

117TH CONGRESS  
1ST SESSION

# H. R. 4809

To amend title XVIII of the Social Security Act to improve access to innovative new medical devices furnished to individuals with end stage renal disease under part B of the Medicare program by establishing a new device add-on payment adjustment under such part.

---

## IN THE HOUSE OF REPRESENTATIVES

JULY 29, 2021

Mr. DANNY K. DAVIS of Illinois 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 improve access to innovative new medical devices furnished to individuals with end stage renal disease under part B of the Medicare program by establishing a new device add-on payment adjustment under such part.

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 “Patient Access to  
5 ESRD New Innovative Devices Act”.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

3 (1) There are approximately 400,000 Medicare  
4 beneficiaries with end-stage renal disease, making up  
5 1 percent of the Medicare population but accounting  
6 for approximately 7 percent of all Medicare spend-  
7 ing.

8 (2) Expected remaining lifetime for dialysis pa-  
9 tients under 80 years old is one-third as long as  
10 their counterparts without ESRD, and for dialysis  
11 patients over 80 years old, it is one-half as long as  
12 that of their counterparts without ESRD.

13 (3) On average, hemodialysis patients are hos-  
14 pitalized nearly twice per year and about 30 percent  
15 have an unplanned rehospitalization within the 30  
16 days following discharge, contributing to high costs  
17 for treating ESRD Medicare beneficiaries.

18 (4) There is a lack of innovative new devices for  
19 ESRD Medicare beneficiaries, in part because of the  
20 lack of reimbursement incentives for novel devices.

21 **SEC. 3. TEMPORARY ADD-ON PAYMENT FOR NEW MEDICAL**  
22 **DEVICES TO DIAGNOSE, TREAT, OR MANAGE**  
23 **END STAGE RENAL DISEASE.**

24 The Secretary of Health and Human Services shall  
25 provide—

1           (1) a three-year temporary add-on payment ad-  
2           justment (as described in section 413.236(d) of title  
3           42, Code of Federal Regulations) for a new medical  
4           device approved by the Food and Drug Administra-  
5           tion under section 513(f)(2) of the Federal Food,  
6           Drug, and Cosmetic Act (21 U.S.C. 360c) on or  
7           after January 1, 2020, and furnished to an indi-  
8           vidual entitled to benefits under part B of title  
9           XVIII of the Social Security Act for the diagnosis,  
10          treatment, or management of end stage renal dis-  
11          ease; and

12          (2) for the adjustment under paragraph (1) to  
13          be implemented in a nonbudget neutral manner  
14          under subparagraph (D)(iv) of section 1881(b)(14)  
15          of the Social Security Act (42 U.S.C.  
16          1395rr(b)(14)(D)(iv)).

○