

Suspend the Rules and Pass the Bill, H.R. 1839, with An Amendment

(The amendment strikes all after the enacting clause and inserts a new text)

116TH CONGRESS
1ST SESSION

H. R. 1839

To amend title XIX to extend protection for Medicaid recipients of home and community-based services against spousal impoverishment, establish a State Medicaid option to provide coordinated care to children with complex medical conditions through health homes, prevent the misclassification of drugs for purposes of the Medicaid drug rebate program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 21, 2019

Mr. RUIZ (for himself, Mr. SCHRADER, Mr. MULLIN, and Mr. UPTON) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend title XIX to extend protection for Medicaid recipients of home and community-based services against spousal impoverishment, establish a State Medicaid option to provide coordinated care to children with complex medical conditions through health homes, prevent the misclassification of drugs for purposes of the Medicaid drug rebate program, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Medicaid Services In-
3 vestment and Accountability Act of 2019”.

4 **SEC. 2. EXTENSION OF PROTECTION FOR MEDICAID RE-**
5 **CIPIENTS OF HOME AND COMMUNITY-BASED**
6 **SERVICES AGAINST SPOUSAL IMPOVERISH-**
7 **MENT.**

8 (a) IN GENERAL.—Section 2404 of Public Law 111–
9 148 (42 U.S.C. 1396r–5 note), as amended by section 3(a)
10 of the Medicaid Extenders Act of 2019 (Public Law 116–
11 3), is amended by striking “March 31, 2019” and insert-
12 ing “September 30, 2019”.

13 (b) RULE OF CONSTRUCTION.—

14 (1) PROTECTING STATE SPOUSAL INCOME AND
15 ASSET DISREGARD FLEXIBILITY UNDER WAIVERS
16 AND PLAN AMENDMENTS.—Nothing in section 2404
17 of Public Law 111–148 (42 U.S.C. 1396r–5 note) or
18 section 1924 of the Social Security Act (42 U.S.C.
19 1396r–5) shall be construed as prohibiting a State
20 from disregarding an individual’s spousal income
21 and assets under a State waiver or plan amendment
22 described in paragraph (2) for purposes of making
23 determinations of eligibility for home and commu-
24 nity-based services or home and community-based
25 attendant services and supports under such waiver
26 or plan amendment.

1 (2) STATE WAIVER OR PLAN AMENDMENT DE-
2 SCRIBED.—A State waiver or plan amendment de-
3 scribed in this paragraph is any of the following:

4 (A) A waiver or plan amendment to pro-
5 vide medical assistance for home and commu-
6 nity-based services under a waiver or plan
7 amendment under subsection (c), (d), or (i) of
8 section 1915 of the Social Security Act (42
9 U.S.C. 1396n) or under section 1115 of such
10 Act (42 U.S.C. 1315).

11 (B) A plan amendment to provide medical
12 assistance for home and community-based serv-
13 ices for individuals by reason of being deter-
14 mined eligible under section 1902(a)(10)(C) of
15 such Act (42 U.S.C. 1396a(a)(10)(C)) or by
16 reason of section 1902(f) of such Act (42
17 U.S.C. 1396a(f)) or otherwise on the basis of a
18 reduction of income based on costs incurred for
19 medical or other remedial care under which the
20 State disregarded the income and assets of the
21 individual's spouse in determining the initial
22 and ongoing financial eligibility of an individual
23 for such services in place of the spousal improv-
24 erishment provisions applied under section 1924
25 of such Act (42 U.S.C. 1396r-5).

1 (C) A plan amendment to provide medical
2 assistance for home and community-based at-
3 tendant services and supports under section
4 1915(k) of such Act (42 U.S.C. 1396n(k)).

5 **SEC. 3. STATE OPTION TO PROVIDE COORDINATED CARE**
6 **THROUGH A HEALTH HOME FOR CHILDREN**
7 **WITH MEDICALLY COMPLEX CONDITIONS.**

8 Title XIX of the Social Security Act (42 U.S.C. 1396
9 et seq.) is amended by inserting after section 1945 the
10 following new section:

11 **“SEC. 1945A. STATE OPTION TO PROVIDE COORDINATED**
12 **CARE THROUGH A HEALTH HOME FOR CHIL-**
13 **DREN WITH MEDICALLY COMPLEX CONDI-**
14 **TIONS.**

15 “(a) IN GENERAL.—Notwithstanding section
16 1902(a)(1) (relating to statewideness) and section
17 1902(a)(10)(B) (relating to comparability), beginning Oc-
18 tober 1, 2022, a State, at its option as a State plan
19 amendment, may provide for medical assistance under this
20 title to children with medically complex conditions who
21 choose to enroll in a health home under this section by
22 selecting a designated provider, a team of health care pro-
23 fessionals operating with such a provider, or a health team
24 as the child’s health home for purposes of providing the
25 child with health home services.

1 “(b) HEALTH HOME QUALIFICATION STANDARDS.—

2 The Secretary shall establish standards for qualification

3 as a health home for purposes of this section. Such stand-

4 ards shall include requiring designated providers, teams

5 of health care professionals operating with such providers,

6 and health teams to demonstrate to the State the ability

7 to do the following:

8 “(1) Coordinate prompt care for children with

9 medically complex conditions, including access to pe-

10 diatric emergency services at all times.

11 “(2) Develop an individualized comprehensive

12 pediatric family-centered care plan for children with

13 medically complex conditions that accommodates pa-

14 tient preferences.

15 “(3) Work in a culturally and linguistically ap-

16 propriate manner with the family of a child with

17 medically complex conditions to develop and incor-

18 porate into such child’s care plan, in a manner con-

19 sistent with the needs of the child and the choices

20 of the child’s family, ongoing home care, community-

21 based pediatric primary care, pediatric inpatient

22 care, social support services, and local hospital pedi-

23 atric emergency care.

24 “(4) Coordinate access to—

1 “(A) subspecialized pediatric services and
2 programs for children with medically complex
3 conditions, including the most intensive diag-
4 nostic, treatment, and critical care levels as
5 medically necessary; and

6 “(B) palliative services if the State pro-
7 vides such services under the State plan (or a
8 waiver of such plan).

9 “(5) Coordinate care for children with medically
10 complex conditions with out-of-State providers fur-
11 nishing care to such children to the maximum extent
12 practicable for the families of such children and
13 where medically necessary, in accordance with guid-
14 ance issued under subsection (e)(1) and section
15 431.52 of title 42, Code of Federal Regulations.

16 “(6) Collect and report information under sub-
17 section (g)(1).

18 “(c) PAYMENTS.—

19 “(1) IN GENERAL.—A State shall provide a des-
20 ignated provider, a team of health care professionals
21 operating with such a provider, or a health team
22 with payments for the provision of health home serv-
23 ices to each child with medically complex conditions
24 that selects such provider, team of health care pro-
25 fessionals, or health team as the child’s health home.

1 Payments made to a designated provider, a team of
2 health care professionals operating with such a pro-
3 vider, or a health team for such services shall be
4 treated as medical assistance for purposes of section
5 1903(a), except that, during the first 2 fiscal year
6 quarters that the State plan amendment is in effect,
7 the Federal medical assistance percentage applicable
8 to such payments shall be increased by 15 percent-
9 age points, but in no case may exceed 90 percent.

10 “(2) METHODOLOGY.—

11 “(A) IN GENERAL.—The State shall speci-
12 fy in the State plan amendment the method-
13 ology the State will use for determining pay-
14 ment for the provision of health home services.
15 Such methodology for determining payment—

16 “(i) may be tiered to reflect, with re-
17 spect to each child with medically complex
18 conditions provided such services by a des-
19 ignated provider, a team of health care
20 professionals operating with such a pro-
21 vider, or a health team, the severity or
22 number of each such child’s chronic condi-
23 tions, life-threatening illnesses, disabilities,
24 or rare diseases, or the specific capabilities

1 of the provider, team of health care profes-
2 sionals, or health team; and

3 “(ii) shall be established consistent
4 with section 1902(a)(30)(A).

5 “(B) ALTERNATE MODELS OF PAYMENT.—

6 The methodology for determining payment for
7 provision of health home services under this
8 section shall not be limited to a per-member
9 per-month basis and may provide (as proposed
10 by the State and subject to approval by the
11 Secretary) for alternate models of payment.

12 “(3) PLANNING GRANTS.—

13 “(A) IN GENERAL.—Beginning October 1,
14 2022, the Secretary may award planning grants
15 to States for purposes of developing a State
16 plan amendment under this section. A planning
17 grant awarded to a State under this paragraph
18 shall remain available until expended.

19 “(B) STATE CONTRIBUTION.—A State
20 awarded a planning grant shall contribute an
21 amount equal to the State percentage deter-
22 mined under section 1905(b) (without regard to
23 section 5001 of Public Law 111–5) for each fis-
24 cal year for which the grant is awarded.

1 “(C) LIMITATION.—The total amount of
2 payments made to States under this paragraph
3 shall not exceed \$5,000,000.

4 “(d) COORDINATING CARE.—

5 “(1) HOSPITAL NOTIFICATION.—A State with a
6 State plan amendment approved under this section
7 shall require each hospital that is a participating
8 provider under the State plan (or a waiver of such
9 plan) to establish procedures for, in the case of a
10 child with medically complex conditions who is en-
11 rolled in a health home pursuant to this section and
12 seeks treatment in the emergency department of
13 such hospital, notifying the health home of such
14 child of such treatment.

15 “(2) EDUCATION WITH RESPECT TO AVAIL-
16 ABILITY OF HEALTH HOME SERVICES.—In order for
17 a State plan amendment to be approved under this
18 section, a State shall include in the State plan
19 amendment a description of the State’s process for
20 educating providers participating in the State plan
21 (or a waiver of such plan) on the availability of
22 health home services for children with medically
23 complex conditions, including the process by which
24 such providers can refer such children to a des-
25 ignated provider, team of health care professionals

1 operating such a provider, or health team for the
2 purpose of establishing a health home through which
3 such children may receive such services.

4 “(3) FAMILY EDUCATION.—In order for a State
5 plan amendment to be approved under this section,
6 a State shall include in the State plan amendment
7 a description of the State’s process for educating
8 families with children eligible to receive health home
9 services pursuant to this section of the availability of
10 such services. Such process shall include the partici-
11 pation of family-to-family entities or other public or
12 private organizations or entities who provide out-
13 reach and information on the availability of health
14 care items and services to families of individuals eli-
15 gible to receive medical assistance under the State
16 plan (or a waiver of such plan).

17 “(4) MENTAL HEALTH COORDINATION.—A
18 State with a State plan amendment approved under
19 this section shall consult and coordinate, as appro-
20 priate, with the Secretary in addressing issues re-
21 garding the prevention and treatment of mental ill-
22 ness and substance use among children with medi-
23 cally complex conditions receiving health home serv-
24 ices under this section.

1 “(e) GUIDANCE ON COORDINATING CARE FROM
2 OUT-OF-STATE PROVIDERS.—

3 “(1) IN GENERAL.—Not later than October 1,
4 2020, the Secretary shall issue (and update as the
5 Secretary determines necessary) guidance to State
6 Medicaid directors on—

7 “(A) best practices for using out-of-State
8 providers to provide care to children with medi-
9 cally complex conditions;

10 “(B) coordinating care for such children
11 provided by such out-of-State providers (includ-
12 ing when provided in emergency and non-emer-
13 gency situations);

14 “(C) reducing barriers for such children
15 receiving care from such providers in a timely
16 fashion; and

17 “(D) processes for screening and enrolling
18 such providers in the respective State plan (or
19 a waiver of such plan), including efforts to
20 streamline such processes or reduce the burden
21 of such processes on such providers.

22 “(2) STAKEHOLDER INPUT.—In carrying out
23 paragraph (1), the Secretary shall issue a request
24 for information to seek input from children with
25 medically complex conditions and their families,

1 States, providers (including children’s hospitals, hos-
2 pitals, pediatricians, and other providers), managed
3 care plans, children’s health groups, family and ben-
4 efiiciary advocates, and other stakeholders with re-
5 spect to coordinating the care for such children pro-
6 vided by out-of-State providers.

7 “(f) MONITORING.—A State shall include in the State
8 plan amendment—

9 “(1) a methodology for tracking reductions in
10 inpatient days and reductions in the total cost of
11 care resulting from improved care coordination and
12 management under this section;

13 “(2) a proposal for use of health information
14 technology in providing health home services under
15 this section and improving service delivery and co-
16 ordination across the care continuum (including the
17 use of wireless patient technology to improve coordi-
18 nation and management of care and patient adher-
19 ence to recommendations made by their provider);
20 and

21 “(3) a methodology for tracking prompt and
22 timely access to medically necessary care for children
23 with medically complex conditions from out-of-State
24 providers.

25 “(g) DATA COLLECTION.—

1 “(1) PROVIDER REPORTING REQUIREMENTS.—

2 In order to receive payments from a State under
3 subsection (c), a designated provider, a team of
4 health care professionals operating with such a pro-
5 vider, or a health team shall report to the State, at
6 such time and in such form and manner as may be
7 required by the State, the following information:

8 “(A) With respect to each such provider,
9 team of health care professionals, or health
10 team, the name, National Provider Identifica-
11 tion number, address, and specific health care
12 services offered to be provided to children with
13 medically complex conditions who have selected
14 such provider, team of health care profes-
15 sionals, or health team as the health home of
16 such children.

17 “(B) Information on all applicable meas-
18 ures for determining the quality of health home
19 services provided by such provider, team of
20 health care professionals, or health team, in-
21 cluding, to the extent applicable, child health
22 quality measures and measures for centers of
23 excellence for children with complex needs de-
24 veloped under this title, title XXI, and section
25 1139A.

1 “(C) Such other information as the Sec-
2 retary shall specify in guidance.

3 When appropriate and feasible, such provider, team
4 of health care professionals, or health team, as the
5 case may be, shall use health information technology
6 in providing the State with such information.

7 “(2) STATE REPORTING REQUIREMENTS.—

8 “(A) COMPREHENSIVE REPORT.—A State
9 with a State plan amendment approved under
10 this section shall report to the Secretary (and,
11 upon request, to the Medicaid and CHIP Pay-
12 ment and Access Commission), at such time
13 and in such form and manner determined by
14 the Secretary to be reasonable and minimally
15 burdensome, the following information:

16 “(i) Information reported under para-
17 graph (1).

18 “(ii) The number of children with
19 medically complex conditions who have se-
20 lected a health home pursuant to this sec-
21 tion.

22 “(iii) The nature, number, and preva-
23 lence of chronic conditions, life-threatening
24 illnesses, disabilities, or rare diseases that
25 such children have.

1 “(iv) The type of delivery systems and
2 payment models used to provide services to
3 such children under this section.

4 “(v) The number and characteristics
5 of designated providers, teams of health
6 care professionals operating with such pro-
7 viders, and health teams selected as health
8 homes pursuant to this section, including
9 the number and characteristics of out-of-
10 State providers, teams of health care pro-
11 fessionals operating with such providers,
12 and health teams who have provided health
13 care items and services to such children.

14 “(vi) The extent to which such chil-
15 dren receive health care items and services
16 under the State plan.

17 “(vii) Quality measures developed spe-
18 cifically with respect to health care items
19 and services provided to children with
20 medically complex conditions.

21 “(B) REPORT ON BEST PRACTICES.—Not
22 later than 90 days after a State has a State
23 plan amendment approved under this section,
24 such State shall submit to the Secretary, and
25 make publicly available on the appropriate

1 State website, a report on how the State is im-
2 plementing guidance issued under subsection
3 (e)(1), including through any best practices
4 adopted by the State.

5 “(h) RULE OF CONSTRUCTION.—Nothing in this sec-
6 tion may be construed—

7 “(1) to require a child with medically complex
8 conditions to enroll in a health home under this sec-
9 tion;

10 “(2) to limit the choice of a child with medically
11 complex conditions in selecting a designated pro-
12 vider, team of health care professionals operating
13 with such a provider, or health team that meets the
14 health home qualification standards established
15 under subsection (b) as the child’s health home; or

16 “(3) to reduce or otherwise modify—

17 “(A) the entitlement of children with medi-
18 cally complex conditions to early and periodic
19 screening, diagnostic, and treatment services
20 (as defined in section 1905(r)); or

21 “(B) the informing, providing, arranging,
22 and reporting requirements of a State under
23 section 1902(a)(43).

24 “(i) DEFINITIONS.—In this section:

1 “(1) CHILD WITH MEDICALLY COMPLEX CONDI-
2 TIONS.—

3 “(A) IN GENERAL.—Subject to subpara-
4 graph (B), the term ‘child with medically com-
5 plex conditions’ means an individual under 21
6 years of age who—

7 “(i) is eligible for medical assistance
8 under the State plan (or under a waiver of
9 such plan); and

10 “(ii) has at least—

11 “(I) one or more chronic condi-
12 tions that cumulatively affect three or
13 more organ systems and severely re-
14 duces cognitive or physical functioning
15 (such as the ability to eat, drink, or
16 breathe independently) and that also
17 requires the use of medication, dura-
18 ble medical equipment, therapy, sur-
19 gery, or other treatments; or

20 “(II) one life-limiting illness or
21 rare pediatric disease (as defined in
22 section 529(a)(3) of the Federal
23 Food, Drug, and Cosmetic Act (21
24 U.S.C. 360ff(a)(3))).

1 “(B) RULE OF CONSTRUCTION.—Nothing
2 in this paragraph shall prevent the Secretary
3 from establishing higher levels as to the number
4 or severity of chronic, life threatening illnesses,
5 disabilities, rare diseases or mental health con-
6 ditions for purposes of determining eligibility
7 for receipt of health home services under this
8 section.

9 “(2) CHRONIC CONDITION.—The term ‘chronic
10 condition’ means a serious, long-term physical, men-
11 tal, or developmental disability or disease, including
12 the following:

13 “(A) Cerebral palsy.

14 “(B) Cystic fibrosis.

15 “(C) HIV/AIDS.

16 “(D) Blood diseases, such as anemia or
17 sickle cell disease.

18 “(E) Muscular dystrophy.

19 “(F) Spina bifida.

20 “(G) Epilepsy.

21 “(H) Severe autism spectrum disorder.

22 “(I) Serious emotional disturbance or seri-
23 ous mental health illness.

24 “(3) HEALTH HOME.—The term ‘health home’
25 means a designated provider (including a provider

1 that operates in coordination with a team of health
2 care professionals) or a health team selected by a
3 child with medically complex conditions (or the fam-
4 ily of such child) to provide health home services.

5 “(4) HEALTH HOME SERVICES.—

6 “(A) IN GENERAL.—The term ‘health
7 home services’ means comprehensive and timely
8 high-quality services described in subparagraph
9 (B) that are provided by a designated provider,
10 a team of health care professionals operating
11 with such a provider, or a health team.

12 “(B) SERVICES DESCRIBED.—The services
13 described in this subparagraph shall include—

14 “(i) comprehensive care management;

15 “(ii) care coordination, health pro-
16 motion, and providing access to the full
17 range of pediatric specialty and sub-
18 specialty medical services, including serv-
19 ices from out-of-State providers, as medi-
20 cally necessary;

21 “(iii) comprehensive transitional care,
22 including appropriate follow-up, from inpa-
23 tient to other settings;

24 “(iv) patient and family support (in-
25 cluding authorized representatives);

1 “(v) referrals to community and social
2 support services, if relevant; and

3 “(vi) use of health information tech-
4 nology to link services, as feasible and ap-
5 propriate.

6 “(5) DESIGNATED PROVIDER.—The term ‘des-
7 ignated provider’ means a physician (including a pe-
8 diatrician or a pediatric specialty or subspecialty
9 provider), children’s hospital, clinical practice or
10 clinical group practice, prepaid inpatient health plan
11 or prepaid ambulatory health plan (as defined by the
12 Secretary), rural clinic, community health center,
13 community mental health center, home health agen-
14 cy, or any other entity or provider that is deter-
15 mined by the State and approved by the Secretary
16 to be qualified to be a health home for children with
17 medically complex conditions on the basis of docu-
18 mentation evidencing that the entity has the sys-
19 tems, expertise, and infrastructure in place to pro-
20 vide health home services. Such term may include
21 providers who are employed by, or affiliated with, a
22 children’s hospital.

23 “(6) TEAM OF HEALTH CARE PROFES-
24 SIONALS.—The term ‘team of health care profes-
25 sionals’ means a team of health care professionals

1 (as described in the State plan amendment under
2 this section) that may—

3 “(A) include—

4 “(i) physicians and other profes-
5 sionals, such as pediatricians or pediatric
6 specialty or subspecialty providers, nurse
7 care coordinators, dietitians, nutritionists,
8 social workers, behavioral health profes-
9 sionals, physical therapists, occupational
10 therapists, speech pathologists, nurses, in-
11 dividuals with experience in medical sup-
12 portive technologies, or any professionals
13 determined to be appropriate by the State
14 and approved by the Secretary;

15 “(ii) an entity or individual who is
16 designated to coordinate such a team; and

17 “(iii) community health workers,
18 translators, and other individuals with cul-
19 turally-appropriate expertise; and

20 “(B) be freestanding, virtual, or based at
21 a children’s hospital, hospital, community
22 health center, community mental health center,
23 rural clinic, clinical practice or clinical group
24 practice, academic health center, or any entity

1 determined to be appropriate by the State and
2 approved by the Secretary.

3 “(7) HEALTH TEAM.—The term ‘health team’
4 has the meaning given such term for purposes of
5 section 3502 of Public Law 111–148.”.

6 **SEC. 4. EXTENSION OF THE COMMUNITY MENTAL HEALTH**
7 **SERVICES DEMONSTRATION PROGRAM.**

8 Section 223(d)(3) of the Protecting Access to Medi-
9 care Act of 2014 (42 U.S.C. 1396a note) is amended by
10 striking “for 2-year demonstration programs under this
11 subsection” and inserting “to conduct demonstration pro-
12 grams under this subsection for 2 years or through June
13 30, 2019, whichever is longer”.

14 **SEC. 5. ADDITIONAL FUNDING FOR THE MONEY FOLLOWS**
15 **THE PERSON REBALANCING DEMONSTRA-**
16 **TION.**

17 Section 6071(h)(1)(F) of the Deficit Reduction Act
18 of 2005 (42 U.S.C. 1396a note) is amended by striking
19 “\$112,000,000” and inserting “132,000,000”.

20 **SEC. 6. PREVENTING THE MISCLASSIFICATION OF DRUGS**
21 **UNDER THE MEDICAID DRUG REBATE PRO-**
22 **GRAM.**

23 (a) APPLICATION OF CIVIL MONEY PENALTY FOR
24 MISCLASSIFICATION OF COVERED OUTPATIENT
25 DRUGS.—

1 (1) IN GENERAL.—Section 1927(b)(3) of the
2 Social Security Act (42 U.S.C. 1396r–8(b)(3)) is
3 amended—

4 (A) in the paragraph heading, by inserting
5 “AND DRUG PRODUCT” after “PRICE”;

6 (B) in subparagraph (A)—

7 (i) in clause (ii), by striking “; and”
8 at the end and inserting a semicolon;

9 (ii) in clause (iii), by striking the pe-
10 riod at the end and inserting a semicolon;

11 (iii) in clause (iv), by striking the
12 semicolon at the end and inserting “;
13 and”; and

14 (iv) by inserting after clause (iv) the
15 following new clause:

16 “(v) not later than 30 days after the
17 last day of each month of a rebate period
18 under the agreement, such drug product
19 information as the Secretary shall require
20 for each of the manufacturer’s covered out-
21 patient drugs.”; and

22 (C) in subparagraph (C)—

23 (i) in clause (ii), by inserting “, in-
24 cluding information related to drug pric-
25 ing, drug product information, and data

1 related to drug pricing or drug product in-
2 formation,” after “provides false informa-
3 tion”;

4 (ii) by adding at the end the following
5 new clauses:

6 “(iii) MISCLASSIFIED DRUG PRODUCT
7 OR MISREPORTED INFORMATION.—

8 “(I) IN GENERAL.—Any manu-
9 facturer with an agreement under this
10 section that knowingly (as defined in
11 section 1003.110 of title 42, Code of
12 Federal Regulations (or any successor
13 regulation)) misclassifies a covered
14 outpatient drug, such as by knowingly
15 submitting incorrect drug product in-
16 formation, is subject to a civil money
17 penalty for each covered outpatient
18 drug that is misclassified in an
19 amount not to exceed 2 times the
20 amount of the difference between—

21 “(aa) the total amount of
22 rebates that the manufacturer
23 paid with respect to the drug to
24 all States for all rebate periods

1 during which the drug was
2 misclassified; and

3 “(bb) the total amount of
4 rebates that the manufacturer
5 would have been required to pay,
6 as determined by the Secretary
7 using drug product information
8 provided by the manufacturer,
9 with respect to the drug to all
10 States for all rebate periods dur-
11 ing which the drug was
12 misclassified if the drug had been
13 correctly classified.

14 “(II) OTHER PENALTIES AND
15 RECOVERY OF UNDERPAID RE-
16 BATES.—The civil money penalties de-
17 scribed in subclause (I) are in addi-
18 tion to other penalties as may be pre-
19 scribed by law and any other recovery
20 of the underlying underpayment for
21 rebates due under this section or the
22 terms of the rebate agreement as de-
23 termined by the Secretary.

24 “(iv) INCREASING OVERSIGHT AND
25 ENFORCEMENT.—Each year the Secretary

1 shall retain, in addition to any amount re-
2 tained by the Secretary to recoup inves-
3 tigation and litigation costs related to the
4 enforcement of the civil money penalties
5 under this subparagraph and subsection
6 (c)(4)(B)(ii)(III), an amount equal to 25
7 percent of the total amount of civil money
8 penalties collected under this subparagraph
9 and subsection (c)(4)(B)(ii)(III) for the
10 year, and such retained amount shall be
11 available to the Secretary, without further
12 appropriation and until expended, for ac-
13 tivities related to the oversight and en-
14 forcement of this section and agreements
15 under this section, including—

16 “(I) improving drug data report-
17 ing systems;

18 “(II) evaluating and ensuring
19 manufacturer compliance with rebate
20 obligations; and

21 “(III) oversight and enforcement
22 related to ensuring that manufactur-
23 ers accurately and fully report drug
24 information, including data related to
25 drug classification.”; and

1 (iii) in subparagraph (D)—

2 (I) in clause (iv), by striking “,
3 and” and inserting a comma;

4 (II) in clause (v), by striking the
5 period and inserting “, and”; and

6 (III) by inserting after clause (v)
7 the following new clause:

8 “(vi) in the case of categories of drug
9 product or classification information that
10 were not considered confidential by the
11 Secretary on the day before the date of the
12 enactment of this clause.”.

13 (2) TECHNICAL AMENDMENTS.—

14 (A) Section 1903(i)(10) of the Social Secu-
15 rity Act (42 U.S.C. 1396b(i)(10)) is amended—

16 (i) in subparagraph (C)—

17 (I) by adjusting the left margin
18 so as to align with the left margin of
19 subparagraph (B); and

20 (II) by striking “, and” and in-
21 serting a semicolon;

22 (ii) in subparagraph (D), by striking
23 “; or” and inserting “; and”; and

24 (iii) by adding at the end the fol-
25 lowing new subparagraph:

1 “(E) with respect to any amount expended for
2 a covered outpatient drug for which a suspension
3 under section 1927(c)(4)(B)(ii)(II) is in effect; or”.

4 (B) Section 1927(b)(3)(C)(ii) of the Social
5 Security Act (42 U.S.C. 1396r–8(b)(3)(C)(ii))
6 is amended by striking “subsections (a) and
7 (b)” and inserting “subsections (a), (b), (f)(3),
8 and (f)(4)”.

9 (b) RECOVERY OF UNPAID REBATE AMOUNTS DUE
10 TO MISCLASSIFICATION OF COVERED OUTPATIENT
11 DRUGS.—

12 (1) IN GENERAL.—Section 1927(c) of the So-
13 cial Security Act (42 U.S.C. 1396r–8(c)) is amended
14 by adding at the end the following new paragraph:

15 “(4) RECOVERY OF UNPAID REBATE AMOUNTS
16 DUE TO MISCLASSIFICATION OF COVERED OUT-
17 PATIENT DRUGS.—

18 “(A) IN GENERAL.—If the Secretary deter-
19 mines that a manufacturer with an agreement
20 under this section paid a lower per-unit rebate
21 amount to a State for a rebate period as a re-
22 sult of the misclassification by the manufac-
23 turer of a covered outpatient drug (without re-
24 gard to whether the manufacturer knowingly
25 made the misclassification or should have

1 known that the misclassification would be
2 made) than the per-unit rebate amount that the
3 manufacturer would have paid to the State if
4 the drug had been correctly classified, the man-
5 ufacturer shall pay to the State an amount
6 equal to the product of—

7 “(i) the difference between—

8 “(I) the per-unit rebate amount
9 paid to the State for the period; and

10 “(II) the per-unit rebate amount
11 that the manufacturer would have
12 paid to the State for the period, as
13 determined by the Secretary, if the
14 drug had been correctly classified; and

15 “(ii) the total units of the drug paid
16 for under the State plan in the period.

17 “(B) AUTHORITY TO CORRECT
18 MISCLASSIFICATIONS.—

19 “(i) IN GENERAL.—If the Secretary
20 determines that a manufacturer with an
21 agreement under this section has
22 misclassified a covered outpatient drug
23 (without regard to whether the manufac-
24 turer knowingly made the misclassification
25 or should have known that the

1 misclassification would be made), the Sec-
2 retary shall notify the manufacturer of the
3 misclassification and require the manufac-
4 turer to correct the misclassification in a
5 timely manner.

6 “(ii) ENFORCEMENT.—If, after receiv-
7 ing notice of a misclassification from the
8 Secretary under clause (i), a manufacturer
9 fails to correct the misclassification by
10 such time as the Secretary shall require,
11 until the manufacturer makes such correc-
12 tion, the Secretary may do any or all of
13 the following:

14 “(I) Correct the misclassification,
15 using drug product information pro-
16 vided by the manufacturer, on behalf
17 of the manufacturer.

18 “(II) Suspend the misclassified
19 drug and the drug’s status as a cov-
20 ered outpatient drug under the manu-
21 facturer’s national rebate agreement,
22 and exclude the misclassified drug
23 from Federal financial participation in
24 accordance with section
25 1903(i)(10)(E).

1 “(III) Impose a civil money pen-
2 alty (which shall be in addition to any
3 other recovery or penalty which may
4 be available under this section or any
5 other provision of law) for each rebate
6 period during which the drug is
7 misclassified not to exceed an amount
8 equal to the product of—

9 “(aa) the total number of
10 units of each dosage form and
11 strength of such misclassified
12 drug paid for under any State
13 plan during such a rebate period;
14 and

15 “(bb) 23.1 percent of the av-
16 erage manufacturer price for the
17 dosage form and strength of such
18 misclassified drug.

19 “(C) REPORTING AND TRANSPARENCY.—

20 “(i) IN GENERAL.—The Secretary
21 shall submit a report to Congress on at
22 least an annual basis that includes infor-
23 mation on the covered outpatient drugs
24 that have been identified as misclassified,
25 any steps taken to reclassify such drugs,

1 the actions the Secretary has taken to en-
2 sure the payment of any rebate amounts
3 which were unpaid as a result of such
4 misclassification, and a disclosure of ex-
5 penditures from the fund created in sub-
6 section (b)(3)(C)(iv), including an account-
7 ing of how such funds have been allocated
8 and spent in accordance with such sub-
9 section.

10 “(ii) PUBLIC ACCESS.—The Secretary
11 shall make the information contained in
12 the report required under clause (i) avail-
13 able to the public on a timely basis.

14 “(D) OTHER PENALTIES AND ACTIONS.—
15 Actions taken and penalties imposed under this
16 clause shall be in addition to other remedies
17 available to the Secretary including terminating
18 the manufacturer’s rebate agreement for non-
19 compliance with the terms of such agreement
20 and shall not exempt a manufacturer from, or
21 preclude the Secretary from pursuing, any civil
22 money penalty under this title or title XI, or
23 any other penalty or action as may be pre-
24 scribed by law.”.

1 (2) OFFSET OF RECOVERED AMOUNTS AGAINST
2 MEDICAL ASSISTANCE.—Section 1927(b)(1)(B) of
3 the Social Security Act (42 U.S.C. 1396r–
4 8(b)(1)(B)) is amended by inserting “, including
5 amounts received by a State under subsection
6 (c)(4),” after “in any quarter”.

7 (c) CLARIFYING DEFINITIONS.—Section 1927(k) of
8 the Social Security Act (42 U.S.C. 1396r–8(k)) is amend-
9 ed—

10 (1) in paragraph (2)(A), by striking “paragraph
11 (5)” and inserting “paragraph (4)”; and

12 (2) in paragraph (7)(A)—

13 (A) by striking “an original new drug ap-
14 plication” and inserting “a new drug applica-
15 tion” each place it appears;

16 (B) in clause (i), by striking “(not includ-
17 ing any drug described in paragraph (5))” and
18 inserting “, including a drug product approved
19 for marketing as a non-prescription drug that is
20 regarded as a covered outpatient drug under
21 paragraph (4),”;

22 (C) in clause (ii)—

23 (i) by striking “was originally mar-
24 keted” and inserting “is marketed”; and

1 (ii) by inserting “, unless the Sec-
2 retary determines that a narrow exception
3 applies (as described in section 447.502 of
4 title 42, Code of Federal Regulations (or
5 any successor regulation))” before the pe-
6 riod; and

7 (D) in clause (iv)—

8 (i) by inserting “, including a drug
9 product approved for marketing as a non-
10 prescription drug that is regarded as a
11 covered outpatient drug under paragraph
12 (4),” after “covered outpatient drug”;

13 (ii) by inserting “unless the Secretary
14 determines that a narrow exception applies
15 (as described in section 447.502 of title
16 42, Code of Federal Regulations (or any
17 successor regulation))” after “under the
18 new drug application”; and

19 (iii) by adding at the end the fol-
20 lowing new sentence: “Such term also in-
21 cludes a covered outpatient drug that is a
22 biological product licensed, produced, or
23 distributed under a biologics license appli-
24 cation approved by the Food and Drug Ad-
25 ministration.”.

1 (d) EXCLUSION OF MANUFACTURERS FOR KNOWING
2 MISCLASSIFICATION OF COVERED OUTPATIENT
3 DRUGS.—Section 1128(b) of the Social Security Act (42
4 U.S.C. 1320a–7(b)) is amended by adding at the end the
5 following new paragraph:

6 “(17) KNOWINGLY MISCLASSIFYING COVERED
7 OUTPATIENT DRUGS.—Any manufacturer or officer,
8 director, agent, or managing employee of such man-
9 ufacturer that knowingly misclassifies a covered out-
10 patient drug under an agreement under section
11 1927, knowingly fails to correct such
12 misclassification, or knowingly provides false infor-
13 mation related to drug pricing, drug product infor-
14 mation, or data related to drug pricing or drug
15 product information.”.

16 (e) EFFECTIVE DATE.—The amendments made by
17 this section shall take effect on the date of the enactment
18 of this Act, and shall apply to covered outpatient drugs
19 supplied by manufacturers under agreements under sec-
20 tion 1927 of the Social Security Act (42 U.S.C. 1396r–
21 8) on or after such date.

1 **SEC. 7. EXTENSION OF THIRD-PARTY LIABILITY PERIOD**
2 **FOR CHILD SUPPORT SERVICES.**

3 (a) IN GENERAL.—Section 202(a)(2) of the Bipar-
4 tisan Budget Act of 2013 (Public Law 113–67) is amend-
5 ed by striking “90 days” and inserting “100 days”.

6 (b) EFFECTIVE DATE.—The amendment made by
7 this section shall take effect on the date of the enactment
8 of this Act.

9 **SEC. 8. DENIAL OF FFP FOR CERTAIN EXPENDITURES RE-**
10 **LATING TO VACUUM ERECTION SYSTEMS**
11 **AND PENILE PROSTHETIC IMPLANTS.**

12 (a) IN GENERAL.—Section 1903(i) of the Social Se-
13 curity Act (42 U.S.C. 1396b(i)) is amended by inserting
14 after paragraph (11) the following:

15 “(12) with respect to any amounts expended
16 for—

17 “(A) a vacuum erection system that is not
18 medically necessary; or

19 “(B) the insertion, repair, or removal and
20 replacement of a penile prosthetic implant (un-
21 less such insertion, repair, or removal and re-
22 placement is medically necessary); or”.

23 (b) EFFECTIVE DATE.—The amendment made by
24 subsection (a) shall apply with respect to items and serv-
25 ices furnished on or after January 1, 2020.

1 **SEC. 9. DETERMINATION OF BUDGETARY EFFECTS.**

2 The budgetary effects of this Act, for the purpose of
3 complying with the Statutory Pay-As-You-Go Act of 2010,
4 shall be determined by reference to the latest statement
5 titled “Budgetary Effects of PAYGO Legislation” for this
6 Act, submitted for printing in the Congressional Record
7 by the Chairman of the House Budget Committee, pro-
8 vided that such statement has been submitted prior to the
9 vote on passage.