115TH CONGRESS 2D SESSION

### H.R. 7217

#### AN ACT

- 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,

#### SECTION 1. SHORT TITLE.

- This Act may be cited as the "Improving Medicaid
- 3 Programs and Opportunities for Eligible Beneficiaries
- 4 Act" or the "IMPROVE Act".

#### 5 TITLE I—ACE KIDS

- 6 SEC. 101. STATE OPTION TO PROVIDE COORDINATED CARE
- 7 THROUGH A HEALTH HOME FOR CHILDREN
- 8 WITH MEDICALLY COMPLEX CONDITIONS.
- 9 Title XIX of the Social Security Act (42 U.S.C. 1396
- 10 et seq.) is amended by inserting after section 1945 the
- 11 following new section:
- 12 "SEC. 1945A. STATE OPTION TO PROVIDE COORDINATED
- 13 CARE THROUGH A HEALTH HOME FOR CHIL-
- 14 DREN WITH MEDICALLY COMPLEX CONDI-
- 15 TIONS.
- 16 "(a) In General.—Notwithstanding section
- 17 1902(a)(1) (relating to statewideness) and section
- 18 1902(a)(10)(B) (relating to comparability), beginning Oc-
- 19 tober 1, 2022, a State, at its option as a State plan
- 20 amendment, may provide for medical assistance under this
- 21 title to children with medically complex conditions who
- 22 choose to enroll in a health home under this section by
- 23 selecting a designated provider, a team of health care pro-
- 24 fessionals operating with such a provider, or a health team
- 25 as the child's health home for purposes of providing the
- 26 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.

"(4) Coordinate access to—

"(A) subspecialized pediatric services and
programs for children with medically complex
conditions, including the most intensive diag-
nostic, treatment, and critical care levels as
medically necessary; and
"(B) palliative services if the State pro-
vides such services under the State plan (or a
waiver of such plan).
"(5) Coordinate care for children with medically
complex conditions with out-of-State providers fur-
nishing care to such children to the maximum extent
practicable for the families of such children and
where medically necessary, in accordance with guid-
ance issued under subsection (e)(1) and section
431.52 of title 42, Code of Federal Regulations.
"(6) Collect and report information under sub-
section $(g)(1)$ .
"(c) Payments.—
"(1) In general.—A State shall provide a des-
ignated provider, a team of health care professionals
operating with such a provider, or a health team
with payments for the provision of health home serv-

ices to each child with medically complex conditions

that selects such provider, team of health care pro-

fessionals, or health team as the child's health home.

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

#### "(2) Methodology.—

"(A) IN GENERAL.—The State shall specify in the State plan amendment the methodology the State will use for determining payment for the provision of health home services. Such methodology for determining payment—

"(i) may be tiered to reflect, with respect to each child with medically complex conditions provided such services by a designated provider, a team of health care professionals operating with such a provider, or a health team, the severity or number of each such child's chronic conditions, life-threatening illnesses, disabilities, 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.

#### "(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.

"(3) Family education.—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 families with children eligible to receive health home services pursuant to this section of the availability of such services. Such process shall include the participation of family-to-family entities or other public or private organizations or entities who provide outreach and information on the availability of health care items and services to families of individuals eligible to receive medical assistance under the State plan (or a waiver of such plan).

"(4) Mental Health Coordination.—A State with a State plan amendment approved under this section shall consult and coordinate, as appropriate, with the Secretary in addressing issues regarding the prevention and treatment of mental illness and substance use among children with medically complex conditions receiving health home services 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-
- pitals, pediatricians, and other providers), managed
- 3 care plans, children's health groups, family and ben-
- 4 eficiary 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 avoidable hos-
- 10 pital readmissions and calculating savings that re-
- sult from improved care coordination and manage-
- ment under this section;
- "(2) a proposal for use of health information
- technology in providing health home services under
- this section and improving service delivery and co-
- ordination across the care continuum (including the
- use of wireless patient technology to improve coordi-
- nation and management of care and patient adher-
- ence to recommendations made by their provider);
- 20 and
- 21 "(3) a methodology for tracking prompt and
- timely access to medically necessary care for children
- with medically complex conditions from out-of-State
- providers.
- 25 "(g) Data Collection.—

"(1) PROVIDER REPORTING REQUIREMENTS.—
In order to receive payments from a State under subsection (c), a designated provider, a team of health care professionals operating with such a provider, or a health team shall report to the State, at such time and in such form and manner as may be required by the State, the following information:

"(A) With respect to each such provider, team of health care professionals, or health team, the name, National Provider Identification number, address, and specific health care services offered to be provided to children with medically complex conditions who have selected such provider, team of health care professionals, or health team as the health home of such children.

"(B) Information on all applicable measures for determining the quality of health home services provided by such provider, team of health care professionals, or health team, including, to the extent applicable, child health quality measures and measures for centers of excellence for children with complex needs developed under this title, title XXI, and section 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	$(\Pi)$ 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):

I	"(v) referrals to community and social
2	support services, if relevant; and
3	"(vi) use of health information tech-

nology to link services, as feasible and ap-

5 propriate.

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- "(5) Designated Provider.—The term 'designated provider' means a physician (including a pediatrician or a pediatric specialty or subspecialty provider), children's hospital, clinical practice or clinical group practice, prepaid inpatient health plan or prepaid ambulatory health plan (as defined by the Secretary), rural clinic, community health center, community mental health center, home health agency, or any other entity or provider that is determined by the State and approved by the Secretary to be qualified to be a health home for children with medically complex conditions on the basis of documentation evidencing that the entity has the systems, expertise, and infrastructure in place to provide health home services. Such term may include providers who are employed by, or affiliated with, a children's hospital.
- "(6) TEAM OF HEALTH CARE PROFES-SIONALS.—The term 'team of health care professionals' 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	TITLE II—OTHER MEDICAID
7	SEC. 201. EXTENSION OF MONEY FOLLOWS THE PERSON
8	REBALANCING DEMONSTRATION.
9	(a) General Funding.—Section 6071(h) of the
10	Deficit Reduction Act of 2005 (42 U.S.C. 1396a note) is
11	amended—
12	(1) in paragraph (1)—
13	(A) in subparagraph (D), by striking
14	"and" after the semicolon;
15	(B) in subparagraph (E), by striking the
16	period at the end and inserting "; and"; and
17	(C) by adding at the end the following:
18	"(F) subject to paragraph (3),
19	\$112,000,000 for fiscal year 2019.";
20	(2) in paragraph (2)—
21	(A) by striking "Amounts made" and in-
22	serting "Subject to paragraph (3), amounts
23	made"; and
24	(B) by striking "September 30, 2016" and
25	inserting "September 30, 2021"; and

- 1 (3) by adding at the end the following new 2 paragraph:
- 3 "(3) Special rule for fy 2019.—Funds ap-
- 4 propriated under paragraph (1)(F) shall be made
- 5 available for grants to States only if such States
- 6 have an approved MFP demonstration project under
- 7 this section as of December 31, 2018.".
- 8 (b) Funding for Quality Assurance and Im-
- 9 PROVEMENT; TECHNICAL ASSISTANCE; OVERSIGHT.—
- 10 Section 6071(f) of the Deficit Reduction Act of 2005 (42
- 11 U.S.C. 1396a note) is amended by striking paragraph (2)
- 12 and inserting the following:
- 13 "(2) Funding.—From the amounts appro-
- priated under subsection (h)(1)(F) for fiscal year
- 15 2019, \$500,000 shall be available to the Secretary
- for such fiscal year to carry out this subsection.".
- 17 (c) Technical Amendment.—Section 6071(b) of
- 18 the Deficit Reduction Act of 2005 (42 U.S.C. 1396a note)
- 19 is amended by adding at the end the following:
- 20 "(10) Secretary.—The term 'Secretary'
- 21 means the Secretary of Health and Human Serv-
- 22 ices.".

1	SEC. 202. EXTENSION OF PROTECTION FOR MEDICAID RE-
2	CIPIENTS OF HOME AND COMMUNITY-BASED
3	SERVICES AGAINST SPOUSAL IMPOVERISH-
4	MENT.
5	(a) In General.—Section 2404 of Public Law 111–
6	148 (42 U.S.C. 1396r–5 note) is amended by striking "the
7	5-year period that begins on January 1, 2014," and in-
8	serting "the period beginning on January 1, 2014, and
9	ending on March 31, 2019,".
10	(b) Rule of Construction.—
11	(1) Protecting state spousal income and
12	ASSET DISREGARD FLEXIBILITY UNDER WAIVERS
13	AND PLAN AMENDMENTS.—Nothing in section 2404
14	of Public Law 111–148 (42 U.S.C. 1396r–5 note) or
15	section 1924 of the Social Security Act (42 U.S.C.
16	1396r-5) shall be construed as prohibiting a State
17	from disregarding an individual's spousal income
18	and assets under a State waiver or plan amendment
19	described in paragraph (2) for purposes of making
20	determinations of eligibility for home and commu-
21	nity-based services or home and community-based
22	attendant services and supports under such waiver
23	or plan amendment.
24	(2) State waiver or plan amendment de-
25	SCRIBED.—A State waiver or plan amendment de-
26	scribed in this paragraph is any of the following:

- 1 (A) A waiver or plan amendment to pro2 vide medical assistance for home and commu3 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).
  - (B) A plan amendment to provide medical assistance for home and community-based services for individuals by reason of being determined eligible under section 1902(a)(10)(C) of such Act (42 U.S.C. 1396a(a)(10)(C)) or by reason of section 1902(f) of such Act (42 U.S.C. 1396a(f)) or otherwise on the basis of a reduction of income based on costs incurred for medical or other remedial care under which the State disregarded the income and assets of the individual's spouse in determining the initial and ongoing financial eligibility of an individual for such services in place of the spousal impoverishment provisions applied under section 1924 of such Act (42 U.S.C. 1396r–5).
  - (C) A plan amendment to provide medical assistance for home and community-based at-

1	tendant services and supports under section
2	1915(k) of such Act (42 U.S.C. 1396n(k)).
3	SEC. 203. REDUCTION IN FMAP AFTER 2020 FOR STATES
4	WITHOUT ASSET VERIFICATION PROGRAM.
5	Section 1940 of the Social Security Act (42 U.S.C.
6	1396w) is amended by adding at the end the following
7	new subsection:
8	"(k) REDUCTION IN FMAP AFTER 2020 FOR NON-
9	COMPLIANT STATES.—
10	"(1) In general.—With respect to a calendar
11	quarter beginning on or after January 1, 2021, the
12	Federal medical assistance percentage otherwise de-
13	termined under section 1905(b) for a non-compliant
14	State shall be reduced—
15	"(A) for calendar quarters in 2021 and
16	2022, by 0.12 percentage points;
17	"(B) for calendar quarters in 2023, by
18	0.25 percentage points;
19	"(C) for calendar quarters in 2024, by
20	0.35 percentage points; and
21	"(D) for calendar quarters in 2025 and
22	each year thereafter, by 0.5 percentage points.
23	"(2) Non-compliant state defined.—For
24	purposes of this subsection, the term 'non-compliant
25	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.

1	SEC. 205. MEDICAID IMPROVEMENT FUND.
2	Section 1941(b)(1) of the Social Security Act (42
3	U.S.C. 1396w-1(b)(1)) is amended by striking
4	"\$31,000,000" and inserting "\$9,000,000".
5	SEC. 206. PREVENTING THE MISCLASSIFICATION OF DRUGS
6	UNDER THE MEDICAID DRUG REBATE PRO-
7	GRAM.
8	(a) Application of Civil Money Penalty for
9	MISCLASSIFICATION OF COVERED OUTPATIENT
10	Drugs.—
11	(1) In General.—Section 1927(b)(3) of the
12	Social Security Act (42 U.S.C. 1396r–8(b)(3)) is
13	amended—
14	(A) in the paragraph heading, by inserting
15	"AND DRUG PRODUCT" after "PRICE";
16	(B) in subparagraph (A)—
17	(i) in clause (ii), by striking "; and"
18	at the end and inserting a semicolon;
19	(ii) in clause (iii), by striking the pe-
20	riod at the end and inserting a semicolon;
21	(iii) in clause (iv), by striking the
22	semicolon at the end and inserting ";
23	and"; and
24	(iv) by inserting after clause (iv) the
25	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
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—
24	"(I) correct the misclassification
25	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.—

GENERAL.—The Secretary 1 "(i) IN 2 shall submit a report to Congress on at least an annual basis that includes infor-3 mation on the covered outpatient drugs 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 misclassification, and a disclosure of ex-10 penditures from the fund created in sub-12 section (b)(3)(C)(iv), including an accounting of how such funds have been allocated 13 14 and spent in accordance with such sub-15 section.

- "(ii) Public Access.—The Secretary shall make the information contained in the report required under clause (i) available to the public on a timely basis.
- "(D) OTHER PENALTIES AND ACTIONS.— Actions taken and penalties imposed under this paragraph shall be in addition to other remedies available to the Secretary including terminating the manufacturer's rebate agreement for noncompliance with the terms of such agreement

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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 1927(k)(7)(A) of the Social Security Act (42 U.S.C. 13 1396r-8(k)(7)(A) is amended— 14 15 (1) by striking "an original new drug application" and inserting "a new drug application" each 16 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 outpatient drug under paragraph (4)" after "drug de-21 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
  - (B) 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.".
- 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 such to correct 23 misclassification, or knowingly provides false information related to drug pricing, drug product infor-24

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1	mation, or data related to drug pricing or drug					
2	product information.".					
3	(e) Effective Date.—The amendments made by					
4	this section shall take effect on the date of the enactment					
5	of this Act, and shall apply to covered outpatient drugs					
6	supplied by manufacturers under agreements under sec					
7	tion 1927 of the Social Security Act (42 U.S.C. 1396r-					
8	8) on or after such date.					
9	TITLE III—MEDICARE					
10	SEC. 301. EXCLUSION OF COMPLEX REHABILITATIVE MAN-					
11	UAL WHEELCHAIRS FROM MEDICARE COM-					
12	PETITIVE ACQUISITION PROGRAM; NON-AP-					
13	PLICATION OF MEDICARE FEE-SCHEDULE					
14	ADJUSTMENTS FOR CERTAIN WHEELCHAIR					
15	ACCESSORIES AND CUSHIONS.					
16	(a) Exclusion of Complex Rehabilitative Man-					
17						
	UAL WHEELCHAIRS FROM COMPETITIVE ACQUISITION					
18	UAL WHEELCHAIRS FROM COMPETITIVE ACQUISITION PROGRAM.—Section 1847(a)(2)(A) of the Social Security					
18 19						
	Program.—Section 1847(a)(2)(A) of the Social Security					
19	Program.—Section 1847(a)(2)(A) of the Social Security Act (42 U.S.C. 1395w-3(a)(2)(A)) is amended—					
19 20	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 man-					
19 20 21	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),					
19 20 21 22	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 Oc-					

- 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
- Human Services shall not, during the period begin-
- ning on January 1, 2019, and ending on June 30,
- 14 2020, use information on the payment determined
- under the competitive acquisition programs under
- 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
- when furnished in connection with complex rehabili-
- tative manual wheelchairs (as determined by the
- 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 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. Passed the House of Representatives December 11, 2018.

Attest:

Clerk.

# 115TH CONGRESS H. R. 7217

## AN ACT

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.