

119TH CONGRESS
2D SESSION

H. R. 9972

To amend title XVIII of the Social Security Act to adjust payment for skin substitute products under the Medicare program.

IN THE HOUSE OF REPRESENTATIVES

JULY 27, 2026

Mr. SESSIONS 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 title XVIII of the Social Security Act to adjust payment for skin substitute products 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 “American Patients
5 First Act of 2026”.

1 **SEC. 2. PAYMENT REFORM FOR SKIN SUBSTITUTE PROD-**
 2 **UCTS.**

3 (a) COVERAGE OF SKIN SUBSTITUTE PRODUCTS.—
 4 Section 1861(s)(2) of the Social Security Act (42 U.S.C.
 5 1395x(s)(2)) is amended—

6 (1) in subparagraph (JJ), by striking “and” at
 7 the end;

8 (2) in subparagraph (KK), by adding “and” at
 9 the end; and

10 (3) by inserting after subparagraph (KK) the
 11 following new subparagraph:

12 “(LL) skin substitute products (as defined in
 13 section 1847A(c)(6)(J)).”.

14 (b) PAYMENT.—

15 (1) PAYMENT AMOUNT.—Section 1847A of the
 16 Social Security Act (42 U.S.C. 1395w–3a) is amend-
 17 ed—

18 (A) in subsection (a)(1)—

19 (i) by striking the period at the end
 20 and inserting “; and”;

21 (ii) by striking “shall apply to” and
 22 inserting “shall apply—

23 “(A) to”; and

24 (iii) by adding at the end the fol-
 25 lowing new subparagraph:

1 “(B) to payment for skin substitute prod-
2 ucts (as defined in subsection (c)(6)(J)) that
3 are furnished during the period beginning on
4 January 1, 2027, and ending on December 31,
5 2030.”; and

6 (B) in subsection (b)—

7 (i) in paragraph (1)—

8 (I) in the text preceding subpara-
9 graph (A), by inserting “or a skin
10 substitute product” after “drug or bi-
11 ological”;

12 (II) in subparagraph (B), by
13 striking “or” at the end;

14 (III) in subparagraph (C), by
15 striking the period at the end and in-
16 serting “; or”; and

17 (IV) by adding at the end the fol-
18 lowing new subparagraph:

19 “(D) in the case of a skin substitute prod-
20 uct (as defined in subsection (c)(6)(J)) fur-
21 nished during the period beginning on January
22 1, 2027, and ending on December 31, 2030,
23 \$457 per square centimeter.”; and

24 (ii) in paragraph (2)—

1 (I) in subparagraph (A), by in-
2 serting “or a skin substitute product”
3 after “drug or biological”; and

4 (II) in subparagraph (B), by in-
5 serting “, and, with respect to a skin
6 substitute product, a square centi-
7 meter” after “pertaining to liquids”.

8 (2) CONFORMING AMENDMENTS.—Section
9 1833(a)(1) of the Social Security Act (42 U.S.C.
10 1395l(a)(1)) is amended—

11 (A) in subparagraph (S)(i), by striking
12 “subject to subparagraph (EE)” and inserting
13 “subject to subparagraphs (EE) and (II)”;

14 (B) by striking “and (HH)” and inserting
15 “(HH)”;

16 (C) by inserting “, and (II) with respect to
17 skin substitute products under section
18 1861(s)(2)(LL) furnished during the period be-
19 ginning on January 1, 2027, and ending on De-
20 cember 31, 2030, the amount paid shall be 80
21 percent of the lesser of the actual charge or the
22 payment amount established under section
23 1847A(b)(1)(D)” before the semicolon at the
24 end.

1 (c) SKIN SUBSTITUTE PRODUCT DEFINED.—Section
2 1847A(c)(6) of the Social Security Act (42 U.S.C. 1395w–
3 3a(c)(6)) is amended by adding at the end the following:

4 “(J) SKIN SUBSTITUTE PRODUCTS.—

5 “(i) IN GENERAL.—Subject to clause
6 (ii), the term ‘skin substitute product’—

7 “(I) means a cellular, tissue, bio-
8 logical or synthetic material that—

9 “(aa) is applied to a wound
10 and intended to remain within
11 the wound bed; and

12 “(bb) is marketed pursuant
13 to section 510(k), 513(f)(2), or
14 515 of the Federal Food, Drug,
15 and Cosmetic Act, or section 361
16 of the Public Health Service Act;
17 and

18 “(II) includes any products reim-
19 bursed pursuant to skin substitutes
20 codes under this title at any time
21 prior to January 1, 2027.

22 “(ii) EXCLUSIONS.—The term ‘skin
23 substitute product’ does not include—

24 “(I) any product that is intended
25 to temporarily protect or cover the

1 wound bed and be removed without
2 resorption such as a dressing; or

3 “(II) any product that does not
4 meet the domestic sourcing and dis-
5 tribution requirements described in
6 clause (iii), unless a waiver under
7 clause (iv) is in effect with respect to
8 such product.

9 “(iii) DOMESTIC SOURCING AND DIS-
10 TRIBUTION REQUIREMENTS.—For pur-
11 poses of clause (ii), the domestic sourcing
12 and distribution requirements described in
13 this clause are, with respect to a product
14 described in clause (i), the following:

15 “(I) All human cellular or tissue
16 material contained in such product
17 was donated by citizens or nationals
18 of the United States, or aliens law-
19 fully admitted for permanent resi-
20 dence in the United States, and any
21 such donation was made within the
22 United States in accordance with ap-
23 plicable Federal law.

24 “(II) All harvesting and proc-
25 essing (as applicable) and all manu-

1 facturing of such product occurred ex-
2 clusively within the United States,
3 and such harvesting, processing, and
4 manufacturing was performed in com-
5 pliance with all applicable standards
6 of the Food and Drug Administration
7 and the American Association of Tis-
8 sue Banks.

9 “(III) The product is distributed
10 solely by the entity holding the appli-
11 cable clearance, approval, or registra-
12 tion for such product under section
13 510(k), 513(f)(2), or 515 of the Fed-
14 eral Food, Drug, and Cosmetic Act,
15 or section 361 of the Public Health
16 Service Act, and no intermediaries, or
17 agents were involved in the distribu-
18 tion of such product to the furnishing
19 provider, except that a third-party dis-
20 tributor that adheres to and is able to
21 perform the contractual requirements
22 associated with the scope of work and
23 is qualified and able to adhere to the
24 legal and regulatory requirements de-

1 fined in the scope of work may be in-
2 volved in such distribution.

3 “(IV) The entity described in
4 subclause (III) with respect to the
5 product submits to the Secretary, in
6 such form and manner as the Sec-
7 retary shall specify (but not less fre-
8 quently than annually), an attestation
9 that the product meets each of the re-
10 quirements under subclauses (I)
11 through (III).

12 “(iv) WAIVER.—The Secretary may
13 waive the requirements under clause (iii)
14 with respect to a specific product, for a pe-
15 riod not to exceed 180 days, if the Sec-
16 retary determines that a domestic supply
17 shortage exists and that a waiver is nec-
18 essary to protect patient access to care.”.

19 (d) EXCLUSION FROM REPORTING REQUIRE-
20 MENTS.—Section 1847A(f)(2)(A) of the Social Security
21 Act (42 U.S.C. 1395w–3a(f)(2)(A)) is amended by insert-
22 ing “(except that, beginning January 1, 2027, a drug or
23 biological so described does not include a skin substitute
24 product (as defined in subsection (c)(6)(J)))” after “prod-

1 icts that are payable under this part as a drug or biological
 2 cal”.

3 (e) CONSOLIDATED BILLING AND PAYMENT CODE.—
 4 Not later than January 1, 2027, the Secretary of Health
 5 and Human Services shall establish a new billing and pay-
 6 ment code for all skin substitute products (as defined in
 7 subparagraph (J) of section 1847A(c)(6) of the Social Se-
 8 curity Act (42 U.S.C. 1395w–3a(c)(6)), as added by sub-
 9 section (c)).

10 **SEC. 3. ENHANCING PROGRAM INTEGRITY FOR SKIN SUB-**
 11 **STITUTE PRODUCTS.**

12 Section 1834 of the Social Security Act (42 U.S.C.
 13 1395m) is amended by adding at the end the following
 14 new subsection:

15 “(bb) SPECIAL PAYMENT RULES FOR SKIN SUB-
 16 STITUTE PRODUCTS.—

17 “(1) PREPAYMENT CLAIM REVIEW AND PRIOR
 18 AUTHORIZATION.—

19 “(A) INITIAL PREPAYMENT CLAIM REVIEW
 20 FOR CERTAIN PROVIDERS.—

21 “(i) IN GENERAL.—Beginning Janu-
 22 ary 1, 2027, the Secretary shall conduct
 23 prepayment review of claims for skin sub-
 24 stitute products submitted under this title
 25 by a specified provider of skin substitute

1 products unless 1 or more of the conditions
2 described in clause (ii) is met with respect
3 to such provider.

4 “(ii) LIMITATION.—For purposes of
5 clause (i), the conditions described in this
6 subparagraph are, with respect to a speci-
7 fied provider of skin substitute products,
8 the following:

9 “(I) Skin substitute products fur-
10 nished by the provider are subject to
11 prior authorization under subpara-
12 graph (B).

13 “(II) The rate of approval for
14 claims for skin substitute products
15 furnished by such provider that are
16 subject to prepayment review under
17 this subparagraph exceeds 90 percent
18 (as determined over a period of time
19 or number of claims specified by the
20 Secretary).

21 “(III) The Secretary determines
22 that the billing practices of the pro-
23 vider are consistent with the applica-
24 ble coverage criteria and requirements
25 under this title.

1 “(B) PRIOR AUTHORIZATION FOR SPECI-
2 FIED PROVIDERS OF SKIN SUBSTITUTE PROD-
3 UCTS.—

4 “(i) IN GENERAL.—Beginning not
5 later than January 1, 2028, subject to
6 clause (ii), the Secretary shall, for a period
7 of 180 days, apply prior authorization for
8 skin substitute products that are furnished
9 by a specified provider of skin substitute
10 products.

11 “(ii) REMOVAL FROM PRIOR AUTHOR-
12 IZATION.—In the event that the Secretary
13 determines, with respect to a specified pro-
14 vider of skin substitute products, that the
15 rate of approval for requests for prior au-
16 thorization under this subparagraph for
17 skin substitute products furnished by such
18 provider exceeds 90 percent (as determined
19 over a period of time or number of claims
20 specified by the Secretary), the Secretary
21 shall cease to apply prior authorization
22 under this paragraph for skin substitute
23 products furnished by such provider.

1 “(C) ENROLLMENT REVOCATION OR EX-
2 CLUSION OF NONCOMPLIANT OUTLIER PRO-
3 VIDERS.—

4 “(i) IN GENERAL.—Beginning Janu-
5 ary 1, 2029, if the rate of denial (as deter-
6 mined after the exhaustion of all appeals
7 and reviews) for requests for prior author-
8 ization under subparagraph (B) for skin
9 substitute products furnished by an outlier
10 provider of skin substitute products ex-
11 ceeds 75 percent over a period of 6 or
12 more consecutive months, the Secretary
13 shall determine that an abuse of billing
14 privileges exists with respect to such pro-
15 vider for purposes of section
16 424.535(a)(8)(ii) of title 42, Code of Fed-
17 eral Regulations.

18 “(ii) REFERRAL FOR EXCLUSION.—If
19 the Secretary determines under clause (i)
20 that an abuse of billing privileges exists
21 with respect to an outlier provider of skin
22 substitute products, the Secretary shall di-
23 rect the Inspector General of the Depart-
24 ment of Health and Human Services to de-
25 termine whether such provider should be

1 excluded from participation in any Federal
2 health care program under section
3 1128(b)(6).

4 “(D) SPECIFIED PROVIDER OF SKIN SUB-
5STITUTE PRODUCTS DEFINED.—

6 “(i) IN GENERAL.—For purposes of
7 this paragraph, the term ‘specified pro-
8 vider of skin substitute products’ means—

9 “(I) an outlier provider of skin
10 substitute products, as determined
11 under clause (ii);

12 “(II) a provider with respect to
13 which, of all claims for payment under
14 this title submitted in the preceding
15 year, 15 percent or more of such
16 claims were for the provision of skin
17 substitute products; and

18 “(III) as the Secretary deter-
19 mines appropriate, a provider of skin
20 substitute products that—

21 “(aa) is newly enrolled
22 under section 1866(j);

23 “(bb) has undergone a
24 change in ownership during the
25 preceding year;

1 “(cc) is a high risk provider
2 (as determined by the Secretary
3 under section 424.518 of title 42,
4 Code of Federal Regulations); or
5 “(dd) has a pattern or prac-
6 tice of noncompliance with condi-
7 tions of participation under this
8 title or a high percentage of pre-
9 viously denied claims (as deter-
10 mined by the Secretary).

11 “(ii) IDENTIFICATION OF OUTLIER
12 PROVIDERS OF SKIN SUBSTITUTE PROD-
13 UCTS.—

14 “(I) IN GENERAL.—Not later
15 than December 1, 2026, and every 2
16 years thereafter through December 1,
17 2036, the Secretary shall determine
18 the 3 percent of the total number of
19 providers of skin substitute products
20 that are outlier providers of skin sub-
21 stitute products.

22 “(II) OUTLIER PROVIDERS OF
23 SKIN SUBSTITUTE PRODUCTS.—The
24 determination of an outlier provider of
25 skin substitute products under this

1 paragraph shall be based upon the
2 providers (as identified by national
3 provider identification number) that
4 received the greatest total payment
5 under this title for skin substitute
6 products furnished in the year pre-
7 ceding the year in which the deter-
8 mination under subclause (I) is made.

9 “(III) REFERRAL TO OIG.—The
10 Secretary shall—

11 “(aa) make publicly avail-
12 able the list of outlier providers
13 of skin substitute products iden-
14 tified under each determination
15 under subclause (I); and

16 “(bb) transmit such list to
17 the Inspector General of the De-
18 partment of Health and Human
19 Services for the assessment of
20 potential fraud, waste, or abuse.

21 “(E) FUNDING.—For purposes of carrying
22 out this paragraph, the Secretary shall provide
23 for the transfer, from the Federal Supple-
24 mentary Medical Insurance Trust Fund under
25 section 1841, to the Centers for Medicare &

1 Medicaid Services Program Management Ac-
2 count, of \$2,500,000 for each of fiscal years
3 2028 through 2031, to remain available until
4 expended.

5 “(2) MEDICARE COVERAGE CRITERIA FOR SKIN
6 SUBSTITUTE PRODUCTS.—Any skin substitute prod-
7 uct furnished during 2027 shall be subject to the
8 same coverage criteria when determining whether
9 the skin substitute product is covered under section
10 1862(a)(1)(A), unless such product is determined by
11 the Secretary to be unsafe based on evidence of con-
12 tamination, serious infectious disease, or serious ad-
13 verse reactions caused by the product. Neither the
14 Secretary nor any Medicare administrative con-
15 tractor may determine, including through a deter-
16 mination made pursuant to the prepayment review
17 program or prior authorization program described in
18 paragraphs (2) and (3), that a specific skin sub-
19 stitute product furnished in 2027 is not covered
20 under this title based solely on analysis of the clin-
21 ical evidence relating to that skin substitute product.

22 “(3) SKIN SUBSTITUTE PRODUCT WASTAGE.—

23 “(A) IN GENERAL.—With respect to skin
24 substitute products furnished for the treatment
25 of chronic or acute wounds, payment may only

1 be made under this title for the reasonable and
2 necessary portion of the skin substitute product
3 used in the treatment of the wound, excluding
4 wastage.

5 “(B) REASONABLE AND NECESSARY DE-
6 FINED.—For the purpose of subparagraph (A),
7 the term ‘reasonable and necessary portion of
8 the skin substitute product’ means the greater
9 of—

10 “(i) 350 square centimeters; or

11 “(ii) 120 percent of the size of the
12 treated wound.

13 “(4) LIMITATION ON REPEATED APPLICA-
14 TIONS.—Payment may not be made under this title
15 for more than 3 distinct applications of a skin sub-
16 stitute product with respect to the same wound if,
17 in the clinical judgment of the provider furnishing
18 such product, there has been no improvement in the
19 wound.

20 “(5) CERTIFICATION REQUIREMENT.—Payment
21 may only be made under this title for a skin sub-
22 stitute product if the provider furnishing such prod-
23 uct is certified—

1 “(A) by the American Board of Wound
2 Management as a certified wound specialist or
3 a certified wound care specialist physician;

4 “(B) by the Wound, Ostomy and Con-
5 tinence Nursing Certification Board as a cer-
6 tified wound care nurse practitioner;

7 “(C) by the National Alliance of Wound
8 Care and Ostomy as wound care certified; or

9 “(D) by the American Foot Care Nurses
10 Association as a certified foot care specialist.

11 “(6) LIMITATION ON PROVIDER DISCOUNTS.—
12 For the period beginning on January 1, 2027, and
13 ending on December 31, 2030, payment may not be
14 made under this title for a skin substitute product
15 if the provider furnishing such product obtained
16 such product for less than \$342.75 per square centi-
17 meter.

18 “(7) SKIN SUBSTITUTE PRODUCT DEFINED.—
19 In this subsection, the term ‘skin substitute product’
20 has the meaning given such term in section
21 1847A(c)(6)(J).”.

22 **SEC. 4. REPORT.**

23 (a) IN GENERAL.—Not later than January 1, 2030,
24 the Secretary of Health and Human Services shall submit
25 to the appropriate committees of Congress a report on the

1 wound care industry, including manufacturers of skin sub-
 2 stitute products, wound dressings, and related wound
 3 management technologies. Such report shall include an
 4 analysis of—

5 (1) the cost of producing skin substitute prod-
 6 ucts in the United States; and

7 (2) patient access to skin substitute products,
 8 and the evidence supporting the effectiveness of such
 9 products.

10 (b) DEFINITIONS.—In this section:

11 (1) APPROPRIATE COMMITTEES OF CON-
 12 GRESS.—The term “appropriate committees of Con-
 13 gress” means—

14 (A) the Committee on Energy and Com-
 15 merce and the Committee on Ways and Means
 16 of the House of Representatives; and

17 (B) the Committee on Health, Education,
 18 Labor, and Pensions and the Committee on Fi-
 19 nance of the Senate.

20 (2) SKIN SUBSTITUTE PRODUCT.—The term
 21 “skin substitute product” has the meaning given
 22 such term in subparagraph (J) of section
 23 1847A(c)(6) of the Social Security Act (42 U.S.C.
 24 1395w–3a(c)(6)), as added by section 2(c).

○