

116TH CONGRESS
1ST SESSION

S. 2751

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

OCTOBER 30, 2019

Mr. CORNYN (for himself, Ms. SINEMA, Mrs. HYDE-SMITH, and Mr. JONES) 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 As part of the promulgation of the annual rule for
 22 the Medicare end stage renal disease prospective payment
 23 system under section 1881(b)(14) of the Social Security
 24 Act (42 U.S.C. 1395rr(b)(14)) for calendar year 2021, the
 25 Secretary of Health and Human Services (in this section

1 referred to as the “Secretary”) shall establish a process
2 to provide—

3 (1) a 3-year temporary add-on payment adjust-
4 ment for a new medical device approved by the Food
5 and Drug Administration under section 513(f)(2) or
6 section 515 of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 360c, 360e) on or after Janu-
8 ary 1, 2020, that provides meaningful clinical im-
9 provement and is furnished to a beneficiary for the
10 diagnosis, treatment, or management of end stage
11 renal disease; and

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

○