

119TH CONGRESS
1ST SESSION

S. 2561

To amend title XVIII of the Social Security Act to reform the payment rules regarding skin substitute products.

IN THE SENATE OF THE UNITED STATES

JULY 31, 2025

Mr. CASSIDY introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act to reform the payment rules regarding skin substitute products.

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 “Skin Substitute Access
5 and Payment Reform Act of 2025”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

8 (1) Skin substitute products are advanced bio-
9 logical therapies used to treat chronic, non-healing
10 wounds, such as diabetic foot ulcers and venous leg

1 ulcers. Each year, more than 10,500,000 Medicare
2 beneficiaries will require medical care for treatment
3 of a wound. By improving healing rates and reduc-
4 ing the rate of lower limb amputation, skin sub-
5 stitute products improve the health and wellness of
6 Medicare beneficiaries.

7 (2) These treatments vary in makeup and
8 source material, including human tissue-derived
9 products, non-human, animal-derived products, and
10 synthetic products. Studies show that different skin
11 substitute products are similarly safe and effective in
12 treating chronic wounds, and Medicare coverage
13 does not currently differentiate between different
14 types of lawfully marketed skin substitutes.
15 Healthcare providers are well-informed about alter-
16 native skin substitute products and are in the best
17 position to determine which specific product would
18 best suit each specific patient based on the patient's
19 specific needs and the provider's knowledge and ex-
20 perience.

21 (3) The Centers for Medicare & Medicaid Serv-
22 ices has faced challenges in determining consistent
23 and accurate pricing and payment for services that
24 involve skin substitute products, resulting in uncer-

1 tainty and significant price differences among these
2 products.

3 (4) The Medicare payment systems in place at
4 the date of enactment of this Act incentivize use of
5 more expensive products and continued price in-
6 creases while failing to recognize the similar clinical
7 effects of skin substitute products. Medicare expend-
8 itures for skin substitute products rose significantly
9 in 2024 and 2025.

10 (5) It is therefore necessary to reform the
11 Medicare payment and coverage rules for skin sub-
12 stitute products to appropriately recognize the well-
13 established and known clinical value of these treat-
14 ments while containing costs.

15 **SEC. 3. PAYMENT REFORM FOR SKIN SUBSTITUTE PROD-**
16 **UCTS.**

17 (a) IN GENERAL.—Section 1847A(b) of the Social
18 Security Act (42 U.S.C. 1395w–3a(b)) is amended—

19 (1) in paragraph (1)—

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

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

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

1 “(D) in the case of a skin substitute prod-
 2 uct (as defined in subsection (c)(6)(J)), the
 3 amount determined under paragraph (9).”; and
 4 (2) by adding at the end the following new
 5 paragraph:

6 “(9) SKIN SUBSTITUTE PRODUCTS.—

7 “(A) IN GENERAL.—Beginning on January
 8 1, 2026, for any skin substitute product (as de-
 9 fined in subsection (c)(6)), the amount specified
 10 in this paragraph is the volume-weighted aver-
 11 age of the payment allowance limit calculated
 12 under subparagraph (B).

13 “(B) VOLUME-WEIGHTED AVERAGE PAY-
 14 MENT LIMIT.—The volume-weighted average of
 15 the payment allowance limit of a skin substitute
 16 product under this paragraph is determined
 17 by—

18 “(i) calculating the sum of the prod-
 19 ucts of—

20 “(I) the published payment allow-
 21 ance limit for each billing and pay-
 22 ment code listed in the ASP Pricing
 23 File published by the Secretary for
 24 the fourth calendar quarter of 2023
 25 for each skin substitute product; and

1 “(II) the total number of units,
 2 as specified under paragraph (2), for
 3 each billing and payment code de-
 4 scribed in subclause (I), billed with
 5 dates of service from October 1, 2023,
 6 to December 31, 2023, and listed in
 7 the Integrated Data Repository for
 8 Part B claims data; and

9 “(ii) dividing the sum calculated
 10 under clause (i) by the total number of
 11 units under subclause (II).

12 “(C) UPDATES TO PAYMENT AMOUNTS.—
 13 For 2027 and each subsequent year, the
 14 amount specified in this paragraph shall be ad-
 15 justed for the percentage increase in the con-
 16 sumer price index for all urban consumers
 17 (U.S. city average) for the 12-month period
 18 ending with June of the previous year.”.

19 (b) DEFINITION AND OTHER RULES FOR SKIN SUB-
 20 STITUTE PRODUCTS.—Section 1847A(c)(6) of the Social
 21 Security Act (42 U.S.C. 1395w–3a(c)(6)) is amended by
 22 adding at the end the following new subparagraph:

23 “(J) SKIN SUBSTITUTE PRODUCTS.—

24 “(i) IN GENERAL.—The term ‘skin
 25 substitute product’—

1 “(I) means a cellular, biological
2 or synthetic material or tissue applied
3 to a wound and intended to remain
4 within the wound bed, including a
5 product approved, cleared, or author-
6 ized to section 510(k), 513(f)(2), or
7 515 of the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 360(k),
9 260c(f)(2), 360e) or section 361 of
10 the Public Health Service Act (42
11 U.S.C. 264), and their implementing
12 regulations; and

13 “(II) does not include—

14 “(aa) any product that is in-
15 tended to temporarily protect or
16 cover the wound bed and be re-
17 moved before complete resorp-
18 tion, such as a dressing;

19 “(bb) any liquid, gel, pow-
20 der, or other similarly constituted
21 item; or

22 “(cc) any product that
23 would otherwise meet the require-
24 ments of subclause (I), but is ap-
25 proved under section 505 of the

1 Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 355) or li-
3 censed under section 351(a) of
4 the Public Health Service Act
5 (42 U.S.C. 262(a)).

6 “(ii) CONSOLIDATED BILLING AND
7 PAYMENT CODE.—Not later than January
8 1, 2026, the Secretary shall establish a
9 new billing and payment code for all skin
10 substitute products.

11 “(iii) SPECIAL RULES.—Beginning on
12 January 1, 2026, the following rules shall
13 apply:

14 “(I) Each skin substitute product
15 shall be subject to the same criteria
16 when determining whether such skin
17 substitute product is reasonable and
18 necessary for the diagnosis or treat-
19 ment of illness or injury under section
20 1862(a)(1)(A), unless determined by
21 the Secretary that such product is un-
22 safe based on evidence of contamina-
23 tion, serious infectious disease, or se-
24 rious adverse reactions caused by such
25 product.

1 “(II) The Secretary may not de-
2 termine that a skin substitute product
3 is not considered reasonable and nec-
4 essary for the diagnosis or treatment
5 of illness or injury under section
6 1862(a)(1)(A) based solely on analysis
7 of any clinical evidence relating to
8 such product.

9 “(III) A manufacturer of a skin
10 substitute product shall not be re-
11 quired to report the average sales
12 price for such product under section
13 1927(b)(3)(A)(iii) or subsection
14 (f)(2).”.

○