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.

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 “Prescription Digital Therapeutics to Support Recovery Act”.

SEC. 2. COVERAGE OF PRESCRIPTION DIGITAL THERAPEUTICS UNDER THE MEDICARE PROGRAM.

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

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

(2) in subparagraph (HH), by striking the period at the end and inserting “; and”; and

(3) by adding at the end the following new subparagraph:

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

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

“(kkk) PRESCRIPTION DIGITAL THERAPEUTICS DEFINED.—

“(1) IN GENERAL.—The term ‘prescription digital therapeutic’ means a product, device, internet application, or other technology that—

“(A) is approved or cleared by the Food and Drug Administration under a relevant authority (within the meaning of paragraph (2));
“(B) has an approved indication for the prevention, management, or treatment of a mental health or substance use disorder, including opioid use disorder;

“(C) uses behavioral treatment or modification to achieve its intended result; and

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

“(2) RELEVANT AUTHORITY DEFINED.—For purposes of paragraph (1), the term ‘relevant authority’ means the following sections of the Federal Food, Drug, and Cosmetic Act:

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

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

(c) PAYMENT FOR PRESCRIPTION DIGITAL THERAPEUTICS.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

“(x) PAYMENT FOR PRESCRIPTION DIGITAL THERAPEUTICS.—

“(1) SEPARATE PAYMENT.—The Secretary shall make a payment (separate from any payment that may otherwise be made under this title for a related
service) in the amount established pursuant to para-
graph (3) for a prescription digital therapeutic (as
defined in section 1861(kkk)) that is furnished on or
after January 1, 2021.

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

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

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

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

“(3) ESTABLISHMENT OF PAYMENT AMOUNT.—

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

“(B) DEVELOPMENT OF FEE SCHED-
ULE.—Within 180 days of the approval or
clearance described in section 1861(kkk)(1)(A),
the Secretary shall develop a proposed fee
schedule for each prescription digital thera-
peutic so approved or cleared. In developing
such fee schedule, the Secretary may use the
gap filling process described on 84 Federal
Register 60729 through 60742 and published
on November 8, 2019.

“(C) NOTICE AND COMMENT REQUIRED.—
Upon the development of the proposed fee
schedule described in subparagraph (B), the
Secretary shall publish in the Federal Register
such proposed fee schedule. Section 1871 shall
apply to any proposed fee scheduled published
pursuant to this subparagraph.

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

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

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

“(C) must, pursuant to the approval or
clearance described in section 1861(kkk)(1)(A),
be adjunctive to the use of the prescription digital therapeutic.”.

(d) Rule of Construction; Effective Date.—

(1) Rule of construction.—No provision of this section, or the enactment of this section, shall be construed to imply that, in the case of an item or service that meets the definition of a prescription digital therapeutic under this section for which coverage or payment under the Medicare program is already available prior to the date of the enactment of this Act may not be covered or reimbursed under such program.

(2) Effective date.—The amendments made by this section shall apply to a prescription digital therapeutic dispensed after December 31, 2020.

SEC. 3. COVERAGE OF PRESCRIPTION DIGITAL THERAPEUTICS UNDER THE MEDICAID PROGRAM.

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

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

(2) by redesignating paragraph (30) as paragraph (31); and

(3) by inserting the following paragraph after paragraph (29):
“(30) prescription digital therapeutics (as defined in section 1861(kkk)); and”.