

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

# S. 1399

To amend title XVIII of the Social Security Act to ensure appropriate payment of certain algorithm-based healthcare services under the Medicare program.

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## IN THE SENATE OF THE UNITED STATES

APRIL 9, 2025

Mr. ROUNDS (for himself, Mr. HEINRICH, and Mrs. BLACKBURN) introduced the following bill; which was read twice and referred to the Committee on Finance

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## A BILL

To amend title XVIII of the Social Security Act to ensure appropriate payment of certain algorithm-based healthcare services under the Medicare 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 “Health Tech Invest-  
5 ment Act”.

1 **SEC. 2. ENSURING APPROPRIATE PAYMENT OF CERTAIN**  
2 **ALGORITHM-BASED HEALTHCARE SERVICES**  
3 **UNDER THE MEDICARE PROGRAM.**

4 (a) IN GENERAL.—Section 1833(t) of the Social Se-  
5 curity Act (42 U.S.C. 1395l(t)) is amended—

6 (1) in paragraph (2)(E), by inserting “and new  
7 technology ambulatory payment classification of al-  
8 gorithm-based healthcare services under paragraph  
9 (16)(H)” after “(16)(G)”; and

10 (2) in paragraph (16), by adding at the end the  
11 following new subparagraph:

12 “(H) SPECIAL RULE FOR CERTAIN ALGO-  
13 RITHM-BASED HEALTHCARE SERVICES.—

14 “(i) IN GENERAL.—In the case of a  
15 covered OPD service furnished on or after  
16 January 1, 2026, that is an algorithm-  
17 based healthcare service (as defined in  
18 clause (ii)) that is assigned to a new tech-  
19 nology ambulatory payment classification  
20 (as described in the final rule entitled  
21 ‘Medicare Program; Changes to the Hos-  
22 pital Outpatient Prospective Payment Sys-  
23 tem for Calendar Year 2002’ published by  
24 the Department of Health and Human  
25 Services on November 30, 2001 (66 Fed.  
26 Reg. 59897)) on or after the date of the

1 enactment of this subparagraph or for  
2 which, as of such date, is currently and  
3 has been assigned to a new technology am-  
4 bulatory payment classification for a pe-  
5 riod of less than 5 years, the Secretary—

6 “(I) shall ensure that such serv-  
7 ice is assigned to a new technology  
8 ambulatory payment classification  
9 based on the cost of such service as  
10 submitted by the manufacturer of  
11 such service in a form and manner  
12 specified by the Secretary, including  
13 costs for the technology based on in-  
14 voice prices, subscription-based prices,  
15 clinical staff, overhead, and other  
16 costs associated with providing the  
17 service;

18 “(II) shall adjust the new tech-  
19 nology ambulatory payment classifica-  
20 tion pursuant to subclause (I) as nec-  
21 essary; and

22 “(III) may not remove such serv-  
23 ice from the new technology ambula-  
24 tory payment classification as deter-  
25 mined under subclauses (I) and (II)

1           until the Secretary determines that  
2           adequate claims data exists to reas-  
3           sign such service to another ambula-  
4           tory payment classification (which in  
5           no case may be before such service  
6           has received payment under the as-  
7           signed new technology ambulatory  
8           payment classification for at least 5  
9           years).

10           “(ii) ADJUSTMENT.—The Secretary  
11           shall adjust the application process and  
12           criteria for the new technology ambulatory  
13           payment classification to ensure that, in  
14           addition to currently eligible algorithm-  
15           based healthcare services, algorithm-based  
16           healthcare services that otherwise meet the  
17           eligibility requirements for such classifica-  
18           tion and are distinct from but performed  
19           concurrently with, adjunctive to, or pro-  
20           vided in any other modality or form as  
21           part of an underlying service and require  
22           additional resources, meet—

23                   “(I) the eligibility requirement  
24                   that they are distinct new procedures  
25                   with a beginning, middle, and end; or

1 “(II) any subsequent similar new  
2 technology ambulatory payment classi-  
3 fication eligibility requirement.

4 “(iii) DEFINITION OF ALGORITHM-  
5 BASED HEALTHCARE SERVICE.—For pur-  
6 poses of this subparagraph, the term ‘algo-  
7 rithm-based healthcare service’ means a  
8 service delivered through a device cleared  
9 or approved by the Food and Drug Admin-  
10 istration that uses artificial intelligence,  
11 machine learning, or other similarly de-  
12 signed software to yield clinical outputs or  
13 generate clinical conclusions for use by a  
14 physician or practitioner in the screening,  
15 detection, diagnosis, or treatment of an in-  
16 dividual’s condition or disease, or any such  
17 other similar service as the Secretary de-  
18 termines appropriate in consultation with  
19 appropriate organizations.”.

20 (b) CODIFYING OPPTS PAYMENT FOR SOFTWARE AS  
21 A SERVICE.—Effective for services provided on or after  
22 January 1, 2023, the Secretary of Health and Human  
23 Services shall apply the hospital outpatient prospective  
24 payment system payment for software as a service policy  
25 described in the final rule entitled, “Medicare Program:

1 Hospital Outpatient Prospective Payment and Ambulatory  
2 Surgical Center Payment Systems and Quality Reporting  
3 Programs; Organ Acquisition; Rural Emergency Hos-  
4 pitals: Payment Policies, Conditions of Participation, Pro-  
5 vider Enrollment, Physician Self-Referral; New Service  
6 Category for Hospital Outpatient Department Prior Au-  
7 thorization Process; Overall Hospital Quality Star Rating;  
8 COVID-19” published by the Department of Health and  
9 Human Services on November 23, 2022 (87 Fed. Reg.  
10 71748).

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