I

115TH CONGRESS
2D SESSION

H. R. 7217

To amend title XIX of the Social Security Act to provide States with the option of providing coordinated care for children with complex medical conditions through a health home, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 6, 2018

Mr. BARTON (for himself, Ms. CASTOR of Florida, Mr. GUTHRIE, Mrs. DINGELL, and Mr. UPTON) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend title XIX of the Social Security Act to provide States with the option of providing coordinated care for children with complex medical conditions through a health home, 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 "Improving Medicaid
5 Programs and Opportunities for Eligible Beneficiaries
6 Act" or the "IMPROVE Act".

TITLE I—ACE KIDS

SEC. 101. STATE OPTION TO PROVIDE COORDINATED CARE THROUGH A HEALTH HOME FOR CHILDREN WITH MEDICALLY COMPLEX CONDITIONS.

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

"SEC. 1945A. STATE OPTION TO PROVIDE COORDINATED CARE THROUGH A HEALTH HOME FOR CHILDREN WITH MEDICALLY COMPLEX CONDITIONS.

"(a) IN GENERAL.—Notwithstanding section 1902(a)(1) (relating to statewideness) and section 1902(a)(10)(B) (relating to comparability), beginning October 1, 2022, a State, at its option as a State plan amendment, may provide for medical assistance under this title to children with medically complex conditions who choose to enroll in a health home under this section by selecting a designated provider, a team of health care professionals operating with such a provider, or a health team as the child's health home for purposes of providing the child with health home services.

"(b) HEALTH HOME QUALIFICATION STANDARDS.—The Secretary shall establish standards for qualification as a health home for purposes of this section. Such stand-

1 ards shall include requiring designated providers, teams
2 of health care professionals operating with such providers,
3 and health teams to demonstrate to the State the ability
4 to do the following:

5 ''(1) Coordinate prompt care for children with
6 medically complex conditions, including access to pe-
7 diatric emergency services at all times.

8 ''(2) Develop an individualized comprehensive
9 pediatric family-centered care plan for children with
10 medically complex conditions that accommodates pa-
11 tient preferences.

12 ''(3) Work in a culturally and linguistically ap-
13 propriate manner with the family of a child with
14 medically complex conditions to develop and incor-
15 porate into such child's care plan, in a manner con-
16 sistent with the needs of the child and the choices
17 of the child's family, ongoing home care, community-
18 based pediatric primary care, pediatric inpatient
19 care, social support services, and local hospital pedi-
20 atric emergency care.

21 ''(4) Coordinate access to—

22 ''(A) subspecialized pediatric services and
23 programs for children with medically complex
24 conditions, including the most intensive diag-

1 nostic, treatment, and critical care levels as
2 medically necessary; and
3 ‘‘(B) palliative services if the State pro-
4 vides such services under the State plan (or a
5 waiver of such plan).
6 ‘‘(5) Coordinate care for children with medically
7 complex conditions with out-of-State providers fur-
8 nishing care to such children to the maximum extent
9 practicable for the families of such children and
10 where medically necessary, in accordance with guid-
11 ance issued under subsection (e)(1) and section
12 431.52 of title 42, Code of Federal Regulations.
13 ‘‘(6) Collect and report information under sub-
14 section (g)(1).
15 ‘‘(c) PAYMENTS.—
16 ‘‘(1) IN GENERAL.—A State shall provide a des-
17 ignated provider, a team of health care professionals
18 operating with such a provider, or a health team
19 with payments for the provision of health home serv-
20 ices to each child with medically complex conditions
21 that selects such provider, team of health care pro-
22 fessionals, or health team as the child's health home.
23 Payments made to a designated provider, a team of
24 health care professionals operating with such a pro-
25 vider, or a health team for such services shall be

1 treated as medical assistance for purposes of section
2 1903(a), except that, during the first 2 fiscal year
3 quarters that the State plan amendment is in effect,
4 the Federal medical assistance percentage applicable
5 to such payments shall be increased by 15 percent-
6 age points, but in no case may exceed 90 percent.
7 "(2) METHODOLOGY.—
8 "(A) IN GENERAL.—The State shall speci-
9 fy in the State plan amendment the method-
10 ology the State will use for determining pay-
11 ment for the provision of health home services.
12 Such methodology for determining payment—
13 "(i) may be tiered to reflect, with re-
14 spect to each child with medically complex
15 conditions provided such services by a des-
16 ignated provider, a team of health care
17 professionals operating with such a pro-
18 vider, or a health team, the severity or
19 number of each such child's chronic condi-
20 tions, life-threatening illnesses, disabilities,
21 or rare diseases, or the specific capabilities
22 of the provider, team of health care profes-
23 sionals, or health team; and
24 "(ii) shall be established consistent
25 with section 1902(a)(30)(A).

1 "(B) ALTERNATE MODELS OF PAYMENT.—
2 The methodology for determining payment for
3 provision of health home services under this
4 section shall not be limited to a per-member
5 per-month basis and may provide (as proposed
6 by the State and subject to approval by the
7 Secretary) for alternate models of payment.
8 "(3) PLANNING GRANTS.—
9 "(A) IN GENERAL.—Beginning October 1,
10 2022, the Secretary may award planning grants
11 to States for purposes of developing a State
12 plan amendment under this section. A planning
13 grant awarded to a State under this paragraph
14 shall remain available until expended.
15 "(B) STATE CONTRIBUTION.—A State
16 awarded a planning grant shall contribute an
17 amount equal to the State percentage deter-
18 mined under section 1905(b) (without regard to
19 section 5001 of Public Law 111–5) for each fis-
20 cal year for which the grant is awarded.
21 "(C) LIMITATION.—The total amount of
22 payments made to States under this paragraph
23 shall not exceed $5,000,000.
24 "(d) COORDINATING CARE.—

"(1) HOSPITAL NOTIFICATION.—A State with a State plan amendment approved under this section shall require each hospital that is a participating provider under the State plan (or a waiver of such plan) to establish procedures for, in the case of a child with medically complex conditions who is enrolled in a health home pursuant to this section and seeks treatment in the emergency department of such hospital, notifying the health home of such child of such treatment.

"(2) EDUCATION WITH RESPECT TO AVAILABILITY OF HEALTH HOME SERVICES.—In order for a State plan amendment to be approved under this section, a State shall include in the State plan amendment a description of the State's process for educating providers participating in the State plan (or a waiver of such plan) on the availability of health home services for children with medically complex conditions, including the process by which such providers can refer such children to a designated provider, team of health care professionals operating such a provider, or health team for the purpose of establishing a health home through which such children may receive such services.

1 "(3) FAMILY EDUCATION.—In order for a State
2 plan amendment to be approved under this section,
3 a State shall include in the State plan amendment
4 a description of the State's process for educating
5 families with children eligible to receive health home
6 services pursuant to this section of the availability of
7 such services. Such process shall include the partici-
8 pation of family-to-family entities or other public or
9 private organizations or entities who provide out-
10 reach and information on the availability of health
11 care items and services to families of individuals eli-
12 gible to receive medical assistance under the State
13 plan (or a waiver of such plan).
14 "(4) MENTAL HEALTH COORDINATION.—A
15 State with a State plan amendment approved under
16 this section shall consult and coordinate, as appro-
17 priate, with the Secretary in addressing issues re-
18 garding the prevention and treatment of mental ill-
19 ness and substance use among children with medi-
20 cally complex conditions receiving health home serv-
21 ices under this section.
22 "(e) GUIDANCE ON COORDINATING CARE FROM
23 OUT-OF-STATE PROVIDERS.—
24 "(1) IN GENERAL.—Not later than October 1,
25 2020, the Secretary shall issue (and update as the

1 Secretary determines necessary) guidance to State
2 Medicaid directors on—
3 ‘‘(A) best practices for using out-of-State
4 providers to provide care to children with medi-
5 cally complex conditions;
6 ‘‘(B) coordinating care for such children
7 provided by such out-of-State providers (includ-
8 ing when provided in emergency and non-emer-
9 gency situations);
10 ‘‘(C) reducing barriers for such children
11 receiving care from such providers in a timely
12 fashion; and
13 ‘‘(D) processes for screening and enrolling
14 such providers in the respective State plan (or
15 a waiver of such plan), including efforts to
16 streamline such processes or reduce the burden
17 of such processes on such providers.
18 ‘‘(2) STAKEHOLDER INPUT.—In carrying out
19 paragraph (1), the Secretary shall issue a request
20 for information to seek input from children with
21 medically complex conditions and their families,
22 States, providers (including children's hospitals, hos-
23 pitals, pediatricians, and other providers), managed
24 care plans, children's health groups, family and ben-
25 eficiary advocates, and other stakeholders with re-

1 spect to coordinating the care for such children pro-
2 vided by out-of-State providers.
3 ''(f) MONITORING.—A State shall include in the State
4 plan amendment—
5 ''(1) a methodology for tracking avoidable hos-
6 pital readmissions and calculating savings that re-
7 sult from improved care coordination and manage-
8 ment under this section;
9 ''(2) a proposal for use of health information
10 technology in providing health home services under
11 this section and improving service delivery and co-
12 ordination across the care continuum (including the
13 use of wireless patient technology to improve coordi-
14 nation and management of care and patient adher-
15 ence to recommendations made by their provider);
16 and
17 ''(3) a methodology for tracking prompt and
18 timely access to medically necessary care for children
19 with medically complex conditions from out-of-State
20 providers.
21 ''(g) DATA COLLECTION.—
22 ''(1) PROVIDER REPORTING REQUIREMENTS.—
23 In order to receive payments from a State under
24 subsection (c), a designated provider, a team of
25 health care professionals operating with such a pro-

1 vider, or a health team shall report to the State, at
2 such time and in such form and manner as may be
3 required by the State, the following information:
4 ‘‘(A) With respect to each such provider,
5 team of health care professionals, or health
6 team, the name, National Provider Identifica-
7 tion number, address, and specific health care
8 services offered to be provided to children with
9 medically complex conditions who have selected
10 such provider, team of health care profes-
11 sionals, or health team as the health home of
12 such children.
13 ‘‘(B) Information on all applicable meas-
14 ures for determining the quality of health home
15 services provided by such provider, team of
16 health care professionals, or health team, in-
17 cluding, to the extent applicable, child health
18 quality measures and measures for centers of
19 excellence for children with complex needs de-
20 veloped under this title, title XXI, and section
21 1139A.
22 ‘‘(C) Such other information as the Sec-
23 retary shall specify in guidance.
24 When appropriate and feasible, such provider, team
25 of health care professionals, or health team, as the

1 case may be, shall use health information technology
2 in providing the State with such information.
3 ‘‘(2) STATE REPORTING REQUIREMENTS.—
4 ‘‘(A) COMPREHENSIVE REPORT.—A State
5 with a State plan amendment approved under
6 this section shall report to the Secretary (and,
7 upon request, to the Medicaid and CHIP Pay-
8 ment and Access Commission), at such time
9 and in such form and manner determined by
10 the Secretary to be reasonable and minimally
11 burdensome, the following information:
12 ‘‘(i) Information reported under para-
13 graph (1).
14 ‘‘(ii) The number of children with
15 medically complex conditions who have se-
16 lected a health home pursuant to this sec-
17 tion.
18 ‘‘(iii) The nature, number, and preva-
19 lence of chronic conditions, life-threatening
20 illnesses, disabilities, or rare diseases that
21 such children have.
22 ‘‘(iv) The type of delivery systems and
23 payment models used to provide services to
24 such children under this section.

1 "(v) The number and characteristics
2 of designated providers, teams of health
3 care professionals operating with such pro-
4 viders, and health teams selected as health
5 homes pursuant to this section, including
6 the number and characteristics of out-of-
7 State providers, teams of health care pro-
8 fessionals operating with such providers,
9 and health teams who have provided health
10 care items and services to such children.
11 "(vi) The extent to which such chil-
12 dren receive health care items and services
13 under the State plan.
14 "(vii) Quality measures developed spe-
15 cifically with respect to health care items
16 and services provided to children with
17 medically complex conditions.
18 "(B) REPORT ON BEST PRACTICES.—Not
19 later than 90 days after a State has a State
20 plan amendment approved under this section,
21 such State shall submit to the Secretary, and
22 make publicly available on the appropriate
23 State website, a report on how the State is im-
24 plementing guidance issued under subsection

(e)(1), including through any best practices adopted by the State.

"(h) RULE OF CONSTRUCTION.—Nothing in this section may be construed—

"(1) to require a child with medically complex conditions to enroll in a health home under this section;

"(2) to limit the choice of a child with medically complex conditions in selecting a designated provider, team of health care professionals operating with such a provider, or health team that meets the health home qualification standards established under subsection (b) as the child's health home; or

"(3) to reduce or otherwise modify—

"(A) the entitlement of children with medically complex conditions to early and periodic screening, diagnostic, and treatment services (as defined in section 1905(r)); or

"(B) the informing, providing, arranging, and reporting requirements of a State under section 1902(a)(43).

"(i) DEFINITIONS.—In this section:

"(1) CHILD WITH MEDICALLY COMPLEX CONDITIONS.—

1 "(A) IN GENERAL.—Subject to subpara-
2 graph (B), the term 'child with medically com-
3 plex conditions' means an individual under 21
4 years of age who—
5 "(i) is eligible for medical assistance
6 under the State plan (or under a waiver of
7 such plan); and
8 "(ii) has at least—
9 "(I) one or more chronic condi-
10 tions that cumulatively affect three or
11 more organ systems and severely re-
12 duces cognitive or physical functioning
13 (such as the ability to eat, drink, or
14 breathe independently) and that also
15 requires the use of medication, dura-
16 ble medical equipment, therapy, sur-
17 gery, or other treatments; or
18 "(II) one life-limiting illness or
19 rare pediatric disease (as defined in
20 section 529(a)(3) of the Federal
21 Food, Drug, and Cosmetic Act (21
22 U.S.C. 360ff(a)(3))).
23 "(B) RULE OF CONSTRUCTION.—Nothing
24 in this paragraph shall prevent the Secretary
25 from establishing higher levels as to the number

1 or severity of chronic, life threatening illnesses,
2 disabilities, rare diseases or mental health con-
3 ditions for purposes of determining eligibility
4 for receipt of health home services under this
5 section.

6 "(2) CHRONIC CONDITION.—The term 'chronic
7 condition' means a serious, long-term physical, men-
8 tal, or developmental disability or disease, including
9 the following:

10 "(A) Cerebral palsy.

11 "(B) Cystic fibrosis.

12 "(C) HIV/AIDS.

13 "(D) Blood diseases, such as anemia or
14 sickle cell disease.

15 "(E) Muscular dystrophy.

16 "(F) Spina bifida.

17 "(G) Epilepsy.

18 "(H) Severe autism spectrum disorder.

19 "(I) Serious emotional disturbance or seri-
20 ous mental health illness.

21 "(3) HEALTH HOME.—The term 'health home'
22 means a designated provider (including a provider
23 that operates in coordination with a team of health
24 care professionals) or a health team selected by a

1 child with medically complex conditions (or the fam-
2 ily of such child) to provide health home services.
3 "(4) HEALTH HOME SERVICES.—
4 "(A) IN GENERAL.—The term 'health
5 home services' means comprehensive and timely
6 high-quality services described in subparagraph
7 (B) that are provided by a designated provider,
8 a team of health care professionals operating
9 with such a provider, or a health team.
10 "(B) SERVICES DESCRIBED.—The services
11 described in this subparagraph shall include—
12 "(i) comprehensive care management;
13 "(ii) care coordination, health pro-
14 motion, and providing access to the full
15 range of pediatric specialty and sub-
16 specialty medical services, including serv-
17 ices from out-of-State providers, as medi-
18 cally necessary;
19 "(iii) comprehensive transitional care,
20 including appropriate follow-up, from inpa-
21 tient to other settings;
22 "(iv) patient and family support (in-
23 cluding authorized representatives);
24 "(v) referrals to community and social
25 support services, if relevant; and

1 ''(vi) use of health information tech-
2 nology to link services, as feasible and ap-
3 propriate.
4 ''(5) DESIGNATED PROVIDER.—The term 'des-
5 ignated provider' means a physician (including a pe-
6 diatrician or a pediatric specialty or subspecialty
7 provider), children's hospital, clinical practice or
8 clinical group practice, prepaid inpatient health plan
9 or prepaid ambulatory health plan (as defined by the
10 Secretary), rural clinic, community health center,
11 community mental health center, home health agen-
12 cy, or any other entity or provider that is deter-
13 mined by the State and approved by the Secretary
14 to be qualified to be a health home for children with
15 medically complex conditions on the basis of docu-
16 mentation evidencing that the entity has the sys-
17 tems, expertise, and infrastructure in place to pro-
18 vide health home services. Such term may include
19 providers who are employed by, or affiliated with, a
20 children's hospital.
21 ''(6) TEAM OF HEALTH CARE PROFES-
22 SIONALS.—The term 'team of health care profes-
23 sionals' means a team of health care professionals
24 (as described in the State plan amendment under
25 this section) that may—

1 "(A) include—

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

13 "(ii) an entity or individual who is
14 designated to coordinate such a team; and

15 "(iii) community health workers,
16 translators, and other individuals with cul-
17 turally-appropriate expertise; and

18 "(B) be freestanding, virtual, or based at
19 a children's hospital, hospital, community
20 health center, community mental health center,
21 rural clinic, clinical practice or clinical group
22 practice, academic health center, or any entity
23 determined to be appropriate by the State and
24 approved by the Secretary.

1 "(7) HEALTH TEAM.—The term 'health team'
2 has the meaning given such term for purposes of
3 section 3502 of Public Law 111–148.".

4 TITLE II—OTHER MEDICAID

5 **SEC. 201. EXTENSION OF MONEY FOLLOWS THE PERSON**
6 **REBALANCING DEMONSTRATION.**

7 (a) GENERAL FUNDING.—Section 6071(h) of the
8 Deficit Reduction Act of 2005 (42 U.S.C. 1396a note) is
9 amended—
10 (1) in paragraph (1)—
11 (A) in subparagraph (D), by striking
12 "and" after the semicolon;
13 (B) in subparagraph (E), by striking the
14 period at the end and inserting "; and"; and
15 (C) by adding at the end the following:
16 "(F) subject to paragraph (3),
17 $112,000,000 for fiscal year 2019.";
18 (2) in paragraph (2)—
19 (A) by striking "Amounts made" and in-
20 serting "Subject to paragraph (3), amounts
21 made"; and
22 (B) by striking "September 30, 2016" and
23 inserting "September 30, 2021"; and
24 (3) by adding at the end the following new
25 paragraph:

1 “(3) SPECIAL RULE FOR FY 2019.—Funds ap-
2 propriated under paragraph (1)(F) shall be made
3 available for grants to States only if such States
4 have an approved MFP demonstration project under
5 this section as of December 31, 2018.”.
6 (b) FUNDING FOR QUALITY ASSURANCE AND IM-
7 PROVEMENT; TECHNICAL ASSISTANCE; OVERSIGHT.—
8 Section 6071(f) of the Deficit Reduction Act of 2005 (42
9 U.S.C. 1396a note) is amended by striking paragraph (2)
10 and inserting the following:
11 “(2) FUNDING.—From the amounts appro-
12 priated under subsection (h)(1)(F) for fiscal year
13 2019, $500,000 shall be available to the Secretary
14 for such fiscal year to carry out this subsection.”.
15 (c) TECHNICAL AMENDMENT.—Section 6071(b) of
16 the Deficit Reduction Act of 2005 (42 U.S.C. 1396a note)
17 is amended by adding at the end the following:
18 “(10) SECRETARY.—The term ‘Secretary’
19 means the Secretary of Health and Human Serv-
20 ices.”.

SEC. 202. EXTENSION OF PROTECTION FOR MEDICAID RECIPIENTS OF HOME AND COMMUNITY-BASED SERVICES AGAINST SPOUSAL IMPOVERISHMENT.

(a) IN GENERAL.—Section 2404 of Public Law 111–148 (42 U.S.C. 1396r–5 note) is amended by striking ''the 5-year period that begins on January 1, 2014,'' and inserting ''the period beginning on January 1, 2014, and ending on March 31, 2019,''.

(b) RULE OF CONSTRUCTION.—

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

(2) STATE WAIVER OR PLAN AMENDMENT DESCRIBED.—A State waiver or plan amendment described in this paragraph is any of the following:

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

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

23 (C) A plan amendment to provide medical
24 assistance for home and community-based at-

tendant services and supports under section 1915(k) of such Act (42 U.S.C. 1396n(k)).

SEC. 203. REDUCTION IN FMAP AFTER 2020 FOR STATES WITHOUT ASSET VERIFICATION PROGRAM.

Section 1940 of the Social Security Act (42 U.S.C. 1396w) is amended by adding at the end the following new subsection:

"(k) REDUCTION IN FMAP AFTER 2020 FOR NON-COMPLIANT STATES.—

"(1) IN GENERAL.—With respect to a calendar quarter beginning on or after January 1, 2021, the Federal medical assistance percentage otherwise determined under section 1905(b) for a non-compliant State shall be reduced—

"(A) for calendar quarters in 2021 and 2022, by 0.12 percentage points;

"(B) for calendar quarters in 2023, by 0.25 percentage points;

"(C) for calendar quarters in 2024, by 0.35 percentage points; and

"(D) for calendar quarters in 2025 and each year thereafter, by 0.5 percentage points.

"(2) NON-COMPLIANT STATE DEFINED.—For purposes of this subsection, the term 'non-compliant State' means a State—

1 "(A) that is one of the 50 States or the
2 District of Columbia;
3 "(B) with respect to which the Secretary
4 has not approved a State plan amendment sub-
5 mitted under subsection (a)(2); and
6 "(C) that is not operating, on an ongoing
7 basis, an asset verification program in accord-
8 ance with this section.".

9 **SEC. 204. 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, 2019.

SEC. 205. MEDICAID IMPROVEMENT FUND.

Section 1941(b)(1) of the Social Security Act (42 U.S.C. 1396w–1(b)(1)) is amended by striking ‘‘$31,000,000’’ and inserting ‘‘$9,000,000’’.

SEC. 206. PREVENTING THE MISCLASSIFICATION OF DRUGS UNDER THE MEDICAID DRUG REBATE PROGRAM.

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

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

(A) in the paragraph heading, by inserting ‘‘AND DRUG PRODUCT’’ after ‘‘PRICE’’;

(B) in subparagraph (A)—

(i) in clause (ii), by striking ‘‘; and’’ at the end and inserting a semicolon;

(ii) in clause (iii), by striking the period at the end and inserting a semicolon;

(iii) in clause (iv), by striking the semicolon at the end and inserting ‘‘; and’’; and

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

1 ''(v) not later than 30 days after the
2 last day of each month of a rebate period
3 under the agreement, such drug product
4 information as the Secretary shall require
5 for each of the manufacturer's covered out-
6 patient drugs.''; and
7 (C) in subparagraph (C)—
8 (i) in clause (ii), by inserting '', in-
9 cluding information related to drug pric-
10 ing, drug product information, and data
11 related to drug pricing or drug product in-
12 formation,'' after ''provides false informa-
13 tion''; and
14 (ii) by adding at the end the following
15 new clauses:
16 ''(iii) MISCLASSIFIED OR
17 MISREPORTED INFORMATION.—
18 ''(I) IN GENERAL.—Any manu-
19 facturer with an agreement under this
20 section that knowingly (as defined in
21 section 1003.110 of title 42, Code of
22 Federal Regulations (or any successor
23 regulation)) misclassifies a covered
24 outpatient drug, such as by knowingly
25 submitting incorrect drug category in-

1 formation, is subject to a civil money
2 penalty for each covered outpatient
3 drug that is misclassified in an
4 amount not to exceed 2 times the
5 amount of the difference, as deter-
6 mined by the Secretary, between—
7 "(aa) the total amount of
8 rebates that the manufacturer
9 paid with respect to the drug to
10 all States for all rebate periods
11 during which the drug was
12 misclassified; and
13 "(bb) the total amount of
14 rebates that the manufacturer
15 would have been required to pay,
16 as determined by the Secretary,
17 with respect to the drug to all
18 States for all rebate periods dur-
19 ing which the drug was
20 misclassified if the drug had been
21 correctly classified.
22 "(II) OTHER PENALTIES AND
23 RECOVERY OF UNDERPAID RE-
24 BATES.—The civil money penalties de-
25 scribed in subclause (I) are in addi-

1 tion to other penalties as may be pre-
2 scribed by law and any other recovery
3 of the underlying underpayment for
4 rebates due under this section or the
5 terms of the rebate agreement as de-
6 termined by the Secretary.
7 ''(iv) INCREASING OVERSIGHT AND
8 ENFORCEMENT.—Each year the Secretary
9 shall retain, in addition to any amount re-
10 tained by the Secretary to recoup inves-
11 tigation and litigation costs related to the
12 enforcement of the civil money penalties
13 under this subparagraph and subsection
14 (c)(4)(B)(ii)(III), an amount equal to 25
15 percent of the total amount of civil money
16 penalties collected under this subparagraph
17 and subsection (c)(4)(B)(ii)(III) for the
18 year, and such retained amount shall be
19 available to the Secretary, without further
20 appropriation and until expended, for ac-
21 tivities related to the oversight and en-
22 forcement of this section and agreements
23 under this section, including—
24 ''(I) improving drug data report-
25 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
13 ‘‘subsection (f).’’ and inserting ‘‘sub-
14 section (f), and’’; and
15 (III) by inserting after clause (v)
16 the following new clause:
17 ‘‘(vi) in the case of categories of drug
18 product or classification information that
19 were not considered confidential by the
20 Secretary on the day before the date of the
21 enactment of the IMPROVE Act.’’.
22 (2) TECHNICAL AMENDMENTS.—
23 (A) Section 1903(i)(10) of the Social Secu-
24 rity Act (42 U.S.C. 1396b(i)(10)) is amended—
25 (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
11 for a covered outpatient drug for which a sus-
12 pension under section 1927(c)(4)(B)(ii)(II) is in
13 effect; or".
14 (B) Section 1927(b)(3)(C)(ii) of the Social
15 Security Act (42 U.S.C. 1396r–8(b)(3)(C)(ii))
16 is amended by striking "subsections (a) and
17 (b)" and inserting "subsections (a), (b), (f)(3),
18 and (f)(4)".
19 (b) RECOVERY OF UNPAID REBATE AMOUNTS DUE
20 TO MISCLASSIFICATION OF COVERED OUTPATIENT
21 DRUGS.—
22 (1) IN GENERAL.—Section 1927(c) of the So-
23 cial Security Act (42 U.S.C. 1396r–8(c)) is amended
24 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 misclassi-
8 fied a covered outpatient drug (without re-
9 gard to whether the manufacturer know-
10 ingly made the misclassification or should
11 have known that the misclassification
12 would be made), the Secretary shall notify
13 the manufacturer of the misclassification
14 and require the manufacturer to correct
15 the misclassification in a timely manner.
16 "(ii) ENFORCEMENT.—If, after receiv-
17 ing notice of a misclassification from the
18 Secretary under clause (i), a manufacturer
19 fails to correct the misclassification by
20 such time as the Secretary shall require,
21 until the manufacturer makes such correc-
22 tion, the Secretary may—
23 "(I) correct the misclassification
24 on behalf of the manufacturer;

1 "(II) suspend the misclassified
2 drug and the drug's status as a cov-
3 ered outpatient drug under the manu-
4 facturer's national rebate agreement;
5 or

6 "(III) impose a civil money pen-
7 alty (which shall be in addition to any
8 other recovery or penalty which may
9 be available under this section or any
10 other provision of law) for each rebate
11 period during which the drug is
12 misclassified not to exceed an amount
13 equal to the product of—

14 "(aa) the total number of
15 units of each dosage form and
16 strength of such misclassified
17 drug paid for under any State
18 plan during such a rebate period;
19 and

20 "(bb) 23.1 percent of the av-
21 erage manufacturer price for the
22 dosage form and strength of such
23 misclassified drug.

24 "(C) REPORTING AND TRANSPARENCY.—

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

16 "(ii) PUBLIC ACCESS.—The Secretary
17 shall make the information contained in
18 the report required under clause (i) avail-
19 able to the public on a timely basis.

20 "(D) OTHER PENALTIES AND ACTIONS.—
21 Actions taken and penalties imposed under this
22 paragraph shall be in addition to other remedies
23 available to the Secretary including terminating
24 the manufacturer's rebate agreement for non-
25 compliance with the terms of such agreement

1 and shall not exempt a manufacturer from, or
2 preclude the Secretary from pursuing, any civil
3 money penalty under this title or title XI, or
4 any other penalty or action as may be pre-
5 scribed by law.''.

6 (2) OFFSET OF RECOVERED AMOUNTS AGAINST
7 MEDICAL ASSISTANCE.—Section 1927(b)(1)(B) of
8 the Social Security Act (42 U.S.C. 1396r–
9 8(b)(1)(B)) is amended by inserting '', including
10 amounts received by a State under subsection
11 (c)(4),'' after ''in any quarter''.

12 (c) CLARIFYING DEFINITIONS.—Section
13 1927(k)(7)(A) of the Social Security Act (42 U.S.C.
14 1396r–8(k)(7)(A)) is amended—

15 (1) by striking ''an original new drug applica-
16 tion'' and inserting ''a new drug application'' each
17 place it appears;

18 (2) in clause (i), by inserting ''but including a
19 drug product approved for marketing as a non-pre-
20 scription drug that is regarded as a covered out-
21 patient drug under paragraph (4)'' after ''drug de-
22 scribed in paragraph (5)'';

23 (3) in clause (ii), by striking ''was originally
24 marketed'' and inserting ''is marketed''; and

25 (4) in clause (iv)—

1 (A) by inserting ", including a drug prod-
2 uct approved for marketing as a non-prescrip-
3 tion drug that is regarded as a covered out-
4 patient drug under paragraph (4)," after "cov-
5 ered outpatient drug"; and
6 (B) by adding at the end the following new
7 sentence: "Such term also includes a covered
8 outpatient drug that is a biological product li-
9 censed, produced, or distributed under a bio-
10 logics license application approved by the Food
11 and Drug Administration.".
12 (d) EXCLUSION OF MANUFACTURERS FOR KNOWING
13 MISCLASSIFICATION OF COVERED OUTPATIENT
14 DRUGS.—Section 1128(b) of the Social Security Act (42
15 U.S.C. 1320a–7(b)) is amended by adding at the end the
16 following new paragraph:
17 "(17) KNOWINGLY MISCLASSIFYING COVERED
18 OUTPATIENT DRUGS.—Any manufacturer or officer,
19 director, agent, or managing employee of such man-
20 ufacturer that knowingly misclassifies a covered out-
21 patient drug under an agreement under section
22 1927, knowingly fails to correct such misclassifica-
23 tion, or knowingly provides false information related
24 to drug pricing, drug product information, or data

related to drug pricing or drug product information.''.

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

TITLE III—MEDICARE

SEC. 301. EXCLUSION OF COMPLEX REHABILITATIVE MANUAL WHEELCHAIRS FROM MEDICARE COMPETITIVE ACQUISITION PROGRAM; NON-APPLICATION OF MEDICARE FEE-SCHEDULE ADJUSTMENTS FOR CERTAIN WHEELCHAIR ACCESSORIES AND CUSHIONS.

(a) EXCLUSION OF COMPLEX REHABILITATIVE MANUAL WHEELCHAIRS FROM COMPETITIVE ACQUISITION PROGRAM.—Section 1847(a)(2)(A) of the Social Security Act (42 U.S.C. 1395w–3(a)(2)(A)) is amended—

(1) by inserting '', complex rehabilitative manual wheelchairs (as determined by the Secretary), and certain manual wheelchairs (identified, as of October 1, 2018, by HCPCS codes E1235, E1236, E1237, E1238, and K0008 or any successor to such codes)'' after ''group 3 or higher''; and

1 (2) by striking "such wheelchairs" and insert-
2 ing "such complex rehabilitative power wheelchairs,
3 complex rehabilitative manual wheelchairs, and cer-
4 tain manual wheelchairs".

5 (b) NON-APPLICATION OF MEDICARE FEE SCHED-
6 ULE ADJUSTMENTS FOR WHEELCHAIR ACCESSORIES AND
7 SEAT AND BACK CUSHIONS WHEN FURNISHED IN CON-
8 NECTION WITH COMPLEX REHABILITATIVE MANUAL
9 WHEELCHAIRS.—

10 (1) IN GENERAL.—Notwithstanding any other
11 provision of law, the Secretary of Health and
12 Human Services shall not, during the period begin-
13 ning on January 1, 2019, and ending on June 30,
14 2020, use information on the payment determined
15 under the competitive acquisition programs under
16 section 1847 of the Social Security Act (42 U.S.C.
17 1395w–3) to adjust the payment amount that would
18 otherwise be recognized under section
19 1834(a)(1)(B)(ii) of such Act (42 U.S.C.
20 1395m(a)(1)(B)(ii)) for wheelchair accessories (in-
21 cluding seating systems) and seat and back cushions
22 when furnished in connection with complex rehabili-
23 tative manual wheelchairs (as determined by the
24 Secretary), and certain manual wheelchairs (identi-
25 fied, as of October 1, 2018, by HCPCS codes

1 E1235, E1236, E1237, E1238, and K0008 or any
2 successor to such codes).
3 (2) IMPLEMENTATION.—Notwithstanding any
4 other provision of law, the Secretary may implement
5 this subsection by program instruction or otherwise.

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