

117TH CONGRESS  
1ST SESSION

# H. R. 4670

To amend title XVIII of the Social Security Act to provide coverage and payment for certain tests and assistive telehealth consultations, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 22, 2021

Mr. SCHWEIKERT introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, and Veterans' Affairs, 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 title XVIII of the Social Security Act to provide coverage and payment for certain tests and assistive telehealth consultations, 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; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the  
5 “Advanced Safe Testing at Residence Telehealth Act of  
6 2021”.

7 (b) **TABLE OF CONTENTS.**—The table of contents is  
8 as follows:

Sec. 1. Short title.

Sec. 2. Coverage and payment for certain tests and assistive telehealth consultations; demonstration program under certain State Medicaid programs.

“Sec. 1859A. Tests and assistive telehealth consultations demonstration.

Sec. 3. Pilot program on improved access to certain tests and assistive telehealth consultations for veterans.

1 **SEC. 2. COVERAGE AND PAYMENT FOR CERTAIN TESTS**  
 2 **AND ASSISTIVE TELEHEALTH CONSULTA-**  
 3 **TIONS; DEMONSTRATION PROGRAM UNDER**  
 4 **CERTAIN STATE MEDICAID PROGRAMS.**

5 (a) TESTS AND ASSISTIVE TELEHEALTH CONSULTA-  
 6 TIONS DEMONSTRATION.—Part C of title XVIII of the So-  
 7 cial Security Act is amended by inserting after section  
 8 1859 (42 U.S.C. 1395w–28) the following new subsection:  
 9 **“SEC. 1859A. TESTS AND ASSISTIVE TELEHEALTH CON-**  
 10 **SULTATIONS DEMONSTRATION.**

11 “(a) ESTABLISHMENT.—

12 “(1) IN GENERAL.—The Secretary shall estab-  
 13 lish a Value-Based Insurance Design Model dem-  
 14 onstration program (in this section referred to as  
 15 the ‘VBID demonstration program’) to provide to el-  
 16 igible Medicare beneficiaries—

17 “(A) an assistive telehealth consultation  
 18 that is furnished via a telecommunications sys-  
 19 tem by a physician or practitioner to an eligible  
 20 telehealth individual enrolled under part B not-  
 21 withstanding that the individual physician or  
 22 practitioner ordering the test did not furnish

1 the test or that the individual physician or  
2 practitioner providing the assistive telehealth  
3 consultation is not at the same location as the  
4 beneficiary; and

5 “(B) home and community-based care.

6 “(2) AGREEMENTS.—The Secretary shall enter  
7 into agreements with eligible MA organizations  
8 under which such organizations shall offer eligible  
9 MA plans under the VBID demonstration program  
10 to eligible Medicare beneficiaries.

11 “(3) LIMITATIONS ON NUMBER OF PLANS FOR  
12 VBID DEMONSTRATION PROGRAM.—The VBID dem-  
13 onstration program shall be carried out with respect  
14 to not greater than 25 MA plans, with a minimum  
15 of 10 MA plans that serve rural or underserved  
16 areas.

17 “(4) ELIGIBLE MA PLANS DEFINED.—For pur-  
18 poses of this section, the term ‘eligible MA plan’  
19 means a plan that, in addition to items and services  
20 for which coverage is otherwise provided under this  
21 part (including benefits under section 1852(a)(3)  
22 and notwithstanding any waivers under section  
23 1915(e)), provides for coverage of—

24 “(A) tests that are medical devices (as de-  
25 fined in section 201(h) of the Federal Food,

1 Drug, and Cosmetic Act or wearable patient  
2 monitoring device, including adaptive artificial  
3 intelligence, machine learning, and software as  
4 a medical device (SaMD) technologies that op-  
5 erate to the full scope of medical purpose de-  
6 fined by the Administrator of the Food and  
7 Drug Administration) and are identified by the  
8 Secretary as having appropriate at home use  
9 that is approved under section 505 of the Fed-  
10 eral Food, Drug, and Cosmetic Act, and are ei-  
11 ther—

12 “(i) a diagnostic test or screening for  
13 the diagnosis of influenza or a similar res-  
14 piratory condition that is required to ob-  
15 tain a final diagnosis of COVID–19 for an  
16 individual when such test is ordered by a  
17 physician or practitioner in conjunction  
18 with a COVID–19 diagnostic test or  
19 screening for purposes of discounting a di-  
20 agnosis of influenza or a related diagnosis  
21 for such individual;

22 “(ii) a serology test for COVID–19;

23 “(iii) a diagnostic test or screening for  
24 the diagnosis of prostate cancer, ovarian  
25 cancer, breast cancer, hypothyroidism,

1           rheumatoid arthritis, celiac disease, vas-  
2           cular inflammation, cardiovascular health,  
3           strep throat, or lipoprotein (A);  
4           ““(iv) a haptoglobin genetic test;  
5           ““(v) a prediabetes and diabetes  
6           screening;  
7           ““(vi) an IgE allergy test;  
8           ““(vii) a screening or diagnostic cap-  
9           sule endoscopy; or  
10          ““(viii) any other test identified by the  
11          Secretary, including those proposed by the  
12          MA organization, as having appropriate for  
13          at-home use that is approved under section  
14          505 of the Federal Food, Drug, and Cos-  
15          metic Act;  
16          “(B) assistive telehealth consultations;  
17          “(C) telehealth services;  
18          “(D) fitness benefits;  
19          “(E) meal benefits (beyond limited basis);  
20          “(F) transportation services;  
21          “(G) safety and other equipment not oth-  
22          erwise covered under this title; and  
23          “(H) care in rural or highly rural areas (as  
24          determined in consultation with the Secretary

1 of Agriculture using the Rural-Urban Com-  
2 muting Areas coding system).

3 “(5) OTHER MATTERS RELATING TO DOCU-  
4 MENTATION AND CLAIMS REVIEW.—The require-  
5 ments of paragraphs (2) and (3) of section  
6 410.32(d) of title 42, Code of Federal Regulations  
7 (as in effect on the date of the enactment of this  
8 paragraph), relating to documentation and claims  
9 review, respectively, shall apply to a test described in  
10 paragraph (4)(A) and an assistive telehealth con-  
11 sultation.

12 “(6) DEMOGRAPHIC DATA.—To be eligible for  
13 reimbursement under this paragraph, each claim for  
14 reimbursement shall include, with respect to each el-  
15 igible Medicare beneficiary, the following demo-  
16 graphic data:

17 “(A) Age.

18 “(B) Race and ethnicity.

19 “(C) Gender.

20 “(D) An affirmative or negative statement  
21 of the existence of any chronic condition.

22 “(E) Any other information the Secretary  
23 determines appropriate.

24 “(7) ASSISTIVE TELEHEALTH CONSULTA-  
25 TION.—In this subsection, the term ‘assistive tele-

1 health consultation’ means a telehealth service (as  
2 defined in section 1834(m)(4)(F)) that is—

3 “(A) an evaluation and management serv-  
4 ice;

5 “(B) an assessment of any evidence of sys-  
6 tems which would make a diagnostic test or  
7 screening necessary to be furnished in the home  
8 of an eligible telehealth individual;

9 “(C) the ordering of a diagnostic test or  
10 screening;

11 “(D) an assessment of an individual suc-  
12 ceeding the delivery of a diagnostic test or  
13 screening;

14 “(E) any assistance in the collection (or  
15 transmission) of images or data necessary for a  
16 diagnostic test or screening and securing the  
17 sample for shipping;

18 “(F) the referral of an eligible telehealth  
19 individual to a physician or practitioner for in-  
20 person treatment; or

21 “(G) the review of a diagnostic test or  
22 screening by a physician or practitioner.

23 “(b) ELIGIBLE MA ORGANIZATIONS.—For purposes  
24 of this section, the term ‘eligible MA organization’ means  
25 an MA organization that—

1           “(1) is located in a State that the Secretary has  
2           determined is able to participate in the VBID dem-  
3           onstration program by agreeing to make available  
4           data necessary for purposes of conducting the inde-  
5           pendent evaluation required under subsection (h);  
6           and

7           “(2) meets such other criteria as the Secretary  
8           may require.

9           “(c) ELIGIBLE MEDICARE BENEFICIARY DE-  
10          FINED.—In this section, the term ‘eligible Medicare bene-  
11          ficiary’ means a Medicare beneficiary who—

12           “(1) is eligible for benefits under this title  
13          and—

14           “(A) is eligible to enroll in an eligible MA  
15          plan under the VBID demonstration program;

16           “(B) is a subsidy-eligible individual (as de-  
17          fined in section 1860D–14(a)(3)(A)); and

18           “(C) is age 65 or older; or

19           “(2) is a dual eligible individual (as defined in  
20          section 1915(h)(2)(B)) or qualified medicare bene-  
21          ficiary (as defined in section 1905(p)(1)) who is eli-  
22          gible for medical assistance under a State plan  
23          under title XIX.

24           “(d) PAYMENTS.—The Secretary shall establish pay-  
25          ment rates for eligible MA organizations offering eligible

1 MA plans under the VBID demonstration program for  
2 benefits covered under such program (and not otherwise  
3 covered under part C) and provided to eligible Medicare  
4 beneficiaries under such plans. Such payment rates  
5 shall—

6           “(1) be based upon payment rates established  
7 for purposes of payment under section 1853;

8           “(2) be in addition to payments otherwise made  
9 to such organization with respect to such plans  
10 under part C;

11           “(3) be adjusted to reflect the costs of treating  
12 eligible Medicare beneficiaries under this section;  
13 and

14           “(4) not be made for a test via a telecommuni-  
15 cations system described in subsection (a)(4), unless  
16 the physician or practitioner determines such a test  
17 is medically necessary and appropriate (as deter-  
18 mined by the Secretary).

19           “(e) SPECIAL ELECTION PERIOD.—Notwithstanding  
20 sections 1852(e)(2)(C) and 1860D–1(b)(1)(B)(iii), an eli-  
21 gible Medicare beneficiary may, other than during the an-  
22 nual, coordinated election periods under such sections dis-  
23 continue enrollment in an MA plan not participating in  
24 the VBID demonstration program and enroll in an MA  
25 plan participating in such program.

1       “(f) BENEFICIARY EDUCATION.—The Secretary shall  
2 help to educate, through State Health Insurance Assist-  
3 ance Programs and other organizations that assist seniors  
4 with respect to benefits and enrollment under this title,  
5 eligible Medicare beneficiaries on the availability of the  
6 VBID demonstration program.

7       “(g) IMPLEMENTATION.—

8           “(1) DEADLINE.—The VBID demonstration  
9 program shall be implemented not later than Janu-  
10 ary 1 of the second year beginning after the date of  
11 the enactment of this section.

12           “(2) DURATION.—Subject to paragraph (3), the  
13 VBID demonstration program shall be conducted for  
14 a period of five years.

15           “(3) EXTENSION OR EXPANSION.—Taking into  
16 account the report under subsection (h)(2), the Sec-  
17 retary may, through notice and comment rule-  
18 making, expand the duration, scope, or both the du-  
19 ration and scope of the VBID demonstration pro-  
20 gram (including implementation on a nationwide or  
21 permanent basis or both), other than under the  
22 original Medicare fee-for-service program under  
23 parts A and B of such title, to the extent determined  
24 appropriate by the Secretary, unless the Secretary  
25 determines that such expansion is expected to—

1           “(A) increase aggregate expenditures  
2 under this title and title XIX with respect to el-  
3 igible Medicare beneficiaries participating in the  
4 VBID demonstration program; or

5           “(B) decrease the quality of health care  
6 services furnished to eligible Medicare bene-  
7 ficiaries participating in the VBID demonstra-  
8 tion program.

9           “(h) INDEPENDENT EVALUATION AND REPORTS.—

10           “(1) INDEPENDENT EVALUATION.—

11           “(A) IN GENERAL.—The Secretary shall  
12 provide for the evaluation of the VBID dem-  
13 onstration program by an independent third  
14 party.

15           “(B) EVALUATION OBJECTIVES.—Such  
16 evaluation shall determine the extent to which  
17 the VBID demonstration program has resulted  
18 in—

19           “(i) improved patient care;

20           “(ii) reduced hospitalizations or rehos-  
21 pitalizations;

22           “(iii) reduced or delayed nursing facil-  
23 ity admissions and lengths of stay under  
24 title XIX;

1           “(iv) reduced spend down of income  
2           and assets for purposes of becoming eligi-  
3           ble for medical assistance under a State  
4           plan under title XIX;

5           “(v) improved quality of life for the  
6           eligible Medicare beneficiaries enrolled in  
7           an eligible MA plan participating in the  
8           VBID demonstration program;

9           “(vi) improved caregiver satisfaction;  
10          and

11          “(vii) addressing disparities and ac-  
12          cess for underserved populations.

13          “(C) EVALUATION PROCESS.—Such eval-  
14          uation shall be completed in accordance with  
15          the following process:

16                 “(i) The Secretary shall, prior to the  
17                 implementation of such program, establish  
18                 goals for such program with respect to the  
19                 evaluation objectives described in subpara-  
20                 graph (B) and criteria for measuring the  
21                 extent to which an eligible MA plan par-  
22                 ticipating in the VBID demonstration pro-  
23                 gram meets such goals.

24                 “(ii) The Secretary shall implement  
25                 clear data collection and reporting require-

1                   ments for such eligible MA plans in order  
2                   to carry out such evaluation.

3                   In carrying out such process, the Secretary  
4                   shall recognize that definitions, benefits, and  
5                   program requirements for long-term care serv-  
6                   ices and supports vary across States.

7                   “(2) REPORTS.—Not later than four years after  
8                   the implementation of the VBID demonstration pro-  
9                   gram, the Secretary shall submit to Congress a re-  
10                  port containing the results of the evaluation con-  
11                  ducted under paragraph (1), together with such rec-  
12                  ommendations for legislative or administrative action  
13                  as the Secretary determines appropriate. In pre-  
14                  paring such report, the Secretary shall use at least  
15                  three years worth of data under the VBID dem-  
16                  onstration program.

17                  “(i) BUDGET NEUTRALITY.—For any year after the  
18                  third year of the VBID demonstration program, the Sec-  
19                  retary shall ensure that the aggregate payments made  
20                  under this title and title XIX, including under the VBID  
21                  demonstration program, do not exceed the amount which  
22                  the Secretary estimates would have been expended under  
23                  such titles during such year if the VBID demonstration  
24                  program had not been implemented.

1       “(j) PAPERWORK REDUCTION ACT.—Chapter 35 of  
2 title 44, United States Code, shall not apply to the testing  
3 and evaluation of the VBID demonstration program.”.

4       (b) DEMONSTRATION PROGRAM UNDER CERTAIN  
5 STATE MEDICAID PROGRAMS.—

6           (1) IN GENERAL.—Not later than 1 year after  
7 the date of the enactment of this Act, subject to  
8 paragraph (3), the Secretary of Health and Human  
9 Services, acting through the Deputy Administrator  
10 and Director of the Center for Medicare and Med-  
11 icaid Innovation of the Centers for Medicare & Med-  
12 icaid Services, shall administer a program that  
13 awards grants to at least 5, but not more than 10  
14 States or territories for purposes of the State Med-  
15 icaid program to provide coverage to individuals en-  
16 titled to benefits under the State plan under title  
17 XIX of the Social Security Act (42 U.S.C. 1396 et  
18 seq.) for tests described in section 1859A(a)(4) of  
19 such Act that are ordered and assistive telehealth  
20 consultations that are furnished via a telecommuni-  
21 cations system by a physician or practitioner to such  
22 individuals notwithstanding that the individual phy-  
23 sician or practitioner ordering the test did not fur-  
24 nish the test or that the individual physician or  
25 practitioner providing the assistive telehealth con-

1 sultation is not at the same location as the individ-  
2 uals.

3 (2) APPLICATIONS.—To be eligible to receive a  
4 grant under this subsection, a State shall submit an  
5 application to the Secretary in such manner, and  
6 containing such information as the Secretary may  
7 require.

8 (3) DURATION; AMOUNT.—

9 (A) DURATION.—A grant under this sub-  
10 section shall be for a 4-year period.

11 (B) AMOUNT.—A State that is awarded a  
12 grant under this subsection shall be for an  
13 amount not to exceed \$12,000,000.

14 (4) FUNDING.—The Secretary, acting through  
15 the Deputy Administrator and Director, shall pro-  
16 vide for not more than \$100,000,000 to carry out  
17 the program described in paragraph (1) from  
18 amounts otherwise appropriated pursuant to section  
19 1115A(f) of the Social Security Act (42 U.S.C.  
20 1315a(f)).

21 **SEC. 3. PILOT PROGRAM ON IMPROVED ACCESS TO CER-**  
22 **TAIN TESTS AND ASSISTIVE TELEHEALTH**  
23 **CONSULTATIONS FOR VETERANS.**

24 (a) PILOT PROGRAM.—

1           (1) ESTABLISHMENT.—Not later than 180 days  
2 after the date of the enactment of this Act, the Sec-  
3 retary of Veterans shall establish a pilot program on  
4 improved access to certain telehealth services for vet-  
5 erans (in this section referred to as the “pilot pro-  
6 gram”). Under the pilot program, the Secretary  
7 shall furnish covered services to participants, at no  
8 cost to the participants, in accordance with this sec-  
9 tion.

10           (2) PROVISION OF COVERED SERVICES.—

11           (A) HEALTH CARE PROVIDERS.—The Sec-  
12 retary shall select not fewer than five facilities  
13 of the Department of Veterans Affairs through  
14 which to carry out the program, of which not  
15 fewer than three shall serve veterans in rural or  
16 highly rural areas (as determined through the  
17 use of the Rural-Urban Commuting Areas cod-  
18 ing system of the Department of Agriculture).

19           (B) COVERED SERVICES.—Under the pilot  
20 program, and notwithstanding that the provider  
21 ordering or providing the service is not at the  
22 same location as the participant receiving the  
23 service, health care providers at each facility se-  
24 lected under subparagraph (A) shall furnish to  
25 program participants the following services:

1 (i) Tests described in subparagraph  
2 (C) that are ordered by the health care  
3 provider via a telecommunications system.

4 (ii) Assistive telehealth consultations  
5 that are provided by the health care pro-  
6 vider via a telecommunications system.

7 (C) TESTS DESCRIBED.—A test described  
8 in this subparagraph is a test that—

9 (i) is a medical device (as defined in  
10 section 201(h) of the Federal Food, Drug,  
11 and Cosmetic Act) or wearable patient  
12 monitoring device, and

13 (ii) is for a condition determined rel-  
14 evant by the Secretary for purposes of the  
15 pilot program.

16 (3) PARTICIPATION IN PROGRAM.—

17 (A) APPLICATION.—To participate in the  
18 pilot program, veterans eligible to apply under  
19 subparagraph (B) shall submit an application  
20 for such participation in such form, at such  
21 time, and containing such information as the  
22 Secretary determines appropriate.

23 (B) ELIGIBILITY.—A veteran is eligible to  
24 submit an application for participation in the  
25 pilot program if the veteran—

1 (i) is enrolled in the system of patient  
2 enrollment of the Department under sec-  
3 tion 1705(a) of title 38, United States  
4 Code; and

5 (ii) has received health care under the  
6 laws administered by the Secretary during  
7 the two-year period preceding the date on  
8 which the veteran is first selected by the  
9 Secretary for participation in the pilot pro-  
10 gram.

11 (4) NO PAYMENT.—

12 (A) PILOT PROGRAM.—The Secretary may  
13 not charge a program participant for any cost  
14 of services furnished under the pilot program.

15 (B) EFFECT ON CERTAIN IN PERSON  
16 TESTS.—While a veteran is a program partici-  
17 pant in the pilot program, the Secretary may  
18 not make payment for a test described in para-  
19 graph (2)(C) that is furnished in-person by a  
20 physician or practitioner to the veteran if a  
21 physician or practitioner has previously ordered  
22 such a test for the veteran under the pilot pro-  
23 gram via a telecommunications system, unless  
24 the physician or practitioner determines such a

1 test is medically necessary and appropriate (as  
2 determined by the Secretary).

3 (5) TERMINATION.—

4 (A) IN GENERAL.—Subject to subpara-  
5 graph (B), the pilot program shall terminate on  
6 the date that is three years after the date on  
7 which the pilot program commences.

8 (B) EXTENSION.—If the Secretary deter-  
9 mines, based on the results of the interim re-  
10 port under subsection (b)(1), that it is appro-  
11 priate to extend the pilot program, the Sec-  
12 retary may extend the termination of such pro-  
13 gram for a period of not more than two years.

14 (b) REPORTS.—

15 (1) INTERIM REPORT.—Not later than one year  
16 after the date on which the pilot program com-  
17 mences, the Secretary shall submit to the appro-  
18 priate congressional committees an interim report.  
19 Such report shall include the following information:

20 (A) The number of veterans who have par-  
21 ticipated in the pilot program.

22 (B) The types of at-home diagnostics fur-  
23 nished under the pilot program.

24 (C) An assessment of whether participation  
25 in the pilot program resulted in any changes in

1 clinically relevant endpoints for the participant  
2 with respect to the conditions identified during  
3 an assistive telehealth consultation or through a  
4 covered test under the pilot program.

5 (D) An assessment of the quality of life of  
6 veterans who have participated in the pilot pro-  
7 gram, including the results of a satisfaction  
8 survey provided to each such veteran.

9 (2) FINAL REPORT.—Not later than 90 days  
10 after the date of termination of the pilot program  
11 under subsection (a)(4)(A) (or, if the pilot program  
12 is extended under subsection (a)(4)(B), the date on  
13 which such extension terminates), the Secretary  
14 shall submit to the appropriate congressional com-  
15 mittees a final report on the pilot program that con-  
16 tains any relevant updates to the information speci-  
17 fied in paragraph (1).

18 (c) DEFINITIONS.—In this section:

19 (1) The term “appropriate congressional com-  
20 mittees” means—

21 (A) the Committee on Energy and Com-  
22 merce, the Committee on Veterans’ Affairs, and  
23 the Committee on Ways and Means of the  
24 House of Representatives; and

1                   (B) the Committee on Health, Education,  
2                   Labor, and Pensions and the Committee on  
3                   Veterans' Affairs of the Senate.

4                   (2) The term “assistive telehealth consultation”  
5                   has the meaning given such term in section  
6                   1859A(a)(7) of the Social Security Act, as added by  
7                   section 1 of this Act.

○