

116TH CONGRESS
1ST SESSION

H. R. 1839

AN ACT

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,*

3 **SECTION 1. SHORT TITLE.**

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

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

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

15 (b) RULE OF CONSTRUCTION.—

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

1 nity-based services or home and community-based
2 attendant services and supports under such waiver
3 or plan amendment.

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

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

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

1 for such services in place of the spousal impoverishment provisions applied under section 1924
 2 of such Act (42 U.S.C. 1396r–5).
 3

4 (C) A plan amendment to provide medical
 5 assistance for home and community-based attendant services and supports under section
 6 1915(k) of such Act (42 U.S.C. 1396n(k)).
 7

8 **SEC. 3. STATE OPTION TO PROVIDE COORDINATED CARE**
 9 **THROUGH A HEALTH HOME FOR CHILDREN**
 10 **WITH MEDICALLY COMPLEX CONDITIONS.**

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

14 **“SEC. 1945A. STATE OPTION TO PROVIDE COORDINATED**
 15 **CARE THROUGH A HEALTH HOME FOR CHILD-**
 16 **DREN WITH MEDICALLY COMPLEX CONDI-**
 17 **TIONS.**

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

1 fessionals operating with such a provider, or a health team
2 as the child's health home for purposes of providing the
3 child with health home services.

4 “(b) HEALTH HOME QUALIFICATION STANDARDS.—
5 The Secretary shall establish standards for qualification
6 as a health home for purposes of this section. Such stand-
7 ards shall include requiring designated providers, teams
8 of health care professionals operating with such providers,
9 and health teams to demonstrate to the State the ability
10 to do the following:

11 “(1) Coordinate prompt care for children with
12 medically complex conditions, including access to pe-
13 diatric emergency services at all times.

14 “(2) Develop an individualized comprehensive
15 pediatric family-centered care plan for children with
16 medically complex conditions that accommodates pa-
17 tient preferences.

18 “(3) Work in a culturally and linguistically ap-
19 propriate manner with the family of a child with
20 medically complex conditions to develop and incor-
21 porate into such child's care plan, in a manner con-
22 sistent with the needs of the child and the choices
23 of the child's family, ongoing home care, community-
24 based pediatric primary care, pediatric inpatient

1 care, social support services, and local hospital pedi-
2 atric emergency care.

3 “(4) Coordinate access to—

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

9 “(B) palliative services if the State pro-
10 vides such services under the State plan (or a
11 waiver of such plan).

12 “(5) Coordinate care for children with medically
13 complex conditions with out-of-State providers fur-
14 nishing care to such children to the maximum extent
15 practicable for the families of such children and
16 where medically necessary, in accordance with guid-
17 ance issued under subsection (e)(1) and section
18 431.52 of title 42, Code of Federal Regulations.

19 “(6) Collect and report information under sub-
20 section (g)(1).

21 “(c) PAYMENTS.—

22 “(1) IN GENERAL.—A State shall provide a des-
23 ignated provider, a team of health care professionals
24 operating with such a provider, or a health team
25 with payments for the provision of health home serv-

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

13 “(2) METHODOLOGY.—

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

19 “(i) may be tiered to reflect, with re-
20 spect to each child with medically complex
21 conditions provided such services by a des-
22 ignated provider, a team of health care
23 professionals operating with such a pro-
24 vider, or a health team, the severity or
25 number of each such child’s chronic condi-

1 tions, life-threatening illnesses, disabilities,
2 or rare diseases, or the specific capabilities
3 of the provider, team of health care profes-
4 sionals, or health team; and

5 “(ii) shall be established consistent
6 with section 1902(a)(30)(A).

7 “(B) ALTERNATE MODELS OF PAYMENT.—

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

14 “(3) PLANNING GRANTS.—

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

21 “(B) STATE CONTRIBUTION.—A State
22 awarded a planning grant shall contribute an
23 amount equal to the State percentage deter-
24 mined under section 1905(b) (without regard to

1 section 5001 of Public Law 111–5) for each fis-
2 cal year for which the grant is awarded.

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

6 “(d) COORDINATING CARE.—

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

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

1 such providers can refer such children to a des-
2 ignated provider, team of health care professionals
3 operating such a provider, or health team for the
4 purpose of establishing a health home through which
5 such children may receive such services.

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

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

1 cally complex conditions receiving health home serv-
2 ices under this section.

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

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

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

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

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

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

24 “(2) STAKEHOLDER INPUT.—In carrying out
25 paragraph (1), the Secretary shall issue a request

1 for information to seek input from children with
2 medically complex conditions and their families,
3 States, providers (including children’s hospitals, hos-
4 pitals, pediatricians, and other providers), managed
5 care plans, children’s health groups, family and ben-
6 eficiary advocates, and other stakeholders with re-
7 spect to coordinating the care for such children pro-
8 vided by out-of-State providers.

9 “(f) MONITORING.—A State shall include in the State
10 plan amendment—

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

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

23 “(3) a methodology for tracking prompt and
24 timely access to medically necessary care for children

1 with medically complex conditions from out-of-State
2 providers.

3 “(g) DATA COLLECTION.—

4 “(1) PROVIDER REPORTING REQUIREMENTS.—

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

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

20 “(B) Information on all applicable meas-
21 ures for determining the quality of health home
22 services provided by such provider, team of
23 health care professionals, or health team, in-
24 cluding, to the extent applicable, child health
25 quality measures and measures for centers of

1 excellence for children with complex needs de-
2 veloped under this title, title XXI, and section
3 1139A.

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

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

10 “(2) STATE REPORTING REQUIREMENTS.—

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

19 “(i) Information reported under para-
20 graph (1).

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

1 “(iii) The nature, number, and preva-
2 lence of chronic conditions, life-threatening
3 illnesses, disabilities, or rare diseases that
4 such children have.

5 “(iv) The type of delivery systems and
6 payment models used to provide services to
7 such children under this section.

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

18 “(vi) The extent to which such chil-
19 dren receive health care items and services
20 under the State plan.

21 “(vii) Quality measures developed spe-
22 cifically with respect to health care items
23 and services provided to children with
24 medically complex conditions.

1 “(B) REPORT ON BEST PRACTICES.—Not
2 later than 90 days after a State has a State
3 plan amendment approved under this section,
4 such State shall submit to the Secretary, and
5 make publicly available on the appropriate
6 State website, a report on how the State is im-
7 plementing guidance issued under subsection
8 (e)(1), including through any best practices
9 adopted by the State.

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

12 “(1) to require a child with medically complex
13 conditions to enroll in a health home under this sec-
14 tion;

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

21 “(3) to reduce or otherwise modify—

22 “(A) the entitlement of children with medi-
23 cally complex conditions to early and periodic
24 screening, diagnostic, and treatment services
25 (as defined in section 1905(r)); or

1 “(B) the informing, providing, arranging,
2 and reporting requirements of a State under
3 section 1902(a)(43).

4 “(i) DEFINITIONS.—In this section:

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

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

11 “(i) is eligible for medical assistance
12 under the State plan (or under a waiver of
13 such plan); and

14 “(ii) has at least—

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

24 “(II) one life-limiting illness or
25 rare pediatric disease (as defined in

1 section 529(a)(3) of the Federal
2 Food, Drug, and Cosmetic Act (21
3 U.S.C. 360ff(a)(3))).

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

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

16 “(A) Cerebral palsy.

17 “(B) Cystic fibrosis.

18 “(C) HIV/AIDS.

19 “(D) Blood diseases, such as anemia or
20 sickle cell disease.

21 “(E) Muscular dystrophy.

22 “(F) Spina bifida.

23 “(G) Epilepsy.

24 “(H) Severe autism spectrum disorder.

1 “(I) Serious emotional disturbance or seri-
2 ous mental health illness.

3 “(3) HEALTH HOME.—The term ‘health home’
4 means a designated provider (including a provider
5 that operates in coordination with a team of health
6 care professionals) or a health team selected by a
7 child with medically complex conditions (or the fam-
8 ily of such child) to provide health home services.

9 “(4) HEALTH HOME SERVICES.—

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

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

18 “(i) comprehensive care management;

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

1 “(iii) comprehensive transitional care,
2 including appropriate follow-up, from inpa-
3 tient to other settings;

4 “(iv) patient and family support (in-
5 cluding authorized representatives);

6 “(v) referrals to community and social
7 support services, if relevant; and

8 “(vi) use of health information tech-
9 nology to link services, as feasible and ap-
10 propriate.

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

1 providers who are employed by, or affiliated with, a
2 children's hospital.

3 “(6) TEAM OF HEALTH CARE PROFES-
4 SIONALS.—The term ‘team of health care profes-
5 sionals’ means a team of health care professionals
6 (as described in the State plan amendment under
7 this section) that may—

8 “(A) include—

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

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

22 “(iii) community health workers,
23 translators, and other individuals with cul-
24 turally-appropriate expertise; and

“(B) be freestanding, virtual, or based at a children’s hospital, hospital, community health center, community mental health center, rural clinic, clinical practice or clinical group practice, academic health center, or any entity determined to be appropriate by the State and approved by the Secretary.

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

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

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

SEC. 5. ADDITIONAL FUNDING FOR THE MONEY FOLLOWS THE PERSON REBALANCING DEMONSTRATION.

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

1 **SEC. 6. PREVENTING THE MISCLASSIFICATION OF DRUGS**
2 **UNDER THE MEDICAID DRUG REBATE PRO-**
3 **GRAM.**

4 (a) APPLICATION OF CIVIL MONEY PENALTY FOR
5 MISCLASSIFICATION OF COVERED OUTPATIENT
6 DRUGS.—

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

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

12 (B) in subparagraph (A)—

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

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

17 (iii) in clause (iv), by striking the
18 semicolon at the end and inserting “;
19 and”; and

20 (iv) by inserting after clause (iv) the
21 following new clause:

22 “(v) not later than 30 days after the
23 last day of each month of a rebate period
24 under the agreement, such drug product
25 information as the Secretary shall require

1 for each of the manufacturer’s covered out-
2 patient drugs.”; and

3 (C) in subparagraph (C)—

4 (i) in clause (ii), by inserting “, in-
5 cluding information related to drug pric-
6 ing, drug product information, and data
7 related to drug pricing or drug product in-
8 formation,” after “provides false informa-
9 tion”;

10 (ii) by adding at the end the following
11 new clauses:

12 “(iii) MISCLASSIFIED DRUG PRODUCT
13 OR MISREPORTED INFORMATION.—

14 “(I) IN GENERAL.—Any manu-
15 facturer with an agreement under this
16 section that knowingly (as defined in
17 section 1003.110 of title 42, Code of
18 Federal Regulations (or any successor
19 regulation)) misclassifies a covered
20 outpatient drug, such as by knowingly
21 submitting incorrect drug product in-
22 formation, is subject to a civil money
23 penalty for each covered outpatient
24 drug that is misclassified in an

1 amount not to exceed 2 times the
2 amount of the difference between—

3 “(aa) the total amount of
4 rebates that the manufacturer
5 paid with respect to the drug to
6 all States for all rebate periods
7 during which the drug was
8 misclassified; and

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

20 “(II) OTHER PENALTIES AND
21 RECOVERY OF UNDERPAID RE-
22 BATES.—The civil money penalties de-
23 scribed in subclause (I) are in addi-
24 tion to other penalties as may be pre-
25 scribed by law and any other recovery

1 of the underlying underpayment for
2 rebates due under this section or the
3 terms of the rebate agreement as de-
4 termined by the Secretary.

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

22 “(I) improving drug data report-
23 ing systems;

1 “(II) evaluating and ensuring
2 manufacturer compliance with rebate
3 obligations; and

4 “(III) oversight and enforcement
5 related to ensuring that manufactur-
6 ers accurately and fully report drug
7 information, including data related to
8 drug classification.”; and

9 (iii) in subparagraph (D)—

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

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

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

16 “(vi) in the case of categories of drug
17 product or classification information that
18 were not considered confidential by the
19 Secretary on the day before the date of the
20 enactment of this clause.”.

21 (2) TECHNICAL AMENDMENTS.—

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

24 (i) in subparagraph (C)—

1 (I) by adjusting the left margin
 2 so as to align with the left margin of
 3 subparagraph (B); and

4 (II) by striking “, and” and in-
 5 serting a semicolon;

6 (ii) in subparagraph (D), by striking
 7 “; or” and inserting “; and”; and

8 (iii) by adding at the end the fol-
 9 lowing new subparagraph:

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

13 (B) Section 1927(b)(3)(C)(ii) of the Social
 14 Security Act (42 U.S.C. 1396r-8(b)(3)(C)(ii))
 15 is amended by striking “subsections (a) and
 16 (b)” and inserting “subsections (a), (b), (f)(3),
 17 and (f)(4)”.

18 (b) RECOVERY OF UNPAID REBATE AMOUNTS DUE
 19 TO MISCLASSIFICATION OF COVERED OUTPATIENT
 20 DRUGS.—

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

1 “(4) RECOVERY OF UNPAID REBATE AMOUNTS
2 DUE TO MISCLASSIFICATION OF COVERED OUT-
3 PATIENT DRUGS.—

4 “(A) IN GENERAL.—If the Secretary deter-
5 mines that a manufacturer with an agreement
6 under this section paid a lower per-unit rebate
7 amount to a State for a rebate period as a re-
8 sult of the misclassification by the manufac-
9 turer of a covered outpatient drug (without re-
10 gard to whether the manufacturer knowingly
11 made the misclassification or should have
12 known that the misclassification would be
13 made) than the per-unit rebate amount that the
14 manufacturer would have paid to the State if
15 the drug had been correctly classified, the man-
16 ufacturer shall pay to the State an amount
17 equal to the product of—

18 “(i) the difference between—

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

21 “(II) the per-unit rebate amount
22 that the manufacturer would have
23 paid to the State for the period, as
24 determined by the Secretary, if the
25 drug had been correctly classified; and

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

3 “(B) AUTHORITY TO CORRECT
4 MISCLASSIFICATIONS.—

5 “(i) IN GENERAL.—If the Secretary
6 determines that a manufacturer with an
7 agreement under this section has
8 misclassified a covered outpatient drug
9 (without regard to whether the manufac-
10 turer knowingly made the misclassification
11 or should have known that the
12 misclassification would be made), the Sec-
13 retary shall notify the manufacturer of the
14 misclassification and require the manufac-
15 turer to correct the misclassification in a
16 timely manner.

17 “(ii) ENFORCEMENT.—If, after receiv-
18 ing notice of a misclassification from the
19 Secretary under clause (i), a manufacturer
20 fails to correct the misclassification by
21 such time as the Secretary shall require,
22 until the manufacturer makes such correc-
23 tion, the Secretary may do any or all of
24 the following:

1 “(I) Correct the misclassification,
2 using drug product information pro-
3 vided by the manufacturer, on behalf
4 of the manufacturer.

5 “(II) Suspend the misclassified
6 drug and the drug’s status as a cov-
7 ered outpatient drug under the manu-
8 facturer’s national rebate agreement,
9 and exclude the misclassified drug
10 from Federal financial participation in
11 accordance with section
12 1903(i)(10)(E).

13 “(III) Impose a civil money pen-
14 alty (which shall be in addition to any
15 other recovery or penalty which may
16 be available under this section or any
17 other provision of law) for each rebate
18 period during which the drug is
19 misclassified not to exceed an amount
20 equal to the product of—

21 “(aa) the total number of
22 units of each dosage form and
23 strength of such misclassified
24 drug paid for under any State

1 plan during such a rebate period;
2 and

3 “(bb) 23.1 percent of the av-
4 erage manufacturer price for the
5 dosage form and strength of such
6 misclassified drug.

7 “(C) REPORTING AND TRANSPARENCY.—

8 “(i) IN GENERAL.—The Secretary
9 shall submit a report to Congress on at
10 least an annual basis that includes infor-
11 mation on the covered outpatient drugs
12 that have been identified as misclassified,
13 any steps taken to reclassify such drugs,
14 the actions the Secretary has taken to en-
15 sure the payment of any rebate amounts
16 which were unpaid as a result of such
17 misclassification, and a disclosure of ex-
18 penditures from the fund created in sub-
19 section (b)(3)(C)(iv), including an account-
20 ing of how such funds have been allocated
21 and spent in accordance with such sub-
22 section.

23 “(ii) PUBLIC ACCESS.—The Secretary
24 shall make the information contained in

1 the report required under clause (i) avail-
 2 able to the public on a timely basis.

3 “(D) OTHER PENALTIES AND ACTIONS.—
 4 Actions taken and penalties imposed under this
 5 clause shall be in addition to other remedies
 6 available to the Secretary including terminating
 7 the manufacturer’s rebate agreement for non-
 8 compliance with the terms of such agreement
 9 and shall not exempt a manufacturer from, or
 10 preclude the Secretary from pursuing, any civil
 11 money penalty under this title or title XI, or
 12 any other penalty or action as may be pre-
 13 scribed by law.”.

14 (2) OFFSET OF RECOVERED AMOUNTS AGAINST
 15 MEDICAL ASSISTANCE.—Section 1927(b)(1)(B) of
 16 the Social Security Act (42 U.S.C. 1396r-
 17 8(b)(1)(B)) is amended by inserting “, including
 18 amounts received by a State under subsection
 19 (c)(4),” after “in any quarter”.

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

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

25 (2) in paragraph (7)(A)—

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

4 (B) in clause (i), by striking “(not includ-
5 ing any drug described in paragraph (5))” and
6 inserting “, including a drug product approved
7 for marketing as a non-prescription drug that is
8 regarded as a covered outpatient drug under
9 paragraph (4),”;

10 (C) in clause (ii)—

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

13 (ii) by inserting “, unless the Sec-
14 retary determines that a narrow exception
15 applies (as described in section 447.502 of
16 title 42, Code of Federal Regulations (or
17 any successor regulation))” before the pe-
18 riod; and

19 (D) in clause (iv)—

20 (i) by inserting “, including a drug
21 product approved for marketing as a non-
22 prescription drug that is regarded as a
23 covered outpatient drug under paragraph
24 (4),” after “covered outpatient drug”;

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

(iii) by adding at the end the following new sentence: “Such term also includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the Food and Drug Administration.”.

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

“(17) KNOWINGLY MISCLASSIFYING COVERED OUTPATIENT DRUGS.—Any manufacturer or officer, director, agent, or managing employee of such manufacturer that knowingly misclassifies a covered outpatient drug under an agreement under section 1927, knowingly fails to correct such misclassification, or knowingly provides false infor-

1 mation related to drug pricing, drug product infor-
2 mation, or data related to drug pricing or drug
3 product information.”.

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

10 **SEC. 7. EXTENSION OF THIRD-PARTY LIABILITY PERIOD**
11 **FOR CHILD SUPPORT SERVICES.**

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

15 (b) EFFECTIVE DATE.—The amendment made by
16 this section shall take effect on the date of the enactment
17 of this Act.

18 **SEC. 8. DENIAL OF FFP FOR CERTAIN EXPENDITURES RE-**
19 **LATING TO VACUUM ERECTION SYSTEMS**
20 **AND PENILE PROSTHETIC IMPLANTS.**

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

24 “(12) with respect to any amounts expended
25 for—

1 “(A) a vacuum erection system that is not
2 medically necessary; or

3 “(B) the insertion, repair, or removal and
4 replacement of a penile prosthetic implant (un-
5 less such insertion, repair, or removal and re-
6 placement is medically necessary); or”.

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

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

11 The budgetary effects of this Act, for the purpose of
12 complying with the Statutory Pay-As-You-Go Act of 2010,
13 shall be determined by reference to the latest statement
14 titled “Budgetary Effects of PAYGO Legislation” for this
15 Act, submitted for printing in the Congressional Record
16 by the Chairman of the House Budget Committee, pro-
17 vided that such statement has been submitted prior to the
18 vote on passage.

Passed the House of Representatives March 25,
2019.

Attest:

Clerk.

116TH CONGRESS
1ST Session

H. R. 1839

AN ACT

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.