

118<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

**S.** \_\_\_\_\_

To amend titles XVIII and XIX of the Social Security Act to provide for coverage of prescription digital therapeutics under such titles, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

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Mrs. SHAHEEN introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

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**A BILL**

To amend titles XVIII and XIX of the Social Security Act to provide for coverage of prescription digital therapeutics under such titles, 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 “Access to Prescription  
5 Digital Therapeutics Act of 2023”.

1 **SEC. 2. COVERAGE AND PAYMENT OF PRESCRIPTION DIG-**  
2 **ITAL THERAPEUTICS UNDER THE MEDICARE**  
3 **PROGRAM.**

4 (a) PRESCRIPTION DIGITAL THERAPEUTIC DE-  
5 FINED.—Section 1861 of the Social Security Act (42  
6 U.S.C. 1395x) is amended by adding at the end the fol-  
7 lowing new subsection:

8 “(nnn) PRESCRIPTION DIGITAL THERAPEUTIC.—  
9 The term ‘prescription digital therapeutic’ means a prod-  
10 uct, device, internet application, or other technology  
11 that—

12 “(1) is cleared or approved under section  
13 510(k), 513(f)(2), or 515 of the Federal Food,  
14 Drug, and Cosmetic Act;

15 “(2) has a cleared or approved indication for  
16 the prevention, management, or treatment of a med-  
17 ical disease, condition, or disorder;

18 “(3) primarily uses software to achieve its in-  
19 tended result; and

20 “(4) is a device that is exempt from section  
21 502(f)(1) of the Federal Food, Drug, and Cosmetic  
22 Act under section 801.109 of title 21 of the Code of  
23 Federal Regulations (or any successor regulation).”.

24 (b) COVERAGE AS MEDICAL AND OTHER HEALTH  
25 SERVICE.—Section 1861(s)(2) of the Social Security Act  
26 (42 U.S.C. 1395x(s)(2)) is amended—

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

3 (2) in subparagraph (JJ), by adding “and” at  
4 the end; and

5 (3) by adding at the end the following new sub-  
6 paragraph:

7 “(KK) prescription digital therapeutics fur-  
8 nished on or after January 1, 2024;”.

9 (c) REQUIREMENTS FOR PRESCRIPTION DIGITAL  
10 THERAPEUTICS UNDER MEDICARE.—Part B of the Social  
11 Security Act (42 U.S.C. 1395j et seq.) is amended by in-  
12 serting after section 1834A the following new section:

13 **“SEC. 1834B. REQUIREMENTS FOR PRESCRIPTION DIGITAL**  
14 **THERAPEUTICS.**

15 **“(a) PAYMENT.—**

16 **“(1) IN GENERAL.—**Not later than 1 year after  
17 the date of enactment of this section, the Secretary  
18 shall establish a payment methodology for manufac-  
19 turers of prescription digital therapeutics, which  
20 may consist of a one-time payment or periodic pay-  
21 ments, as determined appropriate by the Secretary.

22 **“(2) CONSIDERATIONS FOR PAYMENT METHOD-**  
23 **LOGY.—**For purposes of establishing the payment  
24 methodology under paragraph (1), the Secretary  
25 shall consider—

1           “(A) the actual list charge of such pre-  
2           scription digital therapeutic;

3           “(B) the weighted median (calculated by  
4           arraying the distribution of all payment rates  
5           reported for the most recent period for which  
6           such rates were reported under subsection  
7           (c)(1) for each prescription digital therapeutic  
8           weighted by volume for each payor and each  
9           manufacturer) for such prescription digital  
10          therapeutic;

11          “(C) in the case of a prescription digital  
12          therapeutic that requires ongoing use, the  
13          amount for such ongoing use; and

14          “(D) other factors as determined by the  
15          Secretary.

16          “(b) CODING.—

17                 “(1) IN GENERAL.—Not later than 2 years  
18                 after the date of enactment of this section, the Sec-  
19                 retary shall establish product-specific HCPCS codes  
20                 for prescription digital therapeutic covered under  
21                 this title.

22                 “(2) TEMPORARY CODE.—The Secretary shall  
23                 adopt temporary product-specific HCPCS codes for  
24                 purposes of providing payment under this title until

1 a permanent product-specific HCPCS code has been  
2 established under paragraph (1).

3 “(c) MANUFACTURER REPORTING.—

4 “(1) IN GENERAL.—Beginning on January 1,  
5 2024, each manufacturer of a prescription digital  
6 therapeutic covered under this title shall submit to  
7 the Secretary, at such time and in such manner as  
8 specified by the Secretary, and annually thereafter,  
9 a report describing—

10 “(A) the payment rate that was paid by  
11 each private payor for each prescription digital  
12 therapeutic during the period specified by the  
13 Secretary;

14 “(B) the volume of such prescription dig-  
15 ital therapeutic distributed to each such payor  
16 for such period; and

17 “(C) the number of individual users of  
18 such prescription digital therapeutic for such  
19 period.

20 “(2) TREATMENT OF DISCOUNTS.—The pay-  
21 ment rate reported by a manufacturer in accordance  
22 with paragraph (1)(A) shall reflect all discounts, re-  
23 bates, coupons, and other price concessions, includ-  
24 ing those described in section 1847A(c)(3).

25 “(3) CIVIL MONETARY PENALTY.—

1           “(A) IN GENERAL.—If the Secretary deter-  
2           mines that a manufacturer has failed to report,  
3           or made a misrepresentation or omission in re-  
4           porting, information under this subsection with  
5           respect to a prescription digital therapeutic, the  
6           Secretary may apply a civil money penalty in an  
7           amount of up to \$10,000 per day for each fail-  
8           ure to report or each such misrepresentation or  
9           omission.

10           “(B) APPLICATION.—The provisions of  
11           section 1128A (other than subsections (a) and  
12           (b)) shall apply to a civil money penalty under  
13           this paragraph in the same manner as they  
14           apply to a civil money penalty or proceeding  
15           under section 1128A(a).

16           “(4) CONFIDENTIALITY.—Information reported  
17           under this subsection shall be treated in the same  
18           manner in which information disclosed by a manu-  
19           facturer or a wholesaler of a covered outpatient drug  
20           is treated under section 1927(b)(3)(D).

21           “(d) DEFINITIONS.—For purposes of this section:

22           “(1) ACTUAL LIST CHARGE.—The term ‘actual  
23           list charge’ means the publicly available payment  
24           rate for a prescription digital therapeutic on the first

1 day that such prescription digital therapeutic is  
2 available for purchase by a private payor.

3 “(2) HCPCS.—The term ‘HCPCS’ means, with  
4 respect to an item, the code under the Healthcare  
5 Common Procedure Coding System (HCPCS) (or a  
6 successor code) for such item.

7 “(3) MANUFACTURER.—The term ‘manufac-  
8 turer’ has the meaning given such term by section  
9 820.3(o) of title 21, Code of Federal Regulations (or  
10 any successor regulation).

11 “(4) PRESCRIPTION DIGITAL THERAPEUTIC.—  
12 The term ‘prescription digital therapeutic’ has the  
13 meaning given such term in section 1861(nnn).

14 “(5) PRIVATE PAYOR.—The term ‘private  
15 payor’ has the meaning given such term in section  
16 1834A(a)(8).”.

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

19 (a) IN GENERAL.—Section 1905(a) of the Social Se-  
20 curity Act (42 U.S.C. 1396d(a)) is amended—

21 (1) in paragraph (30), by striking “; and” and  
22 inserting a semicolon;

23 (2) by redesignating paragraph (31) as para-  
24 graph (32); and

1           (3) by inserting the following paragraph after  
2 paragraph (30):

3           “(31) prescription digital therapeutics (as de-  
4 fined in section 1861(nnn)); and”.

5           (b) CONFORMING AMENDMENTS.—Effective the day  
6 after the amendments made by sections 5121 and 5122  
7 of division FF of the Consolidated Appropriations Act,  
8 2023 (Public Law 117–328) take effect —

9           (1) subsections (a)(84)(A) and (nn)(3) of sec-  
10 tion 1902 of the Social Security Act (42 U.S.C.  
11 1396a) are each amended by striking “paragraph  
12 (31)” and inserting “the last numbered paragraph”;  
13 and

14           (2) the fifth sentence of section 1905(a) of such  
15 Act (42 U.S.C. 1396d(a)) is amended by striking  
16 “paragraph (30)” and inserting “the last numbered  
17 paragraph”.