a waiting period to carry out paragraph (3)(C)) in the case of a targeted low-income pregnant woman provided pregnancy-related assistance under section 2112;

(iv) at State option, may not apply a waiting period in the case of a child provided dental-only supplemental coverage under section 2110(b)(5); and

(v) shall, beginning January 1, 2014, use modified adjusted gross income and household income (as defined in section 36B(d)(2) of the Internal Revenue Code of 1986) to determine eligibility for child health assistance under the State child health 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, consistent with section 1902(e)(14).

(2) METHODOLOGY.—The plan shall include a description of methods of establishing and continuing eligibility and enrollment.

(3) ELIGIBILITY SCREENING; COORDINATION WITH OTHER HEALTH COVERAGE PROGRAMS.—The plan shall include a description of procedures to be used to ensure—

(A) through both intake and followup screening, that only targeted low-income children are furnished child health assistance under the State child health plan;

(B) that children found through the screening to be eligible for medical assistance under the State medicaid plan under title XIX are enrolled for such assistance under such plan;

(C) that the insurance provided under the State child health plan does not substitute for coverage under group health plans;

(D) the provision of child health assistance to targeted low-income children in the State who are Indians (as defined in section 4(c) of the Indian Health Care Improvement Act, 25 U.S.C. 1603(c)); and

(E) coordination with other public and private programs providing creditable coverage for low-income children.

(4) REDUCTION OF ADMINISTRATIVE BARRIERS TO ENROLLMENT.—

(A) IN GENERAL.—Subject to subparagraph (B), the plan shall include a description of the procedures used to reduce administrative barriers to the enrollment of children and pregnant women who are eligible for medical assistance under title XIX or for child health assistance or health benefits coverage under this title. Such procedures shall be established and revised as often as the State determines appropriate to take into account the most recent information available to the State identifying such barriers.

(B) DEEMED COMPLIANCE IF JOINT APPLICATION AND RENEWAL PROCESS THAT PERMITS APPLICATION OTHER THAN IN PERSON.—A State shall be deemed to comply with subparagraph (A) if the State's application and renewal forms and supplemental forms (if any) and information verification process is the same for purposes of establishing and renewing eligibility for children and pregnant women for medical assistance under title XIX and child health assistance under this title, and such process does not require an application to be made in person or a face-to-face interview.

(5) NONENTITLEMENT.—Nothing in this title shall be construed as providing an individual with an entitlement to child health assistance under a State child health plan.

(c) OUTREACH AND COORDINATION.—A State child health plan shall include a description of the procedures to be used by the State to accomplish the following:

(1) OUTREACH.—Outreach (through community health workers and others) to families of children likely to be eligible for child health assistance under the plan or under other public or private health coverage programs to inform these families of the availability of, and to assist them in enrolling their children in, such a program.

(2) COORDINATION WITH OTHER HEALTH INSURANCE PROGRAMS.—Coordination of the administration of the State program under this title with other public and private health insurance programs.

(3) PREMIUM ASSISTANCE SUBSIDIES.—In the case of a State that provides for premium assistance subsidies under the State child health plan in accordance with paragraph (2)(B), (3), or (10) of section 2105(c), or a waiver approved under section

1115, outreach, education, and enrollment assistance for families of children likely to be eligible for such subsidies, to inform such families of the availability of, and to assist them in enrolling their children in, such subsidies, and for employers likely to provide coverage that is eligible for such subsidies, including the specific, significant resources the State intends to apply to educate employers about the availability of premium assistance subsidies under the State child health plan.

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