

117TH CONGRESS  
2D SESSION

# S. 5238

To require the Administrator of the Centers for Medicare & Medicaid Services to provide guidance regarding coverage of prescription digital therapeutics under Medicaid and the State Children’s Health Insurance Program.

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## IN THE SENATE OF THE UNITED STATES

DECEMBER 12, 2022

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

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## A BILL

To require the Administrator of the Centers for Medicare & Medicaid Services to provide guidance regarding coverage of prescription digital therapeutics under Medicaid and the State Children’s Health Insurance Program.

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 “Medicaid and CHIP  
5 Access to Prescription Digital Therapeutics Act”.

6 **SEC. 2. ASSURANCE OF MEDICAID AND CHIP COVERAGE**

7 **FOR PRESCRIPTION DIGITAL THERAPEUTICS.**

8 (a) IN GENERAL.—

1           (1) ISSUANCE OF GUIDANCE.—Not later than 6  
2 months after the date of enactment of this section,  
3 the Administrator of the Centers for Medicare &  
4 Medicaid Services shall issue guidance to States that  
5 identifies methods for State Medicaid programs  
6 under title XIX of the Social Security Act (42  
7 U.S.C. 1396 et seq.) and State Children’s Health  
8 Insurance Programs under title XXI of such Act (42  
9 U.S.C. 1397aa et seq.) to provide medical assist-  
10 ance, child health assistance, and pregnancy-related  
11 assistance for prescription digital therapeutics and  
12 claim Federal financial participation for providing  
13 such assistance.

14           (2) TECHNICAL ASSISTANCE.—The Adminis-  
15 trator of the Centers for Medicare & Medicaid Serv-  
16 ices may make available technical assistance to a  
17 State that seeks to incur an expenditure for pro-  
18 viding medical assistance, child health assistance, or  
19 pregnancy-related assistance for a prescription dig-  
20 ital therapeutic under the State Medicaid program  
21 or the State Children’s Health Insurance Program  
22 within 30 days of the State submitting a request for  
23 such technical assistance, but in no event shall re-  
24 questing or receiving such technical assistance be a  
25 prerequisite for a State providing any such assist-

1       ance or receiving Federal financial participation for  
2       providing any such assistance.

3           (3) PRESCRIPTION DIGITAL THERAPEUTIC.—In  
4       this section, the term “prescription digital thera-  
5       peutic” means a product, device, internet applica-  
6       tion, or other technology that—

7           (A) is cleared or approved by the Food and  
8       Drug Administration pursuant to section  
9       510(k), 513(f)(2), or 515 of the Federal Food,  
10      Drug, and Cosmetic Act;

11          (B) has a cleared or approved indication  
12      for the prevention, management, or treatment  
13      of a medical disease, condition, or disorder;

14          (C) primarily uses software to achieve its  
15      intended result; and

16          (D) is a device that is exempt from section  
17      502(f)(1) of the Federal Food, Drug, and Cos-  
18      metic Act under section 801.109 of title 21 of  
19      the Code of Federal Regulations (or any suc-  
20      cessor regulation).

21      (b) PROTECTION OF EXISTING MEDICAID AND CHIP  
22      COVERAGE.—Nothing in this section shall be construed to  
23      imply that an expenditure for a prescription digital thera-  
24      peutic that occurred on or before the date of the enact-  
25      ment of this section did not constitute an expenditure for

- 1 medical assistance under a State Medicaid program or for
- 2 child health assistance or pregnancy-related assistance
- 3 under a State Children's Health Insurance Program.

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