

116TH CONGRESS
2D SESSION

S. 3532

To amend titles XVIII and XIX of the Social Security Act to provide coverage of prescription digital therapeutics for the treatment of mental health and substance use disorders under the Medicare and Medicaid programs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 18, 2020

Mrs. CAPITO (for herself and Mrs. SHAHEEN) introduced the following bill;
which was read twice and referred to the Committee on Finance

A BILL

To amend titles XVIII and XIX of the Social Security Act to provide coverage of prescription digital therapeutics for the treatment of mental health and substance use disorders under the Medicare and Medicaid programs, and for other purposes.

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 “Prescription Digital
5 Therapeutics to Support Recovery Act”.

1 **SEC. 2. COVERAGE OF PRESCRIPTION DIGITAL THERA-**
 2 **PEUTICS UNDER THE MEDICARE PROGRAM.**

3 (a) COVERAGE AS MEDICAL AND OTHER HEALTH
 4 SERVICE.—Section 1861(s)(2) of the Social Security Act
 5 (42 U.S.C. 1395x(s)(2)) is amended—

6 (1) in subparagraph (GG), by striking “and” at
 7 the end;

8 (2) in subparagraph (HH), by striking the pe-
 9 riod at the end and inserting “; and”; and

10 (3) by adding at the end the following new sub-
 11 paragraph:

12 “(II) prescription digital therapeutics as defined
 13 in subsection (kkk).”.

14 (b) PRESCRIPTION DIGITAL THERAPEUTICS DE-
 15 FINED.—Section 1861 of the Social Security Act (42
 16 U.S.C. 1395x) is amended by adding at the end thereof
 17 the following new subsection:

18 “(kkk) PRESCRIPTION DIGITAL THERAPEUTICS DE-
 19 FINED.—

20 “(1) IN GENERAL.—The term ‘prescription dig-
 21 ital therapeutic’ means a product, device, internet
 22 application, or other technology that—

23 “(A) is approved or cleared by the Food
 24 and Drug Administration under a relevant au-
 25 thority (within the meaning of paragraph (2));

1 “(B) has an approved indication for the
 2 prevention, management, or treatment of a
 3 mental health or substance use disorder, includ-
 4 ing opioid use disorder;

5 “(C) uses behavioral treatment or modi-
 6 fication to achieve its intended result; and

7 “(D) can only be dispensed pursuant to a
 8 prescription.

9 “(2) RELEVANT AUTHORITY DEFINED.—For
 10 purposes of paragraph (1), the term ‘relevant au-
 11 thority’ means the following sections of the Federal
 12 Food, Drug, and Cosmetic Act:

13 “(A) Section 510(k) of such Act (21
 14 U.S.C. 360(k)).

15 “(B) Section 515 of such Act (21 U.S.C.
 16 360e).”.

17 (c) PAYMENT FOR PRESCRIPTION DIGITAL THERA-
 18 PEUTICS.—Section 1834 of the Social Security Act (42
 19 U.S.C. 1395m) is amended by adding at the end the fol-
 20 lowing new subsection:

21 “(x) PAYMENT FOR PRESCRIPTION DIGITAL THERA-
 22 PEUTICS.—

23 “(1) SEPARATE PAYMENT.—The Secretary shall
 24 make a payment (separate from any payment that
 25 may otherwise be made under this title for a related

1 service) in the amount established pursuant to para-
2 graph (3) for a prescription digital therapeutic (as
3 defined in section 1861(kkk)) that is furnished on or
4 after January 1, 2021.

5 “(2) PAYMENT RECIPIENT.—Payment under
6 this subsection shall be made to any provider of
7 services or supplier enrolled under this title that—

8 “(A) prescribes a prescription digital
9 therapeutic (as defined in such subsection);

10 “(B) uses such prescription digital thera-
11 peutic as an integral part of a treatment for a
12 related service; and

13 “(C) agrees to accept, as payment in full,
14 after the application of any deductible or coin-
15 surance that may be applied under this part,
16 the amount established pursuant to paragraph
17 (3).

18 “(3) ESTABLISHMENT OF PAYMENT AMOUNT.—

19 “(A) IN GENERAL.—The Secretary shall
20 establish a payment methodology for a prescrip-
21 tion digital therapeutic only in accordance with
22 the requirements of this paragraph.

23 “(B) DEVELOPMENT OF FEE SCHED-
24 ULE.—Within 180 days of the approval or
25 clearance described in section 1861(kkk)(1)(A),

1 the Secretary shall develop a proposed fee
2 schedule for each prescription digital thera-
3 peutic so approved or cleared. In developing
4 such fee schedule, the Secretary may use the
5 gap filling process described on 84 Federal
6 Register 60729 through 60742 and published
7 on November 8, 2019.

8 “(C) NOTICE AND COMMENT REQUIRED.—

9 Upon the development of the proposed fee
10 schedule described in subparagraph (B), the
11 Secretary shall publish in the Federal Register
12 such proposed fee schedule. Section 1871 shall
13 apply to any proposed fee scheduled published
14 pursuant to this subparagraph.

15 “(4) RULE OF CONSTRUCTION.—For purposes
16 of paragraph (1), a service is ‘related’ to the use of
17 a prescription digital therapeutic if the service—

18 “(A) is an integral part of the use of the
19 prescription digital therapeutic;

20 “(B) is necessary to achieve the full in-
21 tended result of the prescription digital thera-
22 peutic; and

23 “(C) must, pursuant to the approval or
24 clearance described in section 1861(kkk)(1)(A),

1 be adjunctive to the use of the prescription dig-
 2 ital therapeutic.”.

3 (d) RULE OF CONSTRUCTION; EFFECTIVE DATE.—

4 (1) RULE OF CONSTRUCTION.—No provision of
 5 this section, or the enactment of this section, shall
 6 be construed to imply that, in the case of an item
 7 or service that meets the definition of a prescription
 8 digital therapeutic under this section for which cov-
 9 erage or payment under the Medicare program is al-
 10 ready available prior to the date of the enactment of
 11 this Act may not be covered or reimbursed under
 12 such program.

13 (2) EFFECTIVE DATE.—The amendments made
 14 by this section shall apply to a prescription digital
 15 therapeutic dispensed after December 31, 2020.

16 **SEC. 3. COVERAGE OF PRESCRIPTION DIGITAL THERA-**
 17 **PEUTICS UNDER THE MEDICAID PROGRAM.**

18 Section 1905(a) of the Social Security Act (42 U.S.C.
 19 1396d(a)) is amended—

20 (1) in paragraph (29), by striking “; and” and
 21 inserting a semicolon;

22 (2) by redesignating paragraph (30) as para-
 23 graph (31); and

24 (3) by inserting the following paragraph after
 25 paragraph (29):

- 1 “(30) prescription digital therapeutics (as de-
- 2 fined in section 1861(kkk)); and”.

