

119TH CONGRESS
1ST SESSION

H. R. 6852

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

DECEMBER 18, 2025

Mr. EVANS of Colorado 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 “Advanced Wound Care
5 and Regenerative Medicine Access and Reform Act”.

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 (II), by striking “and” at
7 the end;

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

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

12 “(KK) skin substitute products (as defined
13 in 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:

“(B) to payment for skin substitute products (as defined in subsection (c)(6)(J)) that are furnished on or after January 1, 2026.”; and

(B) in subsection (b)—

(i) in paragraph (1)—

(I) in the text preceding subparagraph (A), by inserting “or a skin substitute product” after “drug or biological”;

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

(III) in subparagraph (C), by striking the period at the end and inserting “; or”; and

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

“(D) in the case of a skin substitute product (as defined in subsection (c)(6)(J)), the amount determined under paragraph (9).”; and

(ii) in paragraph (2)—

(I) in subparagraph (A), by inserting “or a skin substitute product” after “drug or biological”; and

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

6 (iii) by adding at the end the fol-
7 lowing:

8 “(9) SKIN SUBSTITUTE PRODUCTS.—

9 “(A) PAYMENT AMOUNT.—

10 “(i) INITIAL PAYMENT AMOUNT.—For
11 2026, the amount determined under this
12 paragraph for a skin substitute product is
13 the volume-weighted average of the Medi-
14 care payment allowance limits for skin sub-
15 stitute products, as determined under sub-
16 paragraph (B).

17 “(ii) ANNUAL UPDATE.—For 2027
18 and each subsequent year, the amount de-
19 termined under this paragraph for a skin
20 substitute product for such year is equal to
21 the amount determined under this para-
22 graph for the previous year, adjusted by
23 the percentage increase in the Consumer
24 Price Index for All Urban Consumers
25 (United States city average) for the 12-

1 month period ending with June of such
2 previous year.

3 “(B) VOLUME-WEIGHTED AVERAGE PAY-
4 MENT LIMIT.—For purposes of subparagraph
5 (A)(i), the volume-weighted average of the
6 Medicare payment allowance limits for skin sub-
7 stitute products is determined by—

8 “(i) calculating, with respect to each
9 billing and payment code listed in the April
10 2023 ASP Pricing File for each skin sub-
11 stitute product, an amount equal to the
12 product of—

13 “(I) the payment limit included
14 in such file with respect to such code;
15 and

16 “(II) the number of units (as
17 specified under paragraph (2))—

18 “(aa) billed with respect to
19 such code for a date of service in
20 2023; and

21 “(bb) listed in the CMS In-
22 tegrated Data Repository for
23 Part B (Carrier & DME) claims
24 data;

1 “(ii) calculating the sum of all
 2 amounts determined under clause (i); and
 3 “(iii) dividing the sum calculated
 4 under clause (ii) by the total number of
 5 units determined under clause (i)(II).”.

6 (2) CONFORMING AMENDMENTS.—Section
 7 1833(a)(1) of the Social Security Act (42 U.S.C.
 8 1395l(a)(1)) is amended—

9 (A) in subparagraph (S)(i), by striking
 10 “subject to subparagraph (EE)” and inserting “sub-
 11 ject to subparagraphs (EE) and (II)’”;

12 (B) by striking “and (HH)” and inserting
 13 “(HH)”; and

14 (C) by inserting “, and (II) with respect to
 15 skin substitute products under section
 16 1861(s)(2)(KK), the amount paid shall be 80
 17 percent of the lesser of the actual charge or the
 18 payment amount established under section
 19 1847A(b)(9)” before the semicolon at the end.

20 (c) SKIN SUBSTITUTE PRODUCT DEFINED.—Section
 21 1847A(c)(6) of the Social Security Act (42 U.S.C. 1395w–
 22 3a(c)(6)) is amended by adding at the end the following:

23 “(J) SKIN SUBSTITUTE PRODUCTS.—The
 24 term ‘skin substitute product’—

1 “(i) means a cellular, tissue, biological
2 or synthetic material that—

3 “(I) is applied to a wound and
4 intended to remain within the wound
5 bed; and

6 “(II) is marketed pursuant to
7 section 510(k), 513(f)(2), or 515 of
8 the Federal Food, Drug, and Cos-
9 metic Act, or section 361 of the Pub-
10 lic Health Service Act; and

11 “(ii) does not include a product that
12 is intended to temporarily protect or cover
13 the wound bed and be removed without re-
14 sorption such as a dressing; and

15 “(iii) the term ‘skin substitute prod-
16 uct’ shall include any products reimbursed
17 pursuant to skin substitutes codes by the
18 Medicare program at any time prior to
19 January 1, 2026.”.

20 (d) EXCLUSION FROM REPORTING REQUIRE-
21 MENTS.—Section 1847A(f)(2)(A) of the Social Security
22 Act (42 U.S.C. 1395w–3a(f)(2)(A)) is amended by insert-
23 ing “(except that, beginning January 1, 2026, a drug or
24 biological so described does not include a skin substitute
25 product (as defined in subsection (c)(6)(J)))” after “prod-

ucts that are payable under this part as a drug or biological”.

(e) CONSOLIDATED BILLING AND PAYMENT CODE.—
Not later than January 1, 2026, the Secretary of Health and Human Services shall establish a new billing and payment code for all skin substitute products (as defined in subparagraph (J) of section 1847A(c)(6) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)), as added by subsection (b)).

SEC. 3. EQUIVALENT REIMBURSEMENT IN OUTPATIENT SITES OF CARE.

The Secretary shall ensure that reimbursement for skin substitutes products and outpatient applications of skin substitute products are equivalent to those payment amounts outlined in Section 1847A of the Social Security Act (42 U.S.C. 1395w–3a(b)(9)), regardless of the site of care in which the skin substitute product is applied.

SEC. 4. ENHANCING PROGRAM INTEGRITY FOR SKIN SUBSTITUTE PRODUCTS.

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

“(aa) SPECIAL PAYMENT RULES FOR SKIN SUBSTITUTE PRODUCTS.—

1 “(1) IDENTIFICATION OF OUTLIER PROVIDERS
2 OF SKIN SUBSTITUTE PRODUCTS.—

3 “(A) IN GENERAL.—Not later than March
4 1, 2026, and every 2 years thereafter through
5 March 1, 2035, the Secretary shall determine
6 the 3 percent of the total number of providers
7 of skin substitute products that are outlier pro-
8 viders of skin substitute products.

9 “(B) OUTLIER PROVIDERS OF SKIN SUB-
10 STITUTE PRODUCTS.—The determination of an
11 outlier provider of skin substitute products
12 under this paragraph shall be based upon the
13 providers (as identified by national provider
14 identification number) that received the great-
15 est total payment under this title for skin sub-
16 stitute products furnished in the year preceding
17 the year in which the determination under sub-
18 paragraph (A) is made.

19 “(C) REFERRAL TO OIG.—The Secretary
20 shall—

21 “(i) make publicly available the list of
22 outlier providers of skin substitute prod-
23 ucts identified under each determination
24 under subparagraph (A); and

1 “(ii) transmit such list to the Inspec-
2 tor General of the Department of Health
3 and Human Services for the assessment of
4 potential fraud, waste, or abuse.

5 “(2) INITIAL PREPAYMENT CLAIM REVIEW FOR
6 CERTAIN OUTLIER PROVIDERS.—

7 “(A) IN GENERAL.—Beginning March 1,
8 2026, the Secretary shall conduct prepayment
9 review of claims for skin substitute products
10 submitted under this title by an outlier provider
11 of skin substitute products unless 1 or more of
12 the conditions described in subparagraph (B) is
13 met with respect to such provider.

14 “(B) LIMITATION.—For purposes of sub-
15 paragraph (A), the conditions described in this
16 subparagraph are, with respect to an outlier
17 provider of skin substitute products, the fol-
18 lowing:

19 “(i) Skin substitute products fur-
20 nished by the provider are subject to prior
21 authorization under paragraph (3).

22 “(ii) The rate of approval for claims
23 for skin substitute products furnished by
24 such provider that are subject to prepay-
25 ment review under this paragraph exceeds

1 90 percent (as determined over a period of
2 time or number of claims specified by the
3 Secretary).

4 “(iii) The Secretary determines that
5 the billing practices of the provider are
6 consistent with the applicable coverage cri-
7 teria and requirements under this title.

8 “(3) PRIOR AUTHORIZATION FOR OUTLIER PRO-
9 VIDERS OF SKIN SUBSTITUTE PRODUCTS.—

10 “(A) IN GENERAL.—Beginning not later
11 than January 1, 2027, subject to subparagraph
12 (B), the Secretary shall, for a period deter-
13 mined appropriate by the Secretary, apply prior
14 authorization for skin substitute products that
15 are furnished by an outlier provider of skin sub-
16 stitute products identified under paragraph (1).

17 “(B) REMOVAL FROM PRIOR AUTHORIZA-
18 TION.—In the event that the Secretary deter-
19 mines, with respect to an outlier provider of
20 skin substitute products, that the rate of ap-
21 proval for requests for prior authorization
22 under this paragraph for skin substitute prod-
23 ucts furnished by such provider exceeds 90 per-
24 cent (as determined over a period of time or
25 number of claims specified by the Secretary),

1 the Secretary may cease to apply prior author-
2 ization under this paragraph for skin substitute
3 products furnished by such provider.

4 “(C) FUNDING.—For purposes of carrying
5 out this paragraph, the Secretary shall provide
6 for the transfer, from the Federal Supple-
7 mentary Medical Insurance Trust Fund under
8 section 1841, to the Centers for Medicare &
9 Medicaid Services Program Management Ac-
10 count, of \$5,000,000 for each of fiscal years
11 2027 through 2030, to remain available until
12 expended.

13 “(4) ENROLLMENT REVOCATION OR EXCLUSION
14 OF NONCOMPLIANT OUTLIER PROVIDERS.—

15 “(A) IN GENERAL.—Beginning January 1,
16 2028, if the rate of denial for requests for prior
17 authorization under paragraph (3) for skin sub-
18 stitute products furnished by an outlier provider
19 of skin substitute products exceeds 75 percent
20 over a period of 6 or more consecutive months,
21 the Secretary shall determine that an abuse of
22 billing privileges exists with respect to such pro-
23 vider for purposes of section 424.535(a)(8)(ii)
24 of title 42, Code of Federal Regulations.

1 “(B) REFERRAL FOR EXCLUSION.—If the
2 Secretary determines under subparagraph (A)
3 that an abuse of billing privileges exists with re-
4 spect to an outlier provider of skin substitute
5 products, the Secretary shall direct the Inspec-
6 tor General of the Department of Health and
7 Human Services to determine whether such
8 provider should be excluded from participation
9 in any Federal health care program under sec-
10 tion 1128(b)(6).

11 “(5) SKIN SUBSTITUTE PRODUCT WASTAGE.—

12 “(A) With respect to skin substitute prod-
13 ucts furnished for the treatment of chronic or
14 acute wounds, payment shall be only made for
15 the reasonable and necessary portion of the
16 skin substitute product used in the treatment of
17 the wound, excluding wastage.

18 “(B) For the purpose of subparagraph (A),
19 the reasonable and necessary portion of the
20 skin substitute product is defined as the greater
21 of (i) 3 square centimeters, or (ii) 120 percent
22 of the size of the treated wound.

23 “(6) SKIN SUBSTITUTE PRODUCT DEFINED.—

24 In this subsection, the term ‘skin substitute product’ has
25 the meaning given such term in section 1847A(c)(6)(J).”.

1 **SEC. 5. STREAMLINING APPROVAL PROCESSES FOR**
2 **HUMAN CELLS, TISSUES AND CELLULAR AND**
3 **TISSUE-BASED PRODUCTS.**

4 (a) IN GENERAL.—Not later than 18 months after
5 the date of enactment of this Act, the Secretary of Health
6 and Human Services, acting through the Commissioner of
7 Food and Drugs, shall—

8 (1) conduct a comprehensive review of the ap-
9 proval process applied to human cellular and tissue
10 allografts and autografts that are not subject to reg-
11 ulation only under section 361 of the Public Health
12 Service Act, including those processed into liquid,
13 gel, or powder forms;

14 (2) identify opportunities to streamline applica-
15 tion requirements, review timelines, and evidentiary
16 standards for such products while maintaining ap-
17 propriate safety and efficacy oversight;

18 (3) consider the development of a tiered review
19 framework based on risk assessment factors includ-
20 ing degree of manipulation, processing methods,
21 mode or administration, and clinical safety profile;

22 (4) evaluate the need for pre-market clinical
23 evaluation and the appropriateness of leveraging ex-
24 isting clinical data, real-world evidence, and registry
25 data to reduce duplicative clinical trial requirements
26 where scientifically justified; and

1 (5) assess mechanisms to harmonize require-
2 ments between products currently regulated only
3 under section 361 of the Public Health Service Act
4 that may transition to section 351 regulation.

5 (b) STAKEHOLDER CONSULTATION.—In conducting
6 the review under paragraph (1), the Secretary shall con-
7 sult with—

- 8 (1) manufacturers of human tissue allografts;
- 9 (2) tissue banks and procurement organiza-
10 tions;
- 11 (3) clinicians specializing in wound care, sur-
12 gical reconstruction, and regenerative medicine;
- 13 (4) patient advocacy organizations;
- 14 (5) health insurance payors; and
- 15 (6) relevant scientific and medical professional
16 societies.

17 (c) CONSIDERATIONS.—The review shall specifically
18 consider—

- 19 (1) appropriate modifications to Chemistry,
20 Manufacturing, and Controls (CMC) requirements
21 reflecting the biological nature and donor-dependent
22 variability of human tissue;
- 23 (2) potential use of expedited review pathways,
24 including priority review designations;

1 (3) opportunities for modular or staged applica-
2 tion submissions;

3 (4) appropriate clinical endpoint criteria and
4 study designs for different types of allografts and
5 autografts;

6 (5) post-market surveillance requirements as an
7 alternative to pre-market evidence requirements; and

8 (6) international regulatory approaches to simi-
9 lar products.

10 (d) GUIDANCE.—Not later than 24 months after the
11 date of enactment of this Act, the Secretary shall issue
12 draft guidance implementing any streamlining measures
13 identified under subsection (b), and shall finalize such
14 guidance not later than 12 months after the close of the
15 public comment period.

16 (e) REPORT TO CONGRESS.—Not later than 30
17 months after the date of enactment of this Act, the Sec-
18 retary shall submit to the Committee on Health, Edu-
19 cation, Labor, and Pensions of the Senate and the Com-
20 mittee on Energy and Commerce of the House of Rep-
21 resentatives a report on the review conducted under sub-
22 section (b), including—

23 (1) findings and recommendations for regu-
24 latory streamlining;

1 (2) any administrative actions taken or pro-
2 posed;

3 (3) recommendations for additional legislative
4 action, if any; and

5 (4) estimated impacts on patient access and
6 public health.

7 (f) PRESERVATION OF SAFETY STANDARDS.—Noth-
8 ing in this section shall be construed to reduce or eliminate
9 safety or efficacy standards applicable to human tissue
10 allografts or autografts subject to licensure under section
11 351 of the Public Health Service Act.

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