## H. R. 5426

To amend title XVIII of the Social Security Act to provide for Medicare coverage of staff-assisted home dialysis for certain hemodialysis and peritoneal dialysis patients and to ensure all patients are educated on modality options and receive the resources, information, and support to succeed on the modality of their choice, and for other purposes.

## IN THE HOUSE OF REPRESENTATIVES

September 29, 2021

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

## A BILL

To amend title XVIII of the Social Security Act to provide for Medicare coverage of staff-assisted home dialysis for certain hemodialysis and peritoneal dialysis patients and to ensure all patients are educated on modality options and receive the resources, information, and support to succeed on the modality of their choice, 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,

## 1 SECTION 1. SHORT TITLE.

| 2  | This Act may be cited as the "Improving Access to    |
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| 3  | Home Dialysis Act of 2021".                          |
| 4  | SEC. 2. PROVIDING FOR STAFF-ASSISTED HOME DIALYSIS   |
| 5  | FOR CERTAIN HEMODIALYSIS AND PERI-                   |
| 6  | TONEAL DIALYSIS PATIENTS.                            |
| 7  | (a) In General.—Section 1881(b)(14) of the Social    |
| 8  | Security Act (42 U.S.C. 1395rr(b)(14)) is amended by |
| 9  | adding at the end the following new subparagraph:    |
| 10 | "(J)(i) For services furnished on or after           |
| 11 | the date which is 1 year after the date of the       |
| 12 | enactment of this subparagraph which are staff-      |
| 13 | assisted home dialysis (as defined in clause         |
| 14 | (iv)(III)), the Secretary shall increase the single  |
| 15 | payment that would otherwise apply under this        |
| 16 | paragraph for renal dialysis services furnished      |
| 17 | to new and respite individuals in accordance         |
| 18 | with the payment system established under            |
| 19 | clause (iii) by qualified providers.                 |
| 20 | "(ii)(I) Subject to subclause (II), staff-as-        |
| 21 | sisted home dialysis may only be furnished dur-      |
| 22 | ing—   |
| 23 | "(aa) with respect to an individual de-              |
| 24 | scribed in subclause (iv)(I)(aa), one 90-day         |
| 25 | period which may be renewed up to two                |
| 26 | 30-day periods; and                                  |

| 1  | "(bb) with respect to an individual de-            |
|----|--|
| 2  | scribed in subclause (iv)(I)(bb) and not-          |
| 3  | withstanding whether such an individual            |
| 4  | receives any respite care under part A, any        |
| 5  | 30-day period.                                     |
| 6  | "(II) Notwithstanding the limits described         |
| 7  | in subclause (I), staff-assisted home dialysis     |
| 8  | may be furnished for as long as the Secretary      |
| 9  | determines appropriate to an individual who—       |
| 10 | "(aa) is blind;                                    |
| 11 | "(bb) has a cognitive or neurological              |
| 12 | impairment (including a stroke, Alz-               |
| 13 | heimer's, dementia amyotrophic lateral             |
| 14 | sclerosis, or any other impairment deter-          |
| 15 | mined by the Secretary); or                        |
| 16 | "(cc) has any other illness or injury              |
| 17 | that reduces mobility (including cerebral          |
| 18 | palsy, spinal cord injuries, or any other ill-     |
| 19 | ness or injury determined by the Sec-              |
| 20 | retary).   |
| 21 | "(iii) The Secretary shall establish a pro-        |
| 22 | spective payment system through regulations to     |
| 23 | determine the amounts payable to qualified pro-    |
| 24 | viders for staff-assisted home dialysis. In estab- |

| 1  | lishing such system, the Secretary may con- |
|----|---|
| 2  | sider—                                      |
| 3  | "(I) the costs of furnishing staff-as-      |
| 4  | sisted home dialysis;                       |
| 5  | "(II) consultations with dialysis pro-      |
| 6  | viders, dialysis patients, private payers,  |
| 7  | and MA plans;                               |
| 8  | "(III) payment amounts for similar          |
| 9  | items and services under parts A and B;     |
| 10 | and   |
| 11 | "(IV) payment amounts established           |
| 12 | by MA plans under part C, group health      |
| 13 | plans, and health insurance coverage of-    |
| 14 | fered by health insurance issuers.          |
| 15 | "(iv) In this subparagraph:                 |
| 16 | "(I) The term 'new and respite indi-        |
| 17 | vidual' means an individual described in    |
| 18 | subsection (a) who is either—               |
| 19 | "(aa) initiating either peritoneal          |
| 20 | or home hemodialysis; or                    |
| 21 | "(bb) receiving home dialysis and           |
| 22 | is unable to self-dialyze due to illness,   |
| 23 | injury, caregiver issues, or other tem-     |
| 24 | porary circumstances.                       |

| 1  | "(II) The term 'qualified provider'         |
|----|---|
| 2  | means a trained professional (as deter-     |
| 3  | mined by the Secretary, including nurses    |
| 4  | and certified patient technicians) who fur- |
| 5  | nishes renal dialysis services and—         |
| 6  | "(aa) meets requirements (as de-            |
| 7  | termined by the Secretary) that en-         |
| 8  | sures competency in patient care and        |
| 9  | modality usage; and                         |
| 10 | "(bb) provides in-person assist-            |
| 11 | ance to a patient for at least 75 per-      |
| 12 | cent of staff-assisted home dialysis        |
| 13 | sessions during a period described in       |
| 14 | clause (ii)(i).                             |
| 15 | "(III)(aa) The term 'staff-assisted         |
| 16 | home dialysis' means home dialysis using    |
| 17 | trained professionals to assist individuals |
| 18 | who have been determined to have end        |
| 19 | stage renal disease, and the frequency of   |
| 20 | such home dialysis is determined by such    |
| 21 | professionals in coordination with the pa-  |
| 22 | tient and his or her care partner, and out- |
| 23 | lined in a patient plan of care.            |
| 24 | "(bb) In this subclause, the term 'care     |
| 25 | partner' means anyone who is designated     |

| 1  | by the patient who assists the individual          |
|----|--|
| 2  | with the furnishing of home dialysis.              |
| 3  | "(cc) In this subclause, the term 'pa-             |
| 4  | tient plan of care' has the meaning given          |
| 5  | such term in section 494.90 of title 42,           |
| 6  | Code of Federal Regulations.".                     |
| 7  | (b) Patient Education and Training Relating        |
| 8  | TO STAFF-ASSISTED HOME DIALYSIS.—Section           |
| 9  | 1881(b)(5) of the Social Security Act (42 U.S.C.   |
| 10 | 1395rr(b)(5)) is amended—                          |
| 11 | (1) in subparagraph (C), by striking at the end    |
| 12 | "and";   |
| 13 | (2) in subparagraph (D), by striking the period    |
| 14 | at the end and inserting a semicolon; and          |
| 15 | (3) by adding at the end the following new sub-    |
| 16 | paragraphs:  |
| 17 | "(D) educate patients of the opportunity to        |
| 18 | receive staff-assisted home dialysis (as defined   |
| 19 | in paragraph $(14)(J)(iv)(III))$ during the period |
| 20 | beginning 30 days after the first day such facil-  |
| 21 | ity furnishes renal dialysis services to an indi-  |
| 22 | vidual and ending 60 days after such day; and      |
| 23 | "(E) provide for nurses, certified patient         |
| 24 | technicians, or other professionals to train pa-   |
| 25 | tients and their care partners in skills and pro-  |

| 1  | cedures needed to perform home dialysis (as de-   |
|----|---|
| 2  | fined in paragraph $(14)(J)(iv)(III))$ treat-     |
| 3  | ment—   |
| 4  | "(i) regularly and independently;                 |
| 5  | "(ii) through telehealth services or              |
| 6  | through group training (as described in the       |
| 7  | interpretive guidance relating to tag num-        |
| 8  | ber V590 of 'Advance Copy—End Stage               |
| 9  | Renal Disease (ESRD) Program Interpre-            |
| 10 | tive Guidance Version 1.1' (published on          |
| 11 | October 3, 2008)) in accordance with the          |
| 12 | Federal regulations (concerning the privacy       |
| 13 | of individually identifiable health informa-      |
| 14 | tion) promulgated under section 264(c) of         |
| 15 | the Health Insurance Portability and Ac-          |
| 16 | countability Act of 1996; and                     |
| 17 | "(iii) in the home or resident of a pa-           |
| 18 | tient, in a dialysis facility, or the place in    |
| 19 | which the patient intends to receive staff-       |
| 20 | assisted home dialysis.".                         |
| 21 | (c) Other Provisions.—                            |
| 22 | (1) Anti-kickback statute.—Section                |
| 23 | 1128B(b)(3) of the Social Security Act (42 U.S.C. |
| 24 | 1320a-7b(b)(3)) is amended—                       |

| 1  | (A) in subparagraph (J), by striking at the         |
|----|---|
| 2  | end "and";  |
| 3  | (B) in subparagraph (K), by striking the            |
| 4  | period at the end and inserting "; and"; and        |
| 5  | (C) by adding at the end the following new          |
| 6  | subparagraph:                                       |
| 7  | "(L) any remuneration relating to the fur-          |
| 8  | nishing of staff-assisted home dialysis (as de-     |
| 9  | fined in section $1881(b)(14)(J)(iv)(III)$ .".      |
| 10 | (2) CMI MODEL.—Section 1115A(b)(2)(B) of            |
| 11 | the Social Security Act (42 U.S.C. 1320b-(b)(2)(B)) |
| 12 | is amended by adding at the end the following new   |
| 13 | clause:   |
| 14 | "(xxviii) Making payment to anyone                  |
| 15 | who is designated by a patient who re-              |
| 16 | ceives staff-assisted home dialysis (as de-         |
| 17 | fined in section $1881(b)(14)(J)(iv)(III)$          |
| 18 | and otherwise meets the requirements (as            |
| 19 | determined by the Secretary), notwith-              |
| 20 | standing whether an individual is a quali-          |
| 21 | fied provider (as defined in section                |
| 22 | 1881(b)(14)(J)(iv)(II)) or otherwise eligi-         |
| 23 | ble for reimbursement under title XVIII.".          |
| 24 | (3) STUDY.—Not later than 2 years after the         |
| 25 | date of the enactment of this Act, the Secretary of |

- Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate a report that examines racial disparities in the utilization of the home dialysis defined in sec-tion 1881(b)(14)(J)(iv)(III) of the Social Security Act (42 U.S.C. 1395rr(b)(14)(J)(iv)(III)) and make recommendations on how to improve access to such dialysis for communities of color.
  - (4) Patient decision tool.—Not later than December 31, 2023, for the purpose of section 1881(b)(14)(J) of the Social Security Act (42 U.S.C. 1395rr(b)(14)(J)), the Secretary of Health and Human Services shall convene a patient panel to create a patient-centered decision tool for dialysis patients to evaluate their lifestyle and goals and be assisted in choosing the dialysis modality that best suits them. This tool should include an acknowledgment that they are capable of home dialysis and want home dialysis, if that is the modality they choose.
  - (5) PATIENT QUALITY OF LIFE METRIC.—Section 1115A(b)(2)(B) of the Social Security Act (42 U.S.C. 1315a(b)(2)(B)) is amended by adding at the end the following new subparagraph:

| 1 | "(i) A patient quality of life metric for     |
|---|---|
| 2 | all patients utilizing dialysis regardless of |
| 3 | modality with the intent of measuring and     |
| 4 | improving patient quality of life on dialy-   |
| 5 | sis.''.                                       |

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