

117TH CONGRESS
1ST SESSION

S. 2025

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 SENATE OF THE UNITED STATES

JUNE 10, 2021

Mr. CORNYN (for himself, Ms. SINEMA, Mrs. HYDE-SMITH, and Mr. CARPER) introduced the following bill; which was read twice and referred to the Committee on Finance

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”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

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

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

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

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

19 **SEC. 3. INCREASING PATIENT ACCESS TO INNOVATIVE DE-**
20 **VICES FOR THE TREATMENT OF ESRD.**

21 The Secretary of Health and Human Services shall
22 provide, and may implement by program instruction or
23 otherwise—

24 (1) a 3-year temporary add-on payment adjust-
25 ment under section 1881(b)(14) of the Social Secu-

1 rity Act (42 U.S. 1395rr(b)(14)) for a new medical
2 device approved by the Food and Drug Administra-
3 tion under section 513(f)(2) of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 360c) on or
5 after January 1, 2020, that is furnished to a bene-
6 ficiary for the diagnosis, treatment, or management
7 of end stage renal disease; and
8 (2) for such adjustment to be implemented in
9 a nonbudget neutral manner under such section
10 1881(b)(14).

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