

116TH CONGRESS
1ST SESSION

H. R. 2710

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

MAY 14, 2019

Mr. DANNY K. DAVIS of Illinois (for himself and Mr. HOLLINGSWORTH) 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. INCREASING PATIENT ACCESS TO INNOVATIVE DE-**
22 **VICES FOR THE TREATMENT OF ESRD.**

23 As part of the promulgation of the annual rule for
24 the Medicare end stage renal disease prospective payment
25 system under section 1881(b)(14) of the Social Security
26 Act (42 U.S.C. 1395rr(b)(14)) for calendar year 2020, the

1 Secretary of Health and Human Services (in this section
2 referred to as the “Secretary”) shall establish a process
3 to provide—

4 (1) an add-on payment adjustment for a new
5 medical device reviewed by the Food and Drug Ad-
6 ministration under section 513(f)(2) or section 515
7 of the Federal Food, Drug, and Cosmetic Act (21
8 U.S.C. 360c, 360e) on or after January 1, 2020,
9 and furnished to a beneficiary for the diagnosis,
10 treatment, or management of end stage renal dis-
11 ease; and

12 (2) for such adjustment to be implemented in
13 a nonbudget neutral manner under subparagraph
14 (D)(iv) of such section 1881(b)(14).

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