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.

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

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,

Drug, and Cosmetic Act or wearable patient monitoring device, including adaptive artificial intelligence, machine learning, and software as a medical device (SaMD) technologies that operate to the full scope of medical purpose defined by the Administrator of the Food and Drug Administration) and are identified by the Secretary as having appropriate at home use that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act, and are either—

"(i) a diagnostic test or screening for the diagnosis of influenza or a similar respiratory condition that is required to obtain a final diagnosis of COVID-19 for an individual when such test is ordered by a physician or practitioner in conjunction with a COVID-19 diagnostic test or screening for purposes of discounting a diagnosis of influenza or a related diagnosis for such individual;

"(ii) a serology test for COVID-19;

"(iii) a diagnostic test or screening for the diagnosis of prostate cancer, ovarian 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
- 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;
- "(3) be adjusted to reflect the costs of treating
- eligible Medicare beneficiaries under this section;
- 13 and
- 14 "(4) not be made for a test via a telecommuni-
- cations system described in subsection (a)(4), unless
- the physician or practitioner determines such a test
- 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-
- 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
- VBID demonstration program shall be conducted for
- a period of five years.
- 15 "(3) Extension or expansion.—Taking into
- account the report under subsection (h)(2), the Sec-
- 17 retary may, through notice and comment rule-
- making, expand the duration, scope, or both the du-
- ration and scope of the VBID demonstration pro-
- gram (including implementation on a nationwide or
- 21 permanent basis or both), other than under the
- original Medicare fee-for-service program under
- parts A and B of such title, to the extent determined
- appropriate by the Secretary, unless the Secretary
- 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.

In carrying out such process, the Secretary
shall recognize that definitions, benefits, and
program requirements for long-term care services and supports vary across States.

"(2) Reports.—Not later than four years after the implementation of the VBID demonstration program, the Secretary shall submit to Congress a report containing the results of the evaluation conducted under paragraph (1), together with such recommendations for legislative or administrative action as the Secretary determines appropriate. In preparing such report, the Secretary shall use at least three years worth of data under the VBID demonstration program.

"(i) BUDGET NEUTRALITY.—For any year after the third year of the VBID demonstration program, the Sec19 retary shall ensure that the aggregate payments made under this title and title XIX, including under the VBID demonstration program, do not exceed the amount which the Secretary estimates would have been expended under such titles during such year if the VBID demonstration 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
- and Director of the Center for Medicare and Med-
- icaid Innovation of the Centers for Medicare & Med-
- icaid Services, shall administer a program that
- awards grants to at least 5, but not more than 10
- 14 States or territories for purposes of the State Med-
- icaid program to provide coverage to individuals en-
- titled to benefits under the State plan under title
- 17 XIX of the Social Security Act (42 U.S.C. 1396 et
- seq.) for tests described in section 1859A(a)(4) of
- such Act that are ordered and assistive telehealth
- consultations that are furnished via a telecommuni-
- 21 cations system by a physician or practitioner to such
- individuals notwithstanding that the individual phy-
- sician or practitioner ordering the test did not fur-
- 24 nish the test or that the individual physician or
- 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) ESTABLISHMENT.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Veterans shall establish a pilot program on improved access to certain telehealth services for veterans (in this section referred to as the "pilot program"). Under the pilot program, the Secretary shall furnish covered services to participants, at no cost to the participants, in accordance with this section.

(2) Provision of Covered Services.—

- (A) Health care providers.—The Secretary shall select not fewer than five facilities of the Department of Veterans Affairs through which to carry out the program, of which not fewer than three shall serve veterans in rural or highly rural areas (as determined through the use of the Rural-Urban Commuting Areas coding system of the Department of Agriculture).
- (B) COVERED SERVICES.—Under the pilot program, and notwithstanding that the provider ordering or providing the service is not at the same location as the participant receiving the service, health care providers at each facility selected under subparagraph (A) shall furnish to 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—

	10
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
5	laws administered by the Secretary during

Secretary for participation in the pilot program.

(4) No payment.—

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

the two-year period preceding the date on

which the veteran is first selected by the

(B) EFFECT ON CERTAIN IN PERSON TESTS.—While a veteran is a program participant in the pilot program, the Secretary may not make payment for a test described in paragraph (2)(C) that is furnished in-person by a physician or practitioner to the veteran if a physician or practitioner has previously ordered such a test for the veteran under the pilot program via a telecommunications system, unless 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

House of Representatives; and

24

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

 \bigcirc