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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

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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 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 "Access to Prescription Digital Therapeutics Act of 2025".

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

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

''(nnn) PRESCRIPTION DIGITAL THERAPEUTIC.—The term 'prescription digital therapeutic' means a product, device, internet application, or other technology that—

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

''(2) has a cleared or approved indication for the prevention, management, or treatment of a medical disease, condition, or disorder;

''(3) primarily uses software to achieve its intended result; and

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

(b) 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 (JJ), by adding ''and'' at the end; and

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

''(KK) prescription digital therapeutics (as defined in subsection (nnn)) furnished on or after January 1, 2026;''.

(c) REQUIREMENTS FOR PRESCRIPTION DIGITAL THERAPEUTICS UNDER MEDICARE.—Part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.) is amended by inserting after section 1834A the following new section:

''SEC. 1834B. REQUIREMENTS FOR PRESCRIPTION DIGITAL THERAPEUTICS.

''(a) PAYMENT.—

''(1) IN GENERAL.—Not later than 1 year after the date of the enactment of this section, the Secretary shall establish a payment methodology for manufacturers of prescription digital therapeutics, which may consist of a one-time payment or periodic payments, as determined appropriate by the Secretary.

''(2) CONSIDERATIONS FOR PAYMENT METHODOLOGY.—For purposes of establishing the payment

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

"(A) the actual list charge of such prescription digital therapeutic;

"(B) the weighted median (calculated by arraying the distribution of all payment rates reported for the most recent period for which such rates were reported under subsection (c)(1) for each prescription digital therapeutic weighted by volume for each payor and each manufacturer) for such prescription digital therapeutic;

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

"(D) other factors as determined by the Secretary.

"(b) CODING.—

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

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

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

''(c) MANUFACTURER REPORTING.—

''(1) IN GENERAL.—Not later than January 1, 2026, and not less frequently than annually thereafter, each manufacturer of a prescription digital therapeutic covered under this title shall submit to the Secretary, at such time and in such manner as specified by the Secretary, a report describing—

''(A) the payment rate that was paid by each private payor for such prescription digital therapeutic during the period specified by the Secretary;

''(B) the volume of such prescription digital therapeutic distributed to each such payor for such period; and

''(C) the number of individual users of such prescription digital therapeutic for such period.

''(2) TREATMENT OF DISCOUNTS.—The payment rate reported by a manufacturer under paragraph (1)(A) shall reflect all discounts, rebates, coupons, and other price concessions, including those described in section 1847A(c)(3).

''(3) CIVIL MONETARY PENALTY.—

''(A) IN GENERAL.—If the Secretary determines that a manufacturer has failed to report, or made a misrepresentation or omission in reporting, information under this subsection with respect to a prescription digital therapeutic, the Secretary may apply a civil money penalty in an amount of up to $10,000 per day for each failure to report or each such misrepresentation or omission.

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

''(4) CONFIDENTIALITY.—Information reported under this subsection shall be treated in the same manner in which information disclosed by a manufacturer or a wholesaler of a covered outpatient drug is treated under section 1927(b)(3)(D).

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

''(1) ACTUAL LIST CHARGE.—The term 'actual list charge' means the publicly available payment rate for a prescription digital therapeutic on the first

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

''(2) HCPCS.—The term 'HCPCS' means, with respect to an item, the code under the Healthcare Common Procedure Coding System (HCPCS) (or a successor code) for such item.

''(3) MANUFACTURER.—The term 'manufacturer' has the meaning given such term in section 820.3(o) of title 21, Code of Federal Regulations (or any successor regulation).

''(4) PRESCRIPTION DIGITAL THERAPEUTIC.—The term 'prescription digital therapeutic' has the meaning given such term in section 1861(nnn).

''(5) PRIVATE PAYOR.—The term 'private payor' has the meaning given such term in section 1834A(a)(8).''.

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 (31), by striking ''; and'' and inserting a semicolon;

(2) by redesignating paragraph (32) as paragraph (33); and

(3) by inserting after paragraph (31) the following new paragraph:

''(32) prescription digital therapeutics (as defined in section 1861(nnn)); and''.

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