

118TH CONGRESS
1ST SESSION

H. R. 4261

To amend titles XVIII and XIX of the Social Security Act to provide for coverage of peripheral artery disease screening tests furnished to at-risk beneficiaries under the Medicare and Medicaid programs without the imposition of cost-sharing requirements, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 21, 2023

Mr. PAYNE (for himself, Mr. GRIJALVA, Ms. SEWELL, Mr. CARTER of Louisiana, Mrs. WATSON COLEMAN, Mr. VEASEY, Mr. STANTON, Ms. PORTER, Mr. SMITH of New Jersey, Mr. VAN DREW, Ms. NORTON, Mr. GALLEGRO, Mrs. BEATTY, Mr. SESSIONS, Mr. DAVIS of North Carolina, Mr. CÁRDENAS, Mr. DOGGETT, Mr. NEGUSE, Mr. JOHNSON of Georgia, Mr. VARGAS, Mrs. SYKES, Mr. TAKANO, Ms. MCCOLLUM, Ms. BLUNT ROCHESTER, Ms. KUSTER, Mr. THOMPSON of Mississippi, Ms. MATSUI, Mr. ALLRED, Mr. BISHOP of Georgia, and Mr. CARSON) 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

A BILL

To amend titles XVIII and XIX of the Social Security Act to provide for coverage of peripheral artery disease screening tests furnished to at-risk beneficiaries under the Medicare and Medicaid programs without the imposition of cost-sharing requirements, 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; FINDINGS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Amputation Reduction and Compassion Act of 2023” or
6 the “ARC Act of 2023”.

7 (b) **FINDINGS.**—Congress makes the following find-
8 ings:

9 (1) Atherosclerosis occurs when blood flow is
10 reduced because arteries become narrowed or
11 blocked with fatty deposits.

12 (2) Atherosclerosis is responsible for more
13 deaths in the United States than any other condi-
14 tion, and heart attacks, resulting from clogged coro-
15 nary arteries, are the leading cause of death in
16 America.

17 (3) Atherosclerosis also occurs in the legs and
18 is known as peripheral artery disease (in this sub-
19 section referred to as “PAD”) and having PAD sig-
20 nificantly increases the risk for heart attack, stroke,
21 amputation, and death.

22 (4) While most Americans are aware of athero-
23 sclerosis in the heart, many Americans have never
24 heard of PAD and Americans with PAD are often
25 unaware of the serious risks of the disease.

1 (5) An estimated 21 million Americans have
2 PAD, and about 200,000 of them—disproportion-
3 ately minorities—suffer avoidable amputations every
4 year as a result of such disease.

5 (6) According to the Dartmouth Atlas, amputa-
6 tion risks for African Americans living with diabetes
7 are as much as four times higher than the national
8 average.

9 (7) Data analyses have similarly found that Na-
10 tive Americans are more than twice as likely to be
11 subjected to amputation and Hispanics are up to 75
12 percent more likely to have an amputation.

13 (8) Fifty-two percent of patients with an above-
14 the-knee amputation and 33 percent of patients with
15 a below-the-knee amputation will die within two
16 years of their amputation.

17 (9) Screening and arterial testing for PAD is
18 cost-effective and should be part of routine medical
19 care.

20 (10) Once PAD is detected, amputations and
21 deaths can be reduced through the use of national,
22 evidence-based PAD care guidelines.

23 (11) Americans with a PAD diagnosis are asso-
24 ciated with a 67-percent increase in the risk of car-
25 diac death compared to people without a PAD diag-

1 nosis. Consequently, screening for PAD enables
2 health care professionals to identify cardiac risk fac-
3 tors earlier and take proactive measures to reduce
4 the risk of cardiac death.

5 **SEC. 2. PERIPHERAL ARTERY DISEASE EDUCATION PRO-**
6 **GRAM.**

7 Part P of title III of the Public Health Service Act
8 (42 U.S.C. 280g et seq.) is amended by adding at the end
9 the following new section:

10 **“SEC. 399V-7. PERIPHERAL ARTERY DISEASE EDUCATION**
11 **PROGRAM.**

12 “(a) ESTABLISHMENT.—The Secretary, acting
13 through the Director of the Centers for Disease Control
14 and Prevention, in collaboration with the Administrator
15 of the Centers for Medicare & Medicaid Services, the Ad-
16 ministrator of the Health Resources and Services Admin-
17 istration, leading clinical and patient advocacy organiza-
18 tions, and other interested stakeholders shall establish and
19 coordinate a peripheral artery disease education program
20 to support, develop, and implement educational initiatives
21 and outreach strategies that inform health care profes-
22 sionals and the public about the existence of peripheral
23 artery disease and methods to reduce amputations related
24 to such disease, particularly with respect to at-risk popu-
25 lations.

1 “(b) BEST PRACTICES.—The Secretary shall, as ap-
2 propriate, identify and disseminate to health care profes-
3 sionals best practices with respect to peripheral artery dis-
4 ease.

5 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
6 is authorized to be appropriated to carry out this section
7 \$6,000,000 for each of fiscal years 2024 through 2028.”.

8 **SEC. 3. MEDICARE COVERAGE OF PERIPHERAL ARTERY**
9 **DISEASE SCREENING TESTS FURNISHED TO**
10 **AT-RISK BENEFICIARIES WITHOUT IMPOSI-**
11 **TION OF COST-SHARING REQUIREMENTS.**

12 (a) IN GENERAL.—Section 1861 of the Social Secu-
13 rity Act (42 U.S.C. 1395x) is amended—

14 (1) in subsection (s)(2)—

15 (A) in subparagraph (JJ), by striking the
16 semicolon at the end and inserting “; and”; and

17 (B) by adding at the end the following new
18 subparagraph:

19 “(KK) peripheral artery disease screening
20 tests furnished to at-risk beneficiaries (as such
21 terms are defined in subsection (nnn)).”; and

22 (2) by adding at the end the following new sub-
23 section:

1 “(nnn) PERIPHERAL ARTERY DISEASE SCREENING
2 TEST; AT-RISK BENEFICIARY.—(1) The term ‘peripheral
3 artery disease screening test’ means—

4 “(A) noninvasive physiologic studies of extrem-
5 ity arteries (commonly referred to as ankle-brachial
6 index testing);

7 “(B) arterial duplex scans of lower extremity
8 arteries vascular; and

9 “(C) such other items and services as the Sec-
10 retary determines, in consultation with relevant
11 stakeholders, to be appropriate for screening for pe-
12 ripheral artery disease for at-risk beneficiaries.

13 “(2) The term ‘at-risk beneficiary’ means an indi-
14 vidual entitled to, or enrolled for, benefits under part A
15 and enrolled for benefits under part B—

16 “(A) who is 65 years of age or older;

17 “(B) who is at least 50 years of age but not
18 older than 64 years of age with risk factors for ath-
19 erosclerosis (such as diabetes mellitus, a history of
20 smoking, hyperlipidemia, and hypertension) or a
21 family history of peripheral artery disease;

22 “(C) who is younger than 50 years of age with
23 diabetes mellitus and one additional risk factor for
24 atherosclerosis; or

1 “(D) with a known atherosclerotic disease in
2 another vascular bed such as coronary, carotid, sub-
3 clavian, renal, or mesenteric artery stenosis, or ab-
4 dominal aortic aneurysm.

5 “(3) The Secretary shall, in consultation with appro-
6 priate organizations, establish standards regarding the
7 frequency for peripheral artery disease screening tests de-
8 scribed in subsection (s)(2)(KK) for purposes of coverage
9 under this title.”.

10 (b) INCLUSION OF PERIPHERAL ARTERY DISEASE
11 SCREENING TESTS IN INITIAL PREVENTIVE PHYSICAL
12 EXAMINATION.—Section 1861(ww)(2) of the Social Secu-
13 rity Act (42 U.S.C. 1395x(ww)(2)) is amended—

14 (1) in subparagraph (N), by moving the mar-
15 gins of such subparagraph 2 ems to the left;

16 (2) by redesignating subparagraph (O) as sub-
17 paragraph (P); and

18 (3) by inserting after subparagraph (N) the fol-
19 lowing new subparagraph:

20 “(O) Peripheral artery disease screening
21 tests furnished to at risk-beneficiaries (as such
22 terms are defined in subsection (nnn)).”.

23 (c) PAYMENT.—

24 (1) IN GENERAL.—Section 1833(a) of the So-
25 cial Security Act (42 U.S.C. 1395l(a)) is amended—

1 (A) in paragraph (1)—

2 (i) in subparagraph (N), by inserting
3 “and other than peripheral artery disease
4 screening tests furnished to at-risk bene-
5 ficiaries (as such terms are defined in sec-
6 tion 1861(nnn))” after “other than person-
7 alized prevention plan services (as defined
8 in section 1861(hhh)(1))”;

9 (ii) by striking “and” before “(HH)”;

10 and

11 (iii) by adding at the end the fol-
12 lowing: “and (II) with respect to peripheral
13 artery disease screening tests furnished to
14 at-risk beneficiaries (as such terms are de-
15 fined in section 1861(nnn)), the amount
16 paid shall be 100 percent of the lesser of
17 the actual charge for the services or the
18 amount determined under the payment
19 basis determined under section 1848;”;
20 and

21 (B) in paragraph (2)—

22 (i) in subparagraph (G), by striking
23 “and” at the end;

1 (ii) in subparagraph (H), by striking
2 the semicolon at the end and inserting “;
3 and”; and

4 (iii) by inserting after subparagraph
5 (H) the following new subparagraph:

6 “(I) with respect to peripheral artery disease
7 screening tests (as defined in paragraph (1) of sec-
8 tion 1861(nnn)) furnished by an outpatient depart-
9 ment of a hospital to at-risk beneficiaries (as defined
10 in paragraph (2) of such section), the amount deter-
11 mined under paragraph (1)(II);”.

12 (2) NO DEDUCTIBLE.—Section 1833(b) of the
13 Social Security Act (42 U.S.C. 1395l(b)) is amend-
14 ed, in the first sentence—

15 (A) by striking “, and” before “(13)”; and

16 (B) by inserting before the period at the
17 end the following: “, and (14) such deductible
18 shall not apply with respect to peripheral artery
19 disease screening tests furnished to at-risk
20 beneficiaries (as such terms are defined in sec-
21 tion 1861(nnn))”.

22 (3) EXCLUSION FROM PROSPECTIVE PAYMENT
23 SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT
24 SERVICES.—Section 1833(t)(1)(B)(iv) of the Social

1 Security Act (42 U.S.C. 1395l(t)(1)(B)(iv)) is
2 amended—

3 (A) by striking “, or personalized” and in-
4 serting “, personalized”; and

5 (B) by inserting “, or peripheral artery
6 disease screening tests furnished to at-risk
7 beneficiaries (as such terms are defined in sec-
8 tion 1861(nnn))” after “personalized prevention
9 plan services (as defined in section
10 1861(hhh)(1))”.

11 (4) CONFORMING AMENDMENT.—Section
12 1848(j)(3) of the Social Security Act (42 U.S.C.
13 1395w-4(j)(3)) is amended by striking “(2)(FF)
14 (including administration of the health risk assess-
15 ment) ,” and inserting “(2)(FF) (including adminis-
16 tration of the health risk assessment), (2)(KK),”.

17 (d) EXCLUSION FROM COVERAGE AND MEDICARE AS
18 SECONDARY PAYER FOR TESTS PERFORMED MORE FRE-
19 QUENTLY THAN ALLOWED.—Section 1862(a)(1) of the
20 Social Security Act (42 U.S.C. 1395y(a)(1)) is amended—

21 (1) in subparagraph (O), by striking “and” at
22 the end;

23 (2) in subparagraph (P), by striking the semi-
24 colon at the end and inserting “, and”; and

1 (3) by adding at the end the following new sub-
2 paragraph:

3 “(Q) in the case of peripheral artery dis-
4 ease screening tests furnished to at-risk bene-
5 ficiaries (as such terms are defined in section
6 1861(nnn)), which are performed more fre-
7 quently than is covered under such section;”.

8 (e) AUTHORITY TO MODIFY OR ELIMINATE COV-
9 ERAGE OF CERTAIN PREVENTIVE SERVICES.—Section
10 1834(n) of the Social Security Act (42 U.S.C. 1395m(n))
11 is amended—

12 (1) by redesignating subparagraphs (A) and
13 (B) of paragraph (1) as clauses (i) and (ii), respec-
14 tively, and moving the margins of such clauses, as
15 so redesignated, 2 ems to the right;

16 (2) by redesignating paragraphs (1) and (2) as
17 subparagraphs (A) and (B), respectively, and mov-
18 ing the margins of such subparagraphs, as so redesi-
19 gnated, 2 ems to the right;

20 (3) by striking “CERTAIN PREVENTIVE SERV-
21 ICES” and all that follows through “any other provi-
22 sion of this title” and inserting: “CERTAIN PREVEN-
23 TIVE SERVICES.—

24 “(1) IN GENERAL.—Notwithstanding any other
25 provision of this title”; and

1 (4) by adding at the end the following new
2 paragraph:

3 “(2) **INAPPLICABILITY.**—The Secretarial au-
4 thority described in paragraph (1) shall not apply
5 with respect to preventive services described in sec-
6 tion 1861(ww)(2)(O).”.

7 (f) **EFFECTIVE DATE.**—The amendments made by
8 this section shall apply with respect to items and services
9 furnished on or after January 1, 2024.

10 **SEC. 4. MEDICAID COVERAGE OF PERIPHERAL ARTERY**
11 **DISEASE SCREENING TESTS FURNISHED TO**
12 **AT-RISK BENEFICIARIES WITHOUT IMPOSI-**
13 **TION OF COST-SHARING REQUIREMENTS.**

14 (a) **IN GENERAL.**—Section 1905 of the Social Secu-
15 rity Act (42 U.S.C. 1396d) is amended—

16 (1) in subsection (a)—

17 (A) in paragraph (30), by striking “and”
18 at the end;

19 (B) by redesignating paragraph (31) as
20 paragraph (32); and

21 (C) by inserting after paragraph (30) the
22 following new paragraph:

23 “(31) peripheral artery disease screening tests
24 furnished to at-risk beneficiaries (as such terms are
25 defined in subsection (jj)); and”;

1 (2) by adding at the end the following new sub-
2 section:

3 “(jj) PERIPHERAL ARTERY DISEASE SCREENING
4 TEST; AT-RISK BENEFICIARY.—

5 “(1) PERIPHERAL ARTERY DISEASE SCREENING
6 TEST.—The term ‘peripheral artery disease screen-
7 ing test’ means—

8 “(A) noninvasive physiologic studies of ex-
9 tremity arteries (commonly referred to as ankle-
10 brachial index testing);

11 “(B) arterial duplex scans of lower extrem-
12 ity arteries vascular; and

13 “(C) such other items and services as the
14 Secretary determines, in consultation with rel-
15 evant stakeholders, to be appropriate for
16 screening for peripheral artery disease for at-
17 risk beneficiaries.

18 “(2) AT-RISK BENEFICIARY.—The term ‘at-risk
19 beneficiary’ means an individual enrolled under a
20 State plan (or a waiver of such plan)—

21 “(A) who is 65 years of age or older;

22 “(B) who is at least 50 years of age but
23 not older than 64 years of age with risk factors
24 for atherosclerosis (such as diabetes mellitus, a
25 history of smoking, hyperlipidemia, and hyper-

1 tension) or a family history of peripheral artery
2 disease;

3 “(C) who is younger than 50 years of age
4 with diabetes mellitus and one additional risk
5 factor for atherosclerosis; or

6 “(D) with a known atherosclerotic disease
7 in another vascular bed such as coronary, ca-
8 rotid, subclavian, renal, or mesenteric artery
9 stenosis, or abdominal aortic aneurysm.

10 “(3) FREQUENCY.—The Secretary shall, in con-
11 sultation with appropriate organizations, establish
12 standards regarding the frequency for peripheral ar-
13 tery disease screening tests described in subsection
14 (a)(31) for purposes of coverage under a State plan
15 under this title.”.

16 (b) NO COST SHARING.—

17 (1) IN GENERAL.—Subsections (a)(2) and
18 (b)(2) of section 1916 of the Social Security Act (42
19 U.S.C. 1396o) are each amended—

20 (A) in subparagraph (I), by striking “or”
21 at the end;

22 (B) in subparagraph (J), by striking “;
23 and” and inserting “, or”; and

24 (C) by adding at the end the following new
25 subparagraph:

1 “(K) peripheral artery disease screening
2 tests furnished to at-risk beneficiaries (as such
3 terms are defined in section 1905(jj)); and”.

4 (2) APPLICATION TO ALTERNATIVE COST SHAR-
5 ING.—Section 1916A(b)(3)(B) of the Social Security
6 Act (42 U.S.C. 1396o–1(b)(3)(B)) is amended by
7 adding at the end the following new clause:

8 “(xv) Peripheral artery disease screen-
9 ing tests furnished to at-risk beneficiaries
10 (as such terms are defined in section
11 1905(jj)).”.

12 (c) CONFORMING AMENDMENTS.—

13 (1) Section 1902(nn)(3) of the Social Security
14 Act (42 U.S.C. 1396a(nn)(3)) is amended by strik-
15 ing “following paragraph (31)” and inserting “fol-
16 lowing paragraph (32)”.

17 (2) Section 1905(a) of the Social Security Act
18 (42 U.S.C. 1396d(a)) is amended by striking “fol-
19 lowing paragraph (31)” and inserting “following
20 paragraph (32)”.

21 **SEC. 5. DEVELOPMENT AND IMPLEMENTATION OF QUALITY**
22 **MEASURES.**

23 (a) DEVELOPMENT.—The Secretary of Health and
24 Human Services (referred to in this section as the “Sec-
25 retary”) shall, in consultation with relevant stakeholders,

1 develop quality measures for nontraumatic, lower-limb,
2 major amputation that utilize appropriate diagnostic
3 screening (including peripheral artery disease screening)
4 in order to encourage alternative treatments (including
5 revascularization) in lieu of such an amputation.

6 (b) IMPLEMENTATION.—Not later than 18 months
7 after the date of enactment of this Act, the Secretary shall
8 complete appropriate testing and validation of the meas-
9 ures developed under subsection (a) and shall incorporate
10 such measures in quality reporting programs for appro-
11 priate providers of services and suppliers under the Medi-
12 care program under title XVIII of the Social Security Act
13 (42 U.S.C. 1395 et seq.), including for purposes of—

14 (1) the merit-based incentive payment system
15 under section 1848(q) of such Act (42 U.S.C.
16 1395w-4(q));

17 (2) incentive payments for participation in eligi-
18 ble alternative payment models under section
19 1833(z) of such Act (42 U.S.C. 1395l(z));

20 (3) the shared savings program under section
21 1899 of such Act (42 U.S.C. 1395jjj);

22 (4) models under section 1115A of such Act
23 (42 U.S.C. 1315a); and

24 (5) such other payment systems or models as
25 the Secretary may specify.

1 **SEC. 6. AMPUTATION PREVENTION PILOT PROGRAM.**

2 (a) IN GENERAL.—Section 1115A(b)(2)(B) of the
3 Social Security Act (42 U.S.C. 1315a(b)(2)(B)) is amend-
4 ed by adding at the end the following new clause:

5 “(xxviii) Promoting voluntary, non-
6 traumatic lower-limb major amputation
7 prevention programs at hospitals, ambula-
8 tory surgical centers, and office-based cen-
9 ters that will increase access to amputation
10 prevention services, reduce amputation
11 rates, and reduce costs to such hospitals,
12 surgical centers, and office-based centers,
13 through—

14 “(I) patient risk modification and
15 management;

16 “(II) early screening and detec-
17 tion and surveillance;

18 “(III) testing and treatment for
19 peripheral artery disease; and

20 “(IV) improved care coordination
21 for individuals at high risk for ampu-
22 tation.”.

23 (b) TESTING OF MODEL.—Not later than 18 months
24 after the date of the enactment of this Act, the Deputy
25 Administrator and Director of the Center for Medicare

1 and Medicaid Innovation shall test the model described
2 under subsection (a).

○