115TH CONGRESS
2D SESSION

H. R. 7217

IN THE SENATE OF THE UNITED STATES

DECEMBER 12, 2018
Received

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Improving Medicaid Programs and Opportunities for Eligible Beneficiaries 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 standards shall include requiring designated providers, teams of health care professionals operating with such providers, and health teams to demonstrate to the State the ability to do the following:

''(1) Coordinate prompt care for children with medically complex conditions, including access to pediatric emergency services at all times.

''(2) Develop an individualized comprehensive pediatric family-centered care plan for children with medically complex conditions that accommodates patient preferences.

''(3) Work in a culturally and linguistically appropriate manner with the family of a child with medically complex conditions to develop and incorporate into such child's care plan, in a manner consistent with the needs of the child and the choices of the child's family, ongoing home care, community-based pediatric primary care, pediatric inpatient care, social support services, and local hospital pediatric emergency care.

''(4) Coordinate access to—

''(A) subspecialized pediatric services and programs for children with medically complex conditions, including the most intensive diagnostic, treatment, and critical care levels as medically necessary; and

''(B) palliative services if the State provides 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 furnishing care to such children to the maximum extent practicable for the families of such children and where medically necessary, in accordance with guidance issued under subsection (e)(1) and section 431.52 of title 42, Code of Federal Regulations.

''(6) Collect and report information under subsection (g)(1).

''(c) PAYMENTS.—

''(1) IN GENERAL.—A State shall provide a designated provider, a team of health care professionals operating with such a provider, or a health team with payments for the provision of health home services to each child with medically complex conditions that selects such provider, team of health care professionals, or health team as the child's health home.

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

of the provider, team of health care professionals, or health team; and

"(ii) shall be established consistent with section 1902(a)(30)(A).

"(B) ALTERNATE MODELS OF PAYMENT.—The methodology for determining payment for provision of health home services under this section shall not be limited to a per-member per-month basis and may provide (as proposed by the State and subject to approval by the Secretary) for alternate models of payment.

"(3) PLANNING GRANTS.—

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

"(B) STATE CONTRIBUTION.—A State awarded a planning grant shall contribute an amount equal to the State percentage determined under section 1905(b) (without regard to section 5001 of Public Law 111–5) for each fiscal year for which the grant is awarded.

"(C) LIMITATION.—The total amount of payments made to States under this paragraph 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.

''(e) GUIDANCE ON COORDINATING CARE FROM OUT-OF-STATE PROVIDERS.—

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

''(A) best practices for using out-of-State providers to provide care to children with medically complex conditions;

''(B) coordinating care for such children provided by such out-of-State providers (including when provided in emergency and non-emergency situations);

''(C) reducing barriers for such children receiving care from such providers in a timely fashion; and

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

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

States, providers (including children's hospitals, hospitals, pediatricians, and other providers), managed care plans, children's health groups, family and beneficiary advocates, and other stakeholders with respect to coordinating the care for such children provided by out-of-State providers.

''(f) MONITORING.—A State shall include in the State plan amendment—

''(1) a methodology for tracking avoidable hospital readmissions and calculating savings that result from improved care coordination and management 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 coordination across the care continuum (including the use of wireless patient technology to improve coordination and management of care and patient adherence to recommendations made by their provider); and

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

''(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.

''(C) Such other information as the Secretary shall specify in guidance.

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

''(2) STATE REPORTING REQUIREMENTS.—

''(A) COMPREHENSIVE REPORT.—A State with a State plan amendment approved under this section shall report to the Secretary (and, upon request, to the Medicaid and CHIP Payment and Access Commission), at such time and in such form and manner determined by the Secretary to be reasonable and minimally burdensome, the following information:

''(i) Information reported under paragraph (1).

''(ii) The number of children with medically complex conditions who have selected a health home pursuant to this section.

''(iii) The nature, number, and prevalence of chronic conditions, life-threatening illnesses, disabilities, or rare diseases that such children have.

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

''(v) The number and characteristics of designated providers, teams of health care professionals operating with such providers, and health teams selected as health homes pursuant to this section, including the number and characteristics of out-of-State providers, teams of health care professionals operating with such providers, and health teams who have provided health care items and services to such children.

''(vi) The extent to which such children receive health care items and services under the State plan.

''(vii) Quality measures developed specifically with respect to health care items and services provided to children with medically complex conditions.

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

State website, a report on how the State is implementing 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.—

''(A) IN GENERAL.—Subject to subparagraph (B), the term 'child with medically complex conditions' means an individual under 21 years of age who—

''(i) is eligible for medical assistance under the State plan (or under a waiver of such plan); and

''(ii) has at least—

''(I) one or more chronic conditions that cumulatively affect three or more organ systems and severely reduces cognitive or physical functioning (such as the ability to eat, drink, or breathe independently) and that also requires the use of medication, durable medical equipment, therapy, surgery, or other treatments; or

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

"(B) RULE OF CONSTRUCTION.—Nothing in this paragraph shall prevent the Secretary from establishing higher levels as to the number or severity of chronic, life threatening illnesses, disabilities, rare diseases or mental health conditions for purposes of determining eligibility for receipt of health home services under this section.

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

"(A) Cerebral palsy.

"(B) Cystic fibrosis.

"(C) HIV/AIDS.

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

"(E) Muscular dystrophy.

"(F) Spina bifida.

"(G) Epilepsy.

"(H) Severe autism spectrum disorder.

"(I) Serious emotional disturbance or serious mental health illness.

"(3) HEALTH HOME.—The term 'health home' means a designated provider (including a provider

that operates in coordination with a team of health care professionals) or a health team selected by a child with medically complex conditions (or the family of such child) to provide health home services.

''(4) HEALTH HOME SERVICES.—

''(A) IN GENERAL.—The term 'health home services' means comprehensive and timely high-quality services described in subparagraph (B) that are provided by a designated provider, a team of health care professionals operating with such a provider, or a health team.

''(B) SERVICES DESCRIBED.—The services described in this subparagraph shall include—

''(i) comprehensive care management;

''(ii) care coordination, health promotion, and providing access to the full range of pediatric specialty and subspecialty medical services, including services from out-of-State providers, as medically necessary;

''(iii) comprehensive transitional care, including appropriate follow-up, from inpatient to other settings;

''(iv) patient and family support (including authorized representatives);

"(v) referrals to community and social support services, if relevant; and

"(vi) use of health information technology to link services, as feasible and appropriate.

"(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 PROFESSIONALS.—The term 'team of health care professionals' means a team of health care professionals

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

"(A) include—

"(i) physicians and other professionals, such as pediatricians or pediatric specialty or subspecialty providers, nurse care coordinators, dietitians, nutritionists, social workers, behavioral health professionals, physical therapists, occupational therapists, speech pathologists, nurses, individuals with experience in medical supportive technologies, or any professionals determined to be appropriate by the State and approved by the Secretary;

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

"(iii) community health workers, translators, and other individuals with culturally-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.''.

TITLE II—OTHER MEDICAID

SEC. 201. EXTENSION OF MONEY FOLLOWS THE PERSON REBALANCING DEMONSTRATION.

(a) GENERAL FUNDING.—Section 6071(h) of the Deficit Reduction Act of 2005 (42 U.S.C. 1396a note) is amended—

(1) in paragraph (1)—

(A) in subparagraph (D), by striking ''and'' after the semicolon;

(B) in subparagraph (E), by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following:

''(F) subject to paragraph (3), $112,000,000 for fiscal year 2019.'';

(2) in paragraph (2)—

(A) by striking ''Amounts made'' and inserting ''Subject to paragraph (3), amounts made''; and

(B) by striking ''September 30, 2016'' and inserting ''September 30, 2021''; and

(3) by adding at the end the following new paragraph:

''(3) SPECIAL RULE FOR FY 2019.—Funds appropriated under paragraph (1)(F) shall be made available for grants to States only if such States have an approved MFP demonstration project under this section as of December 31, 2018.''.

(b) FUNDING FOR QUALITY ASSURANCE AND IMPROVEMENT; TECHNICAL ASSISTANCE; OVERSIGHT.—Section 6071(f) of the Deficit Reduction Act of 2005 (42 U.S.C. 1396a note) is amended by striking paragraph (2) and inserting the following:

''(2) FUNDING.—From the amounts appropriated under subsection (h)(1)(F) for fiscal year 2019, $500,000 shall be available to the Secretary for such fiscal year to carry out this subsection.''.

(c) TECHNICAL AMENDMENT.—Section 6071(b) of the Deficit Reduction Act of 2005 (42 U.S.C. 1396a note) is amended by adding at the end the following:

''(10) SECRETARY.—The term 'Secretary' means the Secretary of Health and Human Services.''.

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:

(A) A waiver or plan amendment to provide medical assistance for home and community-based services under a waiver or plan amendment under subsection (c), (d), or (i) of section 1915 of the Social Security Act (42 U.S.C. 1396n) or under section 1115 of such 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-

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—

''(A) that is one of the 50 States or the District of Columbia;

''(B) with respect to which the Secretary has not approved a State plan amendment submitted under subsection (a)(2); and

''(C) that is not operating, on an ongoing basis, an asset verification program in accordance with this section.''.

SEC. 204. DENIAL OF FFP FOR CERTAIN EXPENDITURES RELATING TO VACUUM ERECTION SYSTEMS AND PENILE PROSTHETIC IMPLANTS.

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

''(12) with respect to any amounts expended for—

''(A) a vacuum erection system that is not medically necessary; or

''(B) the insertion, repair, or removal and replacement of a penile prosthetic implant (unless such insertion, repair, or removal and replacement is medically necessary); or''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to items and services 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:

''(v) not later than 30 days after the last day of each month of a rebate period under the agreement, such drug product information as the Secretary shall require for each of the manufacturer's covered outpatient drugs.''; and

(C) in subparagraph (C)—

(i) in clause (ii), by inserting '', including information related to drug pricing, drug product information, and data related to drug pricing or drug product information,'' after ''provides false information''; and

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

''(iii) MISCLASSIFIED OR MISREPORTED INFORMATION.—

''(I) IN GENERAL.—Any manufacturer with an agreement under this section that knowingly (as defined in section 1003.110 of title 42, Code of Federal Regulations (or any successor regulation)) misclassifies a covered outpatient drug, such as by knowingly submitting incorrect drug category in-

formation, is subject to a civil money penalty for each covered outpatient drug that is misclassified in an amount not to exceed 2 times the amount of the difference, as determined by the Secretary, between—

"(aa) the total amount of rebates that the manufacturer paid with respect to the drug to all States for all rebate periods during which the drug was misclassified; and

"(bb) the total amount of rebates that the manufacturer would have been required to pay, as determined by the Secretary, with respect to the drug to all States for all rebate periods during which the drug was misclassified if the drug had been correctly classified.

"(II) OTHER PENALTIES AND RECOVERY OF UNDERPAID REBATES.—The civil money penalties described in subclause (I) are in addi-

tion to other penalties as may be prescribed by law and any other recovery of the underlying underpayment for rebates due under this section or the terms of the rebate agreement as determined by the Secretary.

''(iv) INCREASING OVERSIGHT AND ENFORCEMENT.—Each year the Secretary shall retain, in addition to any amount retained by the Secretary to recoup investigation and litigation costs related to the enforcement of the civil money penalties under this subparagraph and subsection (c)(4)(B)(ii)(III), an amount equal to 25 percent of the total amount of civil money penalties collected under this subparagraph and subsection (c)(4)(B)(ii)(III) for the year, and such retained amount shall be available to the Secretary, without further appropriation and until expended, for activities related to the oversight and enforcement of this section and agreements under this section, including—

''(I) improving drug data reporting systems;

"(II) evaluating and ensuring manufacturer compliance with rebate obligations; and

"(III) oversight and enforcement related to ensuring that manufacturers accurately and fully report drug information, including data related to drug classification."; and

(iii) in subparagraph (D)—

(I) in clause (iv), by striking ", and" and inserting a comma;

(II) in clause (v), by striking "subsection (f)." and inserting "subsection (f), and"; and

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

"(vi) in the case of categories of drug product or classification information that were not considered confidential by the Secretary on the day before the date of the enactment of the IMPROVE Act.".

(2) TECHNICAL AMENDMENTS.—

(A) Section 1903(i)(10) of the Social Security Act (42 U.S.C. 1396b(i)(10)) is amended—

(i) in subparagraph (C)—

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

(II) by striking ", and" and inserting a semicolon;

(ii) in subparagraph (D), by striking "; or" and inserting "; and"; and

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

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

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

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

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

''(4) RECOVERY OF UNPAID REBATE AMOUNTS DUE TO MISCLASSIFICATION OF COVERED OUTPATIENT DRUGS.—

''(A) IN GENERAL.—If the Secretary determines that a manufacturer with an agreement under this section paid a lower per-unit rebate amount to a State for a rebate period as a result of the misclassification by the manufacturer of a covered outpatient drug (without regard to whether the manufacturer knowingly made the misclassification or should have known that the misclassification would be made) than the per-unit rebate amount that the manufacturer would have paid to the State if the drug had been correctly classified, the manufacturer shall pay to the State an amount equal to the product of—

''(i) the difference between—

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

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

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

"(B) AUTHORITY TO CORRECT MISCLASSIFICATIONS.—

"(i) IN GENERAL.—If the Secretary determines that a manufacturer with an agreement under this section has misclassified a covered outpatient drug (without regard to whether the manufacturer knowingly made the misclassification or should have known that the misclassification would be made), the Secretary shall notify the manufacturer of the misclassification and require the manufacturer to correct the misclassification in a timely manner.

"(ii) ENFORCEMENT.—If, after receiving notice of a misclassification from the Secretary under clause (i), a manufacturer fails to correct the misclassification by such time as the Secretary shall require, until the manufacturer makes such correction, the Secretary may—

"(I) correct the misclassification on behalf of the manufacturer;

"(II) suspend the misclassified drug and the drug's status as a covered outpatient drug under the manufacturer's national rebate agreement; or

"(III) impose a civil money penalty (which shall be in addition to any other recovery or penalty which may be available under this section or any other provision of law) for each rebate period during which the drug is misclassified not to exceed an amount equal to the product of—

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

"(bb) 23.1 percent of the average manufacturer price for the dosage form and strength of such misclassified drug.

"(C) REPORTING AND TRANSPARENCY.—

"(i) IN GENERAL.—The Secretary shall submit a report to Congress on at least an annual basis that includes information on the covered outpatient drugs that have been identified as misclassified, the steps taken to reclassify such drugs, the actions the Secretary has taken to ensure the payment of any rebate amounts which were unpaid as a result of such misclassification, and a disclosure of expenditures from the fund created in subsection (b)(3)(C)(iv), including an accounting of how such funds have been allocated and spent in accordance with such subsection.

"(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

and shall not exempt a manufacturer from, or preclude the Secretary from pursuing, any civil money penalty under this title or title XI, or any other penalty or action as may be prescribed by law.''.

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

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

(1) by striking ''an original new drug application'' and inserting ''a new drug application'' each place it appears;

(2) in clause (i), by inserting ''but including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under paragraph (4)'' after ''drug described in paragraph (5)'';

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

(4) in clause (iv)—

(A) by inserting ", including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under paragraph (4)," after "covered 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.".

(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 information related to drug pricing, drug product infor-

mation, 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

(2) by striking ''such wheelchairs'' and inserting ''such complex rehabilitative power wheelchairs, complex rehabilitative manual wheelchairs, and certain manual wheelchairs''.

(b) NON-APPLICATION OF MEDICARE FEE SCHEDULE ADJUSTMENTS FOR WHEELCHAIR ACCESSORIES AND SEAT AND BACK CUSHIONS WHEN FURNISHED IN CONNECTION WITH COMPLEX REHABILITATIVE MANUAL WHEELCHAIRS.—

(1) IN GENERAL.—Notwithstanding any other provision of law, the Secretary of Health and Human Services shall not, during the period beginning on January 1, 2019, and ending on June 30, 2020, use information on the payment determined under the competitive acquisition programs under section 1847 of the Social Security Act (42 U.S.C. 1395w–3) to adjust the payment amount that would otherwise be recognized under section 1834(a)(1)(B)(ii) of such Act (42 U.S.C. 1395m(a)(1)(B)(ii)) for wheelchair accessories (including seating systems) and seat and back cushions when furnished in connection with 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).

(2) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this subsection by program instruction or otherwise.

Passed the House of Representatives December 11, 2018.

Attest: KAREN L. HAAS,

Clerk.