

119TH CONGRESS
1ST SESSION

H. R. 3288

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

IN THE HOUSE OF REPRESENTATIVES

MAY 8, 2025

Mr. HERN of Oklahoma (for himself and Mr. THOMPSON of California) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend titles XVIII and XIX of the Social Security Act to provide for coverage of prescription digital therapeutics 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 “Access to Prescription
5 Digital Therapeutics Act of 2025”.

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 (JJ), by adding “and” at
 2 the end; and

3 (2) by adding at the end the following new sub-
 4 paragraph:

5 “(KK) prescription digital therapeutics (as de-
 6 fined in subsection (nnn)) furnished on or after Jan-
 7 uary 1, 2026;”.

8 (c) REQUIREMENTS FOR PRESCRIPTION DIGITAL
 9 THERAPEUTICS UNDER MEDICARE.—Part B of title
 10 XVIII of the Social Security Act (42 U.S.C. 1395j et seq.)
 11 is amended by inserting after section 1834A the following
 12 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 the enactment of this section, the Sec-
 18 retary shall establish a payment methodology for
 19 manufacturers of prescription digital therapeutics,
 20 which may consist of a one-time payment or periodic
 21 payments, as determined appropriate by the Sec-
 22 retary.

23 “(2) CONSIDERATIONS FOR PAYMENT METHOD-
 24 OLOGY.—For purposes of establishing the payment

1 methodology under paragraph (1), the Secretary
2 shall consider—

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

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

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

16 “(D) other factors as determined by the
17 Secretary.

18 “(b) CODING.—

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

24 “(2) TEMPORARY CODE.—The Secretary shall
25 adopt temporary product-specific HCPCS codes for

1 purposes of providing payment under this title until
2 a permanent product-specific HCPCS code has been
3 established under paragraph (1).

4 “(c) MANUFACTURER REPORTING.—

5 “(1) IN GENERAL.—Not later than January 1,
6 2026, and not less frequently than annually there-
7 after, each manufacturer of a prescription digital
8 therapeutic covered under this title shall submit to
9 the Secretary, at such time and in such manner as
10 specified by the Secretary, a report describing—

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

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

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

21 “(2) TREATMENT OF DISCOUNTS.—The pay-
22 ment rate reported by a manufacturer under para-
23 graph (1)(A) shall reflect all discounts, rebates, cou-
24 pons, and other price concessions, including those
25 described in section 1847A(c)(3).

1 “(3) CIVIL MONETARY PENALTY.—

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

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

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

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

23 “(1) ACTUAL LIST CHARGE.—The term ‘actual
 24 list charge’ means the publicly available payment
 25 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 in 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 Section 1905(a) of the Social Security Act (42 U.S.C.
 20 1396d(a)) is amended—

21 (1) in paragraph (31), by striking “; and” and
 22 inserting a semicolon;

23 (2) by redesignating paragraph (32) as para-
 24 graph (33); and

1 (3) by inserting after paragraph (31) the fol-
2 lowing new paragraph:
3 “(32) prescription digital therapeutics (as de-
4 fined in section 1861(nnn)); and”.

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