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118TH CONGRESS
1ST SESSION

H. R. 5027

To improve the understanding of, and promote access to treatment for, chronic kidney disease, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 27, 2023

Mrs. MILLER of West Virginia (for herself and Ms. SEWELL) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, 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 improve the understanding of, and promote access to treatment for, chronic kidney disease, 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; TABLE OF CONTENTS.

This Act may be cited as the ''Chronic Kidney Disease Improvement in Research and Treatment Act of 2023''.

TITLE I—PREVENTING KIDNEY DISEASE AND EXPANDING AWARENESS AND EDUCATION

SEC. 101. EXPANDING MEDICARE ANNUAL WELLNESS BENEFIT TO INCLUDE KIDNEY DISEASE SCREENING.

(a) IN GENERAL.—Section 1861(ww)(2) of the Social Security Act (42 U.S.C. 1395x(ww)(2)) is amended—

(1) by redesignating subparagraph (O) as subparagraph (P); and

(2) by inserting after subparagraph (N) the following new subparagraph:

''(O) Chronic kidney disease screening as defined by the Secretary.''.

(b) EFFECTIVE DATE.—The amendments made by this section apply to items and services furnished on or after January 1, 2022.

SEC. 102. INCREASING ACCESS TO MEDICARE KIDNEY DISEASE EDUCATION BENEFIT.

(a) IN GENERAL.—Section 1861(ggg) of the Social Security Act (42 U.S.C. 1395x(ggg)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A), by inserting ''or stage V'' after ''stage IV''; and

(B) in subparagraph (B), by inserting ''or of a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5)) assisting in the treatment of the individual's kidney condition'' after ''kidney condition''; and

(2) in paragraph (2)—

(A) by striking subparagraph (B); and

(B) in subparagraph (A)—

(i) by striking ''(A)'' after ''(2)'';

(ii) by striking ''and'' at the end of clause (i);

(iii) by striking the period at the end of clause (ii) and inserting ''; and'';

(iv) by redesignating clauses (i) and (ii) as subparagraphs (A) and (B), respectively; and

(v) by adding at the end the following:

''(C) a renal dialysis facility subject to the requirements of section 1881(b)(1) with personnel who—

''(i) provide the services described in paragraph (1); and

''(ii) is a physician (as defined in subsection (r)(1)) or a physician assistant,

nurse practitioner, or clinical nurse specialist (as defined in subsection (aa)(5)).''.

(b) PAYMENT TO RENAL DIALYSIS FACILITIES.—Section 1881(b) of the Social Security Act (42 U.S.C. 1395rr(b)) is amended by adding at the end the following new paragraph:

''(15) For purposes of paragraph (14), the single payment for renal dialysis services under such paragraph shall not take into account the amount of payment for kidney disease education services (as defined in section 1861(ggg)). Instead, payment for such services shall be made to the renal dialysis facility on an assignment-related basis under section 1848.''.

(c) EFFECTIVE DATE.—The amendments made by this section apply to kidney disease education services furnished on or after January 1, 2022.

TITLE II—INCENTIVIZING KIDNEY CARE INNOVATION

SEC. 201. REFINING THE END-STAGE RENAL DISEASE PAYMENT SYSTEM TO IMPROVE ACCURACY IN PAYMENT AND SUPPORT THERAPIES.

(a) IN GENERAL.—Section 1881(b)(14) of the Social Security Act (42 U.S.C. 1395ww(b)(14)) is amended by adding the following new subparagraph:

"(J) PAYMENT FOR NEW AND INNOVATIVE DRUGS, BIOLOGICALS, AND DEVICES THAT ARE RENAL DIALYSIS SERVICES.—

"(i) IN GENERAL.—For drugs or biologicals defined as within a functional category and furnished on or after January 1, 2024, the Secretary shall implement an add-on adjustment for claims that include such drugs or biologicals that, among other things, shall—

"(I) calculate a per-treatment cost using the most recent cost and utilization data collected during a transitional payment period of not less than 3 years by dividing the total spending for such drug or biological during such transitional period by the total number of treatments for which such drug or biological was listed on such claim during such period of time;

"(II) offset the amount of the add-on adjustment by an amount that corresponds with the reduction in expenditures for other formerly separately billed renal dialysis drugs that

were directly the result of the inclusion of the new product;

''(III) update the add-on adjustment annually to account for inflationary changes; and

''(IV) be applied immediately upon the expiration of the TDAPA period for a product to avoid a gap between the TDAPA and availability of the post-TDAPA add-on adjustment.

''(ii) IMPLEMENTATION.—This policy shall not be implemented in a budget neutral manner.''.

(b) NEW DEVICES AND OTHER TECHNOLOGIES.—As part of the promulgation of the annual rule for the Medicare end-stage renal disease prospective payment system under section 1881(b)(14) of the Social Security Act (42 U.S.C. 1395rr(b)(14)) for calendar year 2022, and in consultation with stakeholders, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall ensure that the single payment amount is adequate to cover the cost of the new innovative device or other technology with substantial clinical improvement and increase the single payment amount if the Secretary

determines such payment amount is not adequate to cover such cost. In carrying out the preceding sentence, the Secretary shall use the cost and utilization data collected during a 3-year transitional payment period, as otherwise described in the final regulation published on November 9, 2020 (85 Fed. Reg. 71398 et seq.).

SEC. 202. ENSURING MEDICARE ADVANTAGE SUPPORTS KIDNEY CARE INNOVATIVE THERAPIES.

Section 1853(c) of the Social Security Act (42 U.S.C. 1395ww–23(c)) is amended by adding the following new paragraph:

''(8) ADJUSTMENT FOR INNOVATIVE PRODUCTS FOR ENROLLES WITH END STAGE RENAL DISEASE.—If the Secretary makes a determination with respect to the application of the End Stage Renal Disease Transitional Drug Add-On Payment Adjustment or the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies to a product under this title that will result in an increase in the costs to Medicare+Choice of providing benefits under contracts under this part for the period of the Transitional Drug Add-On Payment Adjustment or the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies, the Secretary shall directly make

the payments adjustments to providers of services or independent dialysis facilities consistent with the application of such adjustments under the ESRD prospective payment system outlined in section 1881(b)(14) of this title for the complete duration that the adjustment applies under such section. After the duration of such adjustment, the Secretary shall adjust appropriately the payments to such organizations under this part.

''(9) POST-TDAPA PAYMENT ADD-ON ADJUSTMENT.—The Secretary shall require providers of services or independent dialysis facilities to apply the adjustment required under subparagraph (J) of section 1881(b)(14) to payments made under this part.''.

SEC. 203. IMPROVING PATIENT LIVES AND QUALITY OF CARE THROUGH RESEARCH AND INNOVATION.

(a) STUDY.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall conduct a study on increasing kidney transplantation rates. Such study shall include an analysis of each of the following:

(1) Any disincentives in the payment systems under the Medicare program under title XVIII of

the Social Security Act (42 U.S.C. 1395 et seq.) that create barriers to kidney transplants and post-transplant care for beneficiaries with end-stage renal disease.

(2) The practices used by States with higher than average donation rates and whether those practices and policies could be successfully utilized in other States.

(3) Practices and policies that could increase deceased donation rates of minority populations.

(4) Whether cultural and policy barriers exist to increasing living donation rates, including an examination of how to better facilitate chained donations.

(5) Other areas determined appropriate by the Secretary.

(b) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under subsection (a), together with such recommendations as the Secretary determines to be appropriate.

TITLE III—ADDRESSING THE KIDNEY CARE WORKFORCE CRISIS

SEC. 301. ENSURING ACCURACY AND STABILITY IN KIDNEY CARE PAYMENT.

Section 1881(b)(14) of the Social Security Act (42 U.S.C. 1395ww(b)(14)) is amended by adding the following new subparagraph:

''(K) Beginning with calendar year 2024, the Secretary shall compute an adjustment to the annual update of the previous calendar year's rate to account for forecast error. The initial adjustment (in calendar year 2024) to the update of the previous calendar year's rate will take into account the cumulative forecast error between calendar years 2021 and 2022. Subsequent adjustments in succeeding fiscal years will take into account the forecast error from the most recently available calendar year for which there is final data. The forecast error adjustment shall apply whenever the difference between the forecasted and actual percentage change in the ESRD market basket index exceeds the threshold of 0.5 percentage points.''.

SEC. 302. ENCOURAGING KIDNEY CARE WORKFORCE IN UNDER SERVED AREAS.

(a) DEFINITION OF PRIMARY CARE SERVICES.—Section 331(a)(3)(D) of the Public Health Service Act (42 U.S.C. 254d(a)(3)(D)) is amended by inserting ''renal dialysis,'' after ''dentistry,''.

(b) NATIONAL HEALTH SERVICE CORPS SCHOLARSHIP PROGRAM.—Section 338A(a)(2) of the Public Health Service Act (42 U.S.C. 254l(a)(2)) is amended by inserting '', which may include nephrology health professionals'' before the period at the end.

(c) NATIONAL HEALTH SERVICE CORPS LOAN REPAYMENT PROGRAM.—Section 338B(a)(2) of the Public Health Service Act (42 U.S.C. 254l–1(a)(2)) is amended by inserting '', which may include nephrology health professionals'' before the period at the end.

TITLE IV—EXPANDING PATIENT CHOICE OF COVERAGE

SEC. 401. MEDIGAP COVERAGE FOR BENEFICIARIES WITH END-STAGE RENAL DISEASE.

(a) GUARANTEED AVAILABILITY OF MEDIGAP POLICIES TO ALL ESRD MEDICARE BENEFICIARIES.—

(1) IN GENERAL.—Section 1882(s) of the Social Security Act (42 U.S.C. 1395ss(s)) is amended—

(A) in paragraph (2)—

(i) in subparagraph (A), by striking ''is 65'' and all that follows through the period and inserting the following: ''is—

''(i) 65 years of age or older and is enrolled for benefits under part B; or

''(ii) entitled to benefits under 226A(b) and is enrolled for benefits under part B.''; and

(ii) in subparagraph (D), in the matter preceding clause (i), by inserting ''(or is entitled to benefits under 226A(b))'' after ''is 65 years of age or older''; and

(B) in paragraph (3)(B)—

(i) in clause (ii), by inserting ''(or is entitled to benefits under 226A(b))'' after ''is 65 years of age or older''; and

(ii) in clause (vi), by inserting ''(or under 226A(b))'' after ''at age 65''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to Medicare supplemental policies effective on or after January 1, 2022.

(b) ADDITIONAL ENROLLMENT PERIOD FOR CERTAIN INDIVIDUALS.—

(1) ONE-TIME ENROLLMENT PERIOD.—

(A) IN GENERAL.—In the case of an individual described in subparagraph (B), the Secretary of Health and Human Services shall establish a one-time enrollment period during which such an individual may enroll in any Medicare supplemental policy under section 1882 of the Social Security Act (42 U.S.C. 1395ss) of the individual's choosing.

(B) ENROLLMENT PERIOD.—The enrollment period established under subparagraph (A) shall begin on January 1, 2023, and shall end June 30, 2023.

(2) INDIVIDUAL DESCRIBED.—An individual described in this paragraph is an individual who—

(A) is entitled to hospital insurance benefits under part A of title XVIII of the Social Security Act under section 226A(b) of such Act (42 U.S.C. 426–1);

(B) is enrolled for benefits under part B of such title XVIII; and

(C) would not, but for the provisions of, and amendments made by, subsection (a) be eligible for the guaranteed issue of a Medicare supplemental policy under paragraph (2) or (3)

of section 1882(s) of such Act (42 U.S.C. 1395ss(s)).

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