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. Gallego, 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.
Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; FINDINGS.

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

(b) FINDINGS.—Congress makes the following findings:

1. Atherosclerosis occurs when blood flow is reduced because arteries become narrowed or blocked with fatty deposits.

2. Atherosclerosis is responsible for more deaths in the United States than any other condition, and heart attacks, resulting from clogged coronary arteries, are the leading cause of death in America.

3. Atherosclerosis also occurs in the legs and is known as peripheral artery disease (in this subsection referred to as “PAD”) and having PAD significantly increases the risk for heart attack, stroke, amputation, and death.

4. While most Americans are aware of atherosclerosis in the heart, many Americans have never heard of PAD and Americans with PAD are often unaware of the serious risks of the disease.
(5) An estimated 21 million Americans have PAD, and about 200,000 of them—disproportionately minorities—suffer avoidable amputations every year as a result of such disease.

(6) According to the Dartmouth Atlas, amputation risks for African Americans living with diabetes are as much as four times higher than the national average.

(7) Data analyses have similarly found that Native Americans are more than twice as likely to be subjected to amputation and Hispanics are up to 75 percent more likely to have an amputation.

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

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

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

(11) Americans with a PAD diagnosis are associated with a 67-percent increase in the risk of cardiac death compared to people without a PAD diag-
nosis. Consequently, screening for PAD enables health care professionals to identify cardiac risk factors earlier and take proactive measures to reduce the risk of cardiac death.

SEC. 2. PERIPHERAL ARTERY DISEASE EDUCATION PROGRAM.

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

“SEC. 399V–7. PERIPHERAL ARTERY DISEASE EDUCATION PROGRAM.

“(a) Establishment.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, in collaboration with the Administrator of the Centers for Medicare & Medicaid Services, the Administrator of the Health Resources and Services Administration, leading clinical and patient advocacy organizations, and other interested stakeholders shall establish and coordinate a peripheral artery disease education program to support, develop, and implement educational initiatives and outreach strategies that inform health care professionals and the public about the existence of peripheral artery disease and methods to reduce amputations related to such disease, particularly with respect to at-risk populations.
“(b) Best Practices.—The Secretary shall, as appropriate, identify and disseminate to health care professionals best practices with respect to peripheral artery disease.

“(c) Authorization of Appropriations.—There is authorized to be appropriated to carry out this section $6,000,000 for each of fiscal years 2024 through 2028.”.

SEC. 3. MEDICARE COVERAGE OF PERIPHERAL ARTERY DISEASE SCREENING TESTS FURNISHED TO AT-RISK BENEFICIARIES WITHOUT IMPOSITION OF COST-SHARING REQUIREMENTS.

(a) In General.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended—

(1) in subsection (s)(2)—

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

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

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

(2) by adding at the end the following new subsection:

...
The term ‘peripheral artery disease screening test’ means—

(A) noninvasive physiologic studies of extremity arteries (commonly referred to as ankle-brachial index testing);

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

(C) such other items and services as the Secretary determines, in consultation with relevant stakeholders, to be appropriate for screening for peripheral artery disease for at-risk beneficiaries.

The term ‘at-risk beneficiary’ means an individual entitled to, or enrolled for, benefits under part A and enrolled for benefits under part B—

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

(B) who is at least 50 years of age but not older than 64 years of age with risk factors for atherosclerosis (such as diabetes mellitus, a history of smoking, hyperlipidemia, and hypertension) or a family history of peripheral artery disease;

(C) who is younger than 50 years of age with diabetes mellitus and one additional risk factor for atherosclerosis; or
“(D) with a known atherosclerotic disease in another vascular bed such as coronary, carotid, subclavian, renal, or mesenteric artery stenosis, or abdominal aortic aneurysm.

“(3) The Secretary shall, in consultation with appropriate organizations, establish standards regarding the frequency for peripheral artery disease screening tests described in subsection (s)(2)(KK) for purposes of coverage under this title.”.

(b) Inclusion of Peripheral Artery Disease Screening Tests in Initial Preventive Physical Examination.—Section 1861(ww)(2) of the Social Security Act (42 U.S.C. 1395x(ww)(2)) is amended—

(1) in subparagraph (N), by moving the margins of such subparagraph 2 ems to the left;

(2) by redesignating subparagraph (O) as subparagraph (P); and

(3) by inserting after subparagraph (N) the following new subparagraph:

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

(e) Payment.—

(1) In general.—Section 1833(a) of the Social Security Act (42 U.S.C. 1395l(a)) is amended—
(A) in paragraph (1)—

(i) in subparagraph (N), by inserting

“and other than peripheral artery disease screening tests furnished to at-risk beneficiaries (as such terms are defined in section 1861(nnn))” after “other than personalized prevention plan services (as defined in section 1861(hhh)(1))”;

(ii) by striking “and” before “(HH)”;

and

(iii) by adding at the end the following: “and (II) with respect to peripheral artery disease screening tests furnished to at-risk beneficiaries (as such terms are defined in section 1861(nnn)), the amount paid shall be 100 percent of the lesser of the actual charge for the services or the amount determined under the payment basis determined under section 1848;”; and

(B) in paragraph (2)—

(i) in subparagraph (G), by striking

“and” at the end;
(ii) in subparagraph (H), by striking the semicolon at the end and inserting ‘‘; and’’; and

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

‘‘(I) with respect to peripheral artery disease screening tests (as defined in paragraph (1) of section 1861(nnn)) furnished by an outpatient department of a hospital to at-risk beneficiaries (as defined in paragraph (2) of such section), the amount determined under paragraph (1)(II);’’.

(2) NO DEDUCTIBLE.—Section 1833(b) of the Social Security Act (42 U.S.C. 1395l(b)) is amended, in the first sentence—

(A) by striking ‘‘, and’’ before ‘‘(13)’’; and

(B) by inserting before the period at the end the following: ‘‘, and (14) such deductible shall not apply with respect to peripheral artery disease screening tests furnished to at-risk beneficiaries (as such terms are defined in section 1861(nnn))’’.

(3) EXCLUSION FROM PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES.—Section 1833(t)(1)(B)(iv) of the Social
Security Act (42 U.S.C. 1395l(t)(1)(B)(iv)) is amended—

(A) by striking “, or personalized” and inserting “, personalized”; and

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

(4) CONFORMING AMENDMENT.—Section 1848(j)(3) of the Social Security Act (42 U.S.C. 1395w–4(j)(3)) is amended by striking “(2)(FF) (including administration of the health risk assessment) ,” and inserting “(2)(FF) (including administration of the health risk assessment), (2)(KK),”.

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

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

(2) in subparagraph (P), by striking the semicolon at the end and inserting “, and”; and
(3) by adding at the end the following new sub-
paragraph:

“(Q) in the case of peripheral artery dis-
ease screening tests furnished to at-risk benef-
ciaries (as such terms are defined in section
1861(mnn)), which are performed more fre-
quently than is covered under such section;”.

(c) Authority To Modify or Eliminate Cov-
erage of Certain Preventive Services.—Section
1834(n) of the Social Security Act (42 U.S.C. 1395m(n))
is amended—

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

(2) by redesignating paragraphs (1) and (2) as
subparagraphs (A) and (B), respectively, and mov-
ing the margins of such subparagraphs, as so redes-
ignated, 2 ems to the right;

(3) by striking “Certain Preventive Serv-
ces” and all that follows through “any other provi-
sion of this title” and inserting: “Certain Preven-
tive Services.—

“(1) In General.—Notwithstanding any other
provision of this title”; and
(4) by adding at the end the following new paragraph:

“(2) INAPPLICABILITY.—The Secretarial authority described in paragraph (1) shall not apply with respect to preventive services described in section 1861(ww)(2)(O).”.

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

SEC. 4. MEDICAID COVERAGE OF PERIPHERAL ARTERY DISEASE SCREENING TESTS FURNISHED TO AT-RISK BENEFICIARIES WITHOUT IMPOSITION OF COST-SHARING REQUIREMENTS.

(a) IN GENERAL.—Section 1905 of the Social Security Act (42 U.S.C. 1396d) is amended—

(1) in subsection (a)—

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

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

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

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

and
(2) by adding at the end the following new subsection:

“(jj) Peripheral Artery Disease Screening Test; At-Risk Beneficiary.—

“(1) Peripheral artery disease screening test.—The term ‘peripheral artery disease screening test’ means—

“(A) noninvasive physiologic studies of extremity arteries (commonly referred to as ankle-brachial index testing);

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

“(C) such other items and services as the Secretary determines, in consultation with relevant stakeholders, to be appropriate for screening for peripheral artery disease for at-risk beneficiaries.

“(2) At-risk beneficiary.—The term ‘at-risk beneficiary’ means an individual enrolled under a State plan (or a waiver of such plan)—

“(A) who is 65 years of age or older;

“(B) who is at least 50 years of age but not older than 64 years of age with risk factors for atherosclerosis (such as diabetes mellitus, a history of smoking, hyperlipidemia, and hyper-
tension) or a family history of peripheral artery disease;

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

“(D) with a known atherosclerotic disease in another vascular bed such as coronary, carotid, subclavian, renal, or mesenteric artery stenosis, or abdominal aortic aneurysm.

“(3) FREQUENCY.—The Secretary shall, in consultation with appropriate organizations, establish standards regarding the frequency for peripheral artery disease screening tests described in subsection (a)(31) for purposes of coverage under a State plan under this title.”.

(b) NO COST SHARING.—

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

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

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

(C) by adding at the end the following new subparagraph:
“(K) peripheral artery disease screening tests furnished to at-risk beneficiaries (as such terms are defined in section 1905(jj)); and”.

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

“(xv) Peripheral artery disease screening tests furnished to at-risk beneficiaries (as such terms are defined in section 1905(jj)).”.

(c) CONFORMING AMENDMENTS.—

(1) Section 1902(nn)(3) of the Social Security Act (42 U.S.C. 1396a(nn)(3)) is amended by striking “following paragraph (31)” and inserting “following paragraph (32)”.

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

SEC. 5. DEVELOPMENT AND IMPLEMENTATION OF QUALITY MEASURES.

(a) DEVELOPMENT.—The Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall, in consultation with relevant stakeholders,
develop quality measures for nontraumatic, lower-limb, major amputation that utilize appropriate diagnostic screening (including peripheral artery disease screening) in order to encourage alternative treatments (including revascularization) in lieu of such an amputation.

(b) Implementation.—Not later than 18 months after the date of enactment of this Act, the Secretary shall complete appropriate testing and validation of the measures developed under subsection (a) and shall incorporate such measures in quality reporting programs for appropriate providers of services and suppliers under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), including for purposes of—

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

(2) incentive payments for participation in eligible alternative payment models under section 1833(z) of such Act (42 U.S.C. 1395l(z));

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

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

(5) such other payment systems or models as the Secretary may specify.
SEC. 6. AMPUTATION PREVENTION PILOT PROGRAM.

(a) In General.—Section 1115A(b)(2)(B) of the Social Security Act (42 U.S.C. 1315a(b)(2)(B)) is amended by adding at the end the following new clause:

“(xxviii) Promoting voluntary, non-traumatic lower-limb major amputation prevention programs at hospitals, ambulatory surgical centers, and office-based centers that will increase access to amputation prevention services, reduce amputation rates, and reduce costs to such hospitals, surgical centers, and office-based centers, through—

“(I) patient risk modification and management;

“(II) early screening and detection and surveillance;

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

“(IV) improved care coordination for individuals at high risk for amputation.”.

(b) Testing of Model.—Not later than 18 months after the date of the enactment of this Act, the Deputy Administrator and Director of the Center for Medicare
1 and Medicaid Innovation shall test the model described
2 under subsection (a).