

108TH CONGRESS  
1ST SESSION

# H. R. 3635

To amend the Social Security Act to provide for coverage under the Medicare Program of chronic kidney disease patients who are not end-stage renal disease patients.

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## IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 21, 2003

Mr. STARK (for himself, Mr. McDERMOTT, Mr. KENNEDY of Rhode Island, Mr. FROST, Mrs. CHRISTENSEN, Mr. JEFFERSON, and Mr. McNULTY) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend the Social Security Act to provide for coverage under the Medicare Program of chronic kidney disease patients who are not end-stage renal disease patients.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Medicare Chronic Kid-  
5       ney Disease Management Act of 2003”.

6       **SEC. 2. FINDINGS.**

7       Congress makes the following findings:

1           (1) Clinical research indicates that in 2003,  
2           more than 300,000 Americans suffer from end-stage  
3           renal disease.

4           (2) Clinical research also indicates that by  
5           2010, the number of Americans who will suffer from  
6           end-stage renal disease is expected to exceed  
7           600,000.

8           (3) Clinical research also indicates that adult  
9           patients who are diagnosed as having advanced  
10          chronic kidney disease have a high likelihood of re-  
11          quiring treatment for end-stage renal disease within  
12          6- to 18-month period after such diagnosis.

13          (4) Clinical research also indicates that appro-  
14          priate medical treatment, and education and coun-  
15          seling services, furnished during the period referred  
16          to in paragraph (3) has been found to—

17                (A) decrease significantly both morbidity  
18                and mortality rates for such patients when  
19                treatment for end-stage renal disease is initi-  
20                ated; and

21                (B) slow down the progression from ad-  
22                vanced kidney disease to end-stage renal dis-  
23                ease.

1 **SEC. 3. DELAYING ONSET OF AND DECREASING MORBIDITY**  
2 **AND MORTALITY RATES FOR END-STAGE**  
3 **RENAL DISEASE.**

4 (a) MEDICARE COVERAGE OF CHRONIC KIDNEY DIS-  
5 EASE PATIENTS.—

6 (1) IN GENERAL.—Section 226A of the Social  
7 Security Act (42 U.S.C. 426–1) is amended—

8 (A) by redesignating the last subsection as  
9 subsection (e); and

10 (B) by inserting after subsection (c) the  
11 following new subsection:

12 “(d)(1)(A) Notwithstanding any provision to the con-  
13 trary in section 226 of title XVIII, every qualified chronic  
14 kidney disease patient (as defined in paragraph (2)) shall,  
15 in accordance with the succeeding provisions of this sec-  
16 tion, be entitled to benefits under part A and eligible to  
17 enroll under part B of title XVIII, subject to the deduct-  
18 ible, premium, and coinsurance provisions of that title.

19 “(B) No qualified chronic kidney disease patient may  
20 enroll under part C of title XVIII.

21 “(2) For purposes of this subsection, the term ‘quali-  
22 fied chronic kidney disease patient’ means an individual—

23 “(A) who would otherwise be described in sub-  
24 section (a) but for paragraph (2) of that subsection;

25 “(B) who has been diagnosed with chronic kid-  
26 ney disease;

1 “(C) with respect to whom, a physician makes  
2 a certification that the individual—

3 “(i) has advanced chronic kidney disease  
4 (as defined in paragraph (3)), and, in the case  
5 of such an individual who is under 18 years of  
6 age, will likely need dialysis treatments or a  
7 kidney transplant within the 18-month period  
8 beginning on the date of the certification; and

9 “(ii) may benefit from a program of pre-  
10 ESRD services (as defined in section  
11 1861(w)(1)); and

12 “(D) who does not have health insurance cov-  
13 erage, as certified by the individual, parent, or legal  
14 guardian, as the case may be.

15 “(3) For purposes of this subsection, the term ‘ad-  
16 vanced chronic kidney disease’ means with respect to kid-  
17 ney disease a glomerular filtration rate of 30ml/min per  
18 1.73 m<sup>2</sup> or less.”.

19 (2) CONFORMING AMENDMENT.—Section 1811  
20 of such Act (42 U.S.C. 1395c) is amended by insert-  
21 ing before the period the following: “or who are  
22 qualified chronic kidney disease patients (as defined  
23 in section 226A(d)(2))”.

24 (3) EFFECTIVE DATE.—The amendments made  
25 by this subsection shall take effect on the date that

1 is 6 months after the date of the enactment of this  
2 Act.

3 (b) COVERAGE OF PRE-ESRD SERVICES.—

4 (1) IN GENERAL.—Section 1861(s)(2) of the  
5 Social Security Act (42 U.S.C. 1395x(s)(2)) is  
6 amended—

7 (A) by striking “and” at the end of sub-  
8 paragraph (U);

9 (B) by inserting “and” at the end of sub-  
10 paragraph (V); and

11 (C) by adding at the end the following new  
12 subparagraph:

13 “(W) pre-ESRD services (as defined in sub-  
14 section (ww)(1)) for an individual who has been di-  
15 agnosed with chronic kidney disease and, with re-  
16 spect to whom, a physician makes a certification de-  
17 scribed in section 226A(d)(2)(C);”.

18 (2) SERVICES DESCRIBED.—Section 1861 of  
19 such Act (42 U.S.C. 1395x) is amended by adding  
20 at the end the following new subsection:

21 “Pre-ESRD Services

22 “(ww) The term ‘pre-ESRD Services’ means any or  
23 all of the following services:

24 “(1) Individual and group nutritional coun-  
25 seling services for the purpose of chronic kidney dis-

1 ease management that are furnished by a registered  
2 dietitian or nutrition professional (as defined in sub-  
3 section (vv)(2)) pursuant to a referral by a physician  
4 (as defined in subsection (r)(1)).

5 “(2) Counseling furnished by qualified health  
6 care providers that—

7 “(A) provides comprehensive information  
8 regarding the management of comorbidities,  
9 and the prevention of uremic complications;

10 “(B) ensures active participation of the in-  
11 dividual in the choice of therapy or therapies;  
12 and

13 “(C) provides comprehensive information  
14 regarding modalities of treatment for kidney  
15 disease and end-stage renal disease, including  
16 organ transplantation, hemodialysis, peritoneal  
17 dialysis, and home dialysis.

18 “(3) Counseling, items and services, including  
19 tissue typing, furnished by qualified health care pro-  
20 viders for preparation of possible organ transplan-  
21 tation.

22 “(4) Items and services furnished by qualified  
23 health care providers for the preparation of vascular  
24 access required for dialysis treatment.

1           “(5) Such other services as the Secretary deter-  
2           mines appropriate, in consultation with national or-  
3           ganizations representing individuals and entities who  
4           furnish pre-ESRD services and patients receiving  
5           such services.”.

6           (3) QUALIFICATION CRITERIA.—The Secretary  
7           of Health and Human Services shall establish such  
8           criteria as the Secretary determines appropriate for  
9           qualifications required for individuals to furnish pre-  
10          ESRD services under section 1861(w) of the Social  
11          Security Act, as added by paragraph (2), after con-  
12          sulting with representatives of the following:

13                (A) Physicians, including board certified  
14                nephrologists.

15                (B) Certified nephrology nurses.

16                (C) Certified nephrology dietitians.

17                (D) Certified nephrology nutritionists.

18                (E) Certified nephrology social workers.

19                (F) Kidney patient organizations.

20                (G) Health educators.

21                (H) Dialysis facilities.

22                (I) Transplant centers.

23                (J) Network administrative organization  
24                designated under section 1881(c) of the Social  
25                Security Act (42 U.S.C. 1395rr(c)).

1           (K) Such other individuals with appro-  
 2           priate expertise as the Secretary may specify.

3           (c) PAYMENT AMOUNT.—

4           (1) IN GENERAL.—Section 1833(a)(1) of the  
 5           Social Security Act (42 U.S.C. 1395l(a)(1)) is  
 6           amended—

7                     (A) by striking “and” before “(U)”;

8                     (B) by inserting before the semicolon at  
 9           the end the following: “, and (V) with respect  
 10          to pre-ESRD services, the amount paid shall be  
 11          80 percent of the amount determined under the  
 12          fee schedule established under section 1834(e)”.

13          (2) ESTABLISHMENT OF FEE SCHEDULE.—Sec-  
 14          tion 1834 of such Act (42 U.S.C. 1395m) is amend-  
 15          ed by inserting after subsection (d) the following  
 16          new subsection:

17          “(e) FEE SCHEDULE FOR PRE-ESRD SERVICES.—

18                     “(1) IN GENERAL.—The Secretary shall estab-  
 19          lish a fee schedule for payment for pre-ESRD serv-  
 20          ices in accordance with the requirements of this sub-  
 21          section.

22                     “(2) CONSIDERATIONS.—In establishing such  
 23          fee schedule, the Secretary shall—

24                             “(A) establish mechanisms to promote the  
 25          efficient delivery of care;

1           “(B) establish definitions for pre-ESRD  
2           services which link payments to the type of  
3           services provided;

4           “(C) consider appropriate regional and  
5           operational differences; and

6           “(D) consider adjustments to payment  
7           rates to account for inflation and other relevant  
8           factors.

9           “(3) CONSULTATION.—In establishing the fee  
10          schedule for pre-ESRD services under this sub-  
11          section, the Secretary shall consult with various na-  
12          tional organizations representing individuals and en-  
13          tities who furnish pre-ESRD services and patients  
14          receiving such services.

15          “(4) CODING SYSTEM.—The Secretary may re-  
16          quire the claim for any services for which the  
17          amount of payment is determined under this sub-  
18          section to include a code (or codes) under a uniform  
19          coding system specified by the Secretary that identi-  
20          fies the services furnished.”.

21          (3) PERMITTING DIALYSIS FACILITIES TO BILL  
22          FOR PRE-ESRD SERVICES FURNISHED IN THE FACIL-  
23          ITY.—Section 1881(b) is amended by adding at the  
24          end the following new paragraph:

1       “(12) A renal dialysis facility may provide for the fur-  
2 nishing of some or all pre-ESRD services (as defined in  
3 section 1861(ww)(2)). The facility may submit to the Sec-  
4 retary a claim for payment for such services furnished in  
5 the facility, and the Secretary shall not require the facility,  
6 or the employee of the facility who is qualified to furnish  
7 such services, to apply for a separate provider number for  
8 purposes of payment under this title.”.

9       (d) ANNUAL REPORTS TO CONGRESS.—

10           (1) IN GENERAL.—Not later than 18 months  
11 after the date of the enactment of this Act, and an-  
12 nually thereafter, the Secretary of Health and  
13 Human Services shall submit to Congress reports on  
14 the matters described in paragraph (2) with respect  
15 to pre-ESRD services (described in section  
16 1861(ww) of the Social Security Act) furnished dur-  
17 ing the preceding year.

18           (2) MATTERS DESCRIBED.—Reports under  
19 paragraph (1) shall include—

20               (A) an assessment of the number of medi-  
21 care beneficiaries who are entitled to pre-ESRD  
22 services;

23               (B) an assessment of the number of medi-  
24 care beneficiaries who are furnished such serv-  
25 ices under the medicare program;

1 (C) an analysis of the patient outcomes  
2 and costs of furnishing care to the medicare  
3 beneficiaries who are furnished such pre-ESRD  
4 services as compared to such outcomes and  
5 costs with respect to other beneficiaries for the  
6 same health conditions;

7 (D) an evaluation of patient satisfaction;  
8 and

9 (E) such recommendations for legislative  
10 and administrative action as the Secretary de-  
11 termines appropriate.

12 **SEC. 4. DEMONSTRATION PROJECT FOR HOME DIALYSIS**  
13 **PEER EDUCATION.**

14 (a) ESTABLISHMENT.—Subject to the succeeding  
15 provisions of this section, the Secretary shall establish  
16 demonstration projects to evaluate methods through which  
17 peer education may—

18 (1) slow down or prevent the progress of kidney  
19 disease to end-stage renal disease in medicare bene-  
20 ficiaries;

21 (2) improve the management of co-morbid con-  
22 ditions associated with kidney disease;

23 (3) improve choice in selection of renal replace-  
24 ment therapies (including home dialysis); and

1           (4) improve other outcomes (such as employ-  
2       ment).

3       (b) CONDUCT THROUGH KIDNEY PATIENT ORGANI-  
4       ZATIONS.—The Secretary shall carry out the demonstra-  
5       tion projects in collaboration with kidney patient organiza-  
6       tions with demonstrated expertise in kidney patient peer  
7       education programs.

8       (c) PAYMENT.—Payment under the demonstration  
9       project shall be made by the Secretary in such amounts  
10      and using such methodology as the Secretary determines  
11      to be appropriate.

12      (d) VOLUNTARY PARTICIPATION.—Participation of  
13      medicare beneficiaries in the demonstration projects shall  
14      be voluntary.

15      (e) DEMONSTRATION PROJECTS SITES.—Not later  
16      than 1 years after the date of the enactment of this Act,  
17      the Secretary shall conduct no fewer than 2 demonstration  
18      projects established under this section. Of those dem-  
19      onstration projects, the Secretary shall conduct at least  
20      one in an urban area and one in a rural area.

21      (f) DURATION.—The Secretary shall carry out the  
22      demonstration projects over a period of three years.

23      (g) EVALUATION AND REPORT.—

1           (1) EVALUATIONS.—The Secretary shall con-  
2       duct evaluations of the clinical and cost effectiveness  
3       of the demonstration projects.

4           (2) REPORTS.—After the conclusion of the  
5       demonstration projects under this section, the Sec-  
6       retary shall submit to Congress a report on the eval-  
7       uation, and shall include in the report the following:

8           (A) An analysis of the patient outcomes  
9       and costs of furnishing care to the medicare  
10      beneficiaries participating in the projects as  
11      compared to such outcomes and costs to other  
12      beneficiaries for the same health conditions.

13          (B) Evaluation of patient satisfaction  
14      under the demonstration projects.

15          (C) Such recommendations regarding the  
16      extension or expansion of the projects as the  
17      Secretary determines appropriate.

18      (h) WAIVER AUTHORITY.—The Secretary may waive  
19   such requirements of title XVIII of the Social Security Act  
20   as may be necessary for the purposes of carrying out the  
21   demonstration project.

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