116TH CONGRESS
1ST SESSION

S. _____

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

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 _____

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Patient Access to ESRD New Innovative Devices Act''.

SEC. 2. FINDINGS.

Congress finds the following:

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

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

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

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

SEC. 3. INCREASING PATIENT ACCESS TO INNOVATIVE DEVICES FOR THE TREATMENT OF ESRD.

As part of the promulgation of the annual rule for the Medicare end stage renal disease prospective payment system under section 1881(b)(14) of the Social Security Act (42 U.S.C. 1395rr(b)(14)) for calendar year 2021, the Secretary of Health and Human Services (in this section

referred to as the ''Secretary'') shall establish a process to provide—

(1) a 3-year temporary add-on payment adjustment for a new medical device approved by the Food and Drug Administration under section 513(f)(2) or section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c, 360e) on or after January 1, 2020, that provides meaningful clinical improvement and is furnished to a beneficiary for the diagnosis, treatment, or management of end stage renal disease; and

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