

119TH CONGRESS
1ST SESSION

H. R. 5768

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

OCTOBER 17, 2025

Mr. CARTER of Georgia (for himself, Mr. VEASEY, Mr. STEUBE, and Mr. McCORMICK) 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 “Skin Substitute Access
5 and Payment 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 (JJ), by adding “and” at
7 the end; and

8 (2) by inserting after subparagraph (JJ) the
9 following new subparagraph:

10 “(KK) skin substitute products (as defined
11 in section 1847A(c)(6)(J)).”.

12 (b) PAYMENT.—

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

16 (A) in subsection (a)(1)—

17 (i) by striking the period at the end
18 and inserting “; and”;

19 (ii) by striking “shall apply to” and
20 inserting “shall apply—

21 “(A) to”; and

22 (iii) by adding at the end the fol-
23 lowing new subparagraph:

24 “(B) to payment for skin substitute prod-
25 ucts (as defined in subsection (c)(6)(J)) that
26 are furnished on or after January 1, 2026.”;

1 (B) in subsection (b)—

2 (i) in paragraph (1)—

3 (I) in the text preceding subpara-
4 graph (A), by inserting “or a skin
5 substitute product” after “drug or bi-
6 ological”;

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

9 (III) in subparagraph (C), by
10 striking the period at the end and in-
11 serting “; or”; and

12 (IV) by adding at the end the fol-
13 lowing new subparagraph:

14 “(D) in the case of a skin substitute prod-
15 uct (as defined in subsection (c)(6)(J)), the
16 amount determined under paragraph (9).”; and

17 (ii) in paragraph (2)—

18 (I) in subparagraph (A), by in-
19 serting “or a skin substitute product”
20 after “drug or biological”; and

21 (II) in subparagraph (B), by in-
22 serting “, and, with respect to a skin
23 substitute product, a square centi-
24 meter” after “pertaining to liquids”;
25 and

1 (iii) by adding at the end the fol-
2 lowing:

3 “(9) SKIN SUBSTITUTE PRODUCTS.—

4 “(A) PAYMENT AMOUNT.—

5 “(i) INITIAL PAYMENT AMOUNT.—For
6 2026, the amount determined under this
7 paragraph for a skin substitute product is
8 the volume-weighted average of the Medi-
9 care payment allowance limits for skin sub-
10 stitute products, as determined under sub-
11 paragraph (B).

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

23 “(B) VOLUME-WEIGHTED AVERAGE PAY-
24 MENT LIMIT.—For purposes of subparagraph
25 (A)(i), the volume-weighted average of the

1 Medicare payment allowance limits for skin sub-
2 stitute products is determined by—

3 “(i) calculating, with respect to each
4 billing and payment code listed in the Oc-
5 tober 2023 ASP Pricing File for each skin
6 substitute product, an amount equal to the
7 product of—

8 “(I) the payment limit included
9 in such file with respect to such code;
10 and

11 “(II) the number of units (as
12 specified under paragraph (2))—

13 “(aa) billed with respect to
14 such code for a date of service in
15 2023; and

16 “(bb) listed in the CMS In-
17 tegrated Data Repository for
18 Part B (Carrier & DME) claims
19 data;

20 “(ii) calculating the sum of all
21 amounts determined under clause (i); and

22 “(iii) dividing the sum calculated
23 under clause (ii) by the total number of
24 units determined under clause (i)(II).”.

1 (2) CONFORMING AMENDMENTS.—Section
 2 1833(a)(1) of the Social Security Act (42 U.S.C.
 3 1395l(a)(1)) is amended—

4 (A) in subparagraph (S)(i), by striking
 5 “subject to subparagraph (EE)” and inserting
 6 “subject to subparagraphs (EE) and (II)”;

7 (B) by striking “and (HH)” and inserting
 8 “(HH)”; and

9 (C) by inserting “, and (II) with respect to
 10 skin substitute products under section
 11 1861(s)(2)(KK), the amount paid shall be 80
 12 percent of the lesser of the actual charge or the
 13 payment amount established under section
 14 1847A(b)(9)” before the semicolon at the end.

15 (c) SKIN SUBSTITUTE PRODUCT DEFINED.—Section
 16 1847A(c)(6) of the Social Security Act (42 U.S.C. 1395w–
 17 3a(c)(6)) is amended by adding at the end the following:

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

20 “(i) means a cellular, tissue, biological
 21 or synthetic material that—

22 “(I) is applied to a wound and
 23 intended to remain within the wound
 24 bed; and

1 “(II) is marketed pursuant to
2 section 510(k), 513(f)(2), or 515 of
3 the Federal Food, Drug, and Cos-
4 metic Act, or section 361 of the Pub-
5 lic Health Service Act; and

6 “(ii) does not include—

7 “(I) a product that is intended to
8 temporarily protect or cover the
9 wound bed and be removed before
10 complete resorption (such as a dress-
11 ing); or

12 “(II) a liquid, gel, powder, or
13 other similarly constituted item.”.

14 (d) EXCLUSION FROM REPORTING REQUIRE-
15 MENTS.—Section 1847A(f)(2)(A) of the Social Security
16 Act (42 U.S.C. 1395w–3a(f)(2)(A)) is amended by insert-
17 ing “(except that, beginning January 1, 2026, a drug or
18 biological so described does not include a skin substitute
19 product (as defined in subsection (c)(6)(J)))” after “prod-
20 ucts that are payable under this part as a drug or biologi-
21 cal”.

22 (e) CONSOLIDATED BILLING AND PAYMENT CODE.—
23 Not later than January 1, 2026, the Secretary of Health
24 and Human Services shall establish a new billing and pay-
25 ment code for all skin substitute products (as defined in

1 subparagraph (J) of section 1847A(c)(6) of the Social Se-
 2 curity Act (42 U.S.C. 1395w–3a(c)(6)), as added by sub-
 3 section (b)).

4 **SEC. 3. ENHANCING PROGRAM INTEGRITY FOR SKIN SUB-**
 5 **STITUTE PRODUCTS.**

6 Section 1834 of the Social Security Act (42 U.S.C.
 7 1395m) is amended by adding at the end the following
 8 new subsection:

9 “(aa) SPECIAL PAYMENT RULES FOR SKIN SUB-
 10 STITUTE PRODUCTS.—

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

13 “(A) IN GENERAL.—Not later than De-
 14 cember 1, 2025, and every 2 years thereafter
 15 through December 1, 2035, the Secretary shall
 16 determine the 3 percent of the total number of
 17 providers of skin substitute products that are
 18 outlier providers of skin substitute products.

19 “(B) OUTLIER PROVIDERS OF SKIN SUB-
 20 STITUTE PRODUCTS.—The determination of an
 21 outlier provider of skin substitute products
 22 under this paragraph shall be based upon the
 23 providers (as identified by national provider
 24 identification number) that received the great-
 25 est total payment under this title for skin sub-

stitute products furnished in the year preceding the year in which the determination under subparagraph (A) is made.

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

“(i) make publicly available the list of outlier providers of skin substitute products identified under each determination under subparagraph (A); and

“(ii) transmit such list to the Inspector General of the Department of Health and Human Services for the assessment of potential fraud, waste, or abuse.

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

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

“(B) LIMITATION.—For purposes of subparagraph (A), the conditions described in this subparagraph are, with respect to an outlier

1 provider of skin substitute products, the fol-
2 lowing:

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

6 “(ii) The rate of approval for claims
7 for skin substitute products furnished by
8 such provider that are subject to prepay-
9 ment review under this paragraph exceeds
10 90 percent (as determined over a period of
11 time or number of claims specified by the
12 Secretary).

13 “(iii) The Secretary determines that
14 the billing practices of the provider are
15 consistent with the applicable coverage cri-
16 teria and requirements under this title.

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

19 “(A) IN GENERAL.—Beginning not later
20 than January 1, 2027, subject to subparagraph
21 (B), the Secretary shall, for a period deter-
22 mined appropriate by the Secretary, apply prior
23 authorization for skin substitute products that
24 are furnished by an outlier provider of skin sub-
25 stitute products identified under paragraph (1).

1 “(B) REMOVAL FROM PRIOR AUTHORIZA-
2 TION.—In the event that the Secretary deter-
3 mines, with respect to an outlier provider of
4 skin substitute products, that the rate of ap-
5 proval for requests for prior authorization
6 under this paragraph for skin substitute prod-
7 ucts furnished by such provider exceeds 90 per-
8 cent (as determined over a period of time or
9 number of claims specified by the Secretary),
10 the Secretary shall cease to apply prior author-
11 ization under this paragraph for skin substitute
12 products furnished by such provider.

13 “(C) FUNDING.—For purposes of carrying
14 out this paragraph, the Secretary shall provide
15 for the transfer, from the Federal Supple-
16 mentary Medical Insurance Trust Fund under
17 section 1841, to the Centers for Medicare &
18 Medicaid Services Program Management Ac-
19 count, of \$5,000,000 for each of fiscal years
20 2027 through 2030, to remain available until
21 expended.

22 “(4) ENROLLMENT REVOCATION OR EXCLUSION
23 OF NONCOMPLIANT OUTLIER PROVIDERS.—

24 “(A) IN GENERAL.—Beginning January 1,
25 2028, if the rate of denial for requests for prior

1 authorization under paragraph (3) for skin sub-
2 stitute products furnished by an outlier provider
3 of skin substitute products exceeds 75 percent
4 over a period of 6 or more consecutive months,
5 the Secretary shall determine that an abuse of
6 billing privileges exists with respect to such pro-
7 vider for purposes of section 424.535(a)(8)(ii)
8 of title 42, Code of Federal Regulations.

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

19 “(5) MEDICARE COVERAGE CRITERIA FOR SKIN
20 SUBSTITUTE PRODUCTS.—Any skin substitute prod-
21 uct defined in section 1847A(c)(6)(J) of the Social
22 Security Act and furnished during 2026 shall be
23 subject to the same coverage criteria when deter-
24 mining whether the skin substitute product is cov-
25 ered under section 1862(a)(1)(A), unless such prod-

1 uct is determined by the Secretary to be unsafe
2 based on evidence of contamination, serious infec-
3 tious disease, or serious adverse reactions caused by
4 the product. Neither the Secretary nor any Medicare
5 administrative contractor may determine, including
6 through a determination made pursuant to the pre-
7 payment review program or prior authorization pro-
8 gram described in paragraphs (2) and (3), that a
9 specific skin substitute product furnished in 2026 is
10 not covered by Medicare based solely on analysis of
11 the clinical evidence relating to that skin substitute
12 product.

13 “(6) SKIN SUBSTITUTE PRODUCT DEFINED.—
14 In this subsection, the term ‘skin substitute product’
15 has the meaning given such term in section
16 1847A(c)(6)(J).”.

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