I

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

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A BILL

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

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Advanced Wound Care and Regenerative Medicine Access and Reform Act''.

SEC. 2. PAYMENT REFORM FOR SKIN SUBSTITUTE PRODUCTS.

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

(1) in subparagraph (II), by striking ''and'' at the end;

(2) in subparagraph (JJ), by adding ''and'' at the end; and

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

''(KK) skin substitute products (as defined in section 1847A(c)(6)(J)).''.

(b) PAYMENT.—

(1) PAYMENT AMOUNT.—Section 1847A of the Social Security Act (42 U.S.C. 1395w–3a) is amended—

(A) in subsection (a)(1)—

(i) by striking the period at the end and inserting ''; and'';

(ii) by striking ''shall apply to'' and inserting ''shall apply—

''(A) to''; and

(iii) by adding at the end the following 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

(II) in subparagraph (B), by inserting ", and, with respect to a skin substitute product, a square centimeter" after "pertaining to liquids"; and

(iii) by adding at the end the following:

"(9) SKIN SUBSTITUTE PRODUCTS.—

"(A) PAYMENT AMOUNT.—

"(i) INITIAL PAYMENT AMOUNT.—For 2026, the amount determined under this paragraph for a skin substitute product is the volume-weighted average of the Medicare payment allowance limits for skin substitute products, as determined under subparagraph (B).

"(ii) ANNUAL UPDATE.—For 2027 and each subsequent year, the amount determined under this paragraph for a skin substitute product for such year is equal to the amount determined under this paragraph for the previous year, adjusted by the percentage increase in the Consumer Price Index for All Urban Consumers (United States city average) for the 12-

month period ending with June of such previous year.

"(B) VOLUME-WEIGHTED AVERAGE PAYMENT LIMIT.—For purposes of subparagraph (A)(i), the volume-weighted average of the Medicare payment allowance limits for skin substitute products is determined by—

"(i) calculating, with respect to each billing and payment code listed in the April 2023 ASP Pricing File for each skin substitute product, an amount equal to the product of—

"(I) the payment limit included in such file with respect to such code; and

"(II) the number of units (as specified under paragraph (2))—

"(aa) billed with respect to such code for a date of service in 2023; and

"(bb) listed in the CMS Integrated Data Repository for Part B (Carrier & DME) claims data;

"(ii) calculating the sum of all amounts determined under clause (i); and

"(iii) dividing the sum calculated under clause (ii) by the total number of units determined under clause (i)(II).".

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

(A) in subparagraph (S)(i), by striking "subject to subparagraph (EE)" and inserting "subject to subparagraphs (EE) and (II)' ";

(B) by striking "and (HH)" and inserting "(HH)"; and

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

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

"(J) SKIN SUBSTITUTE PRODUCTS.—The term 'skin substitute product'—

''(i) means a cellular, tissue, biological or synthetic material that—

''(I) is applied to a wound and intended to remain within the wound bed; and

''(II) is marketed pursuant to section 510(k), 513(f)(2), or 515 of the Federal Food, Drug, and Cosmetic Act, or section 361 of the Public Health Service Act; and

''(ii) does not include a product that is intended to temporarily protect or cover the wound bed and be removed without resorption such as a dressing; and

''(iii) the term 'skin substitute product' shall include any products reimbursed pursuant to skin substitutes codes by the Medicare program at any time prior to January 1, 2026.''.

(d) EXCLUSION FROM REPORTING REQUIREMENTS.—Section 1847A(f)(2)(A) of the Social Security Act (42 U.S.C. 1395w–3a(f)(2)(A)) is amended by inserting ''(except that, beginning January 1, 2026, a drug or biological so described does not include a skin substitute 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) IDENTIFICATION OF OUTLIER PROVIDERS OF SKIN SUBSTITUTE PRODUCTS.—

"(A) IN GENERAL.—Not later than March 1, 2026, and every 2 years thereafter through March 1, 2035, the Secretary shall determine the 3 percent of the total number of providers of skin substitute products that are outlier providers of skin substitute products.

"(B) OUTLIER PROVIDERS OF SKIN SUBSTITUTE PRODUCTS.—The determination of an outlier provider of skin substitute products under this paragraph shall be based upon the providers (as identified by national provider identification number) that received the greatest total payment under this title for skin substitute 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 March 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 provider of skin substitute products, the following:

"(i) Skin substitute products furnished by the provider are subject to prior authorization under paragraph (3).

"(ii) The rate of approval for claims for skin substitute products furnished by such provider that are subject to prepayment review under this paragraph exceeds

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

"(iii) The Secretary determines that the billing practices of the provider are consistent with the applicable coverage criteria and requirements under this title.

"(3) PRIOR AUTHORIZATION FOR OUTLIER PROVIDERS OF SKIN SUBSTITUTE PRODUCTS.—

"(A) IN GENERAL.—Beginning not later than January 1, 2027, subject to subparagraph (B), the Secretary shall, for a period determined appropriate by the Secretary, apply prior authorization for skin substitute products that are furnished by an outlier provider of skin substitute products identified under paragraph (1).

"(B) REMOVAL FROM PRIOR AUTHORIZATION.—In the event that the Secretary determines, with respect to an outlier provider of skin substitute products, that the rate of approval for requests for prior authorization under this paragraph for skin substitute products furnished by such provider exceeds 90 percent (as determined over a period of time or number of claims specified by the Secretary),

the Secretary may cease to apply prior authorization under this paragraph for skin substitute products furnished by such provider.

"(C) FUNDING.—For purposes of carrying out this paragraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, to the Centers for Medicare & Medicaid Services Program Management Account, of $5,000,000 for each of fiscal years 2027 through 2030, to remain available until expended.

"(4) ENROLLMENT REVOCATION OR EXCLUSION OF NONCOMPLIANT OUTLIER PROVIDERS.—

"(A) IN GENERAL.—Beginning January 1, 2028, if the rate of denial for requests for prior authorization under paragraph (3) for skin substitute products furnished by an outlier provider of skin substitute products exceeds 75 percent over a period of 6 or more consecutive months, the Secretary shall determine that an abuse of billing privileges exists with respect to such provider for purposes of section 424.535(a)(8)(ii) of title 42, Code of Federal Regulations.

"(B) REFERRAL FOR EXCLUSION.—If the Secretary determines under subparagraph (A) that an abuse of billing privileges exists with respect to an outlier provider of skin substitute products, the Secretary shall direct the Inspector General of the Department of Health and Human Services to determine whether such provider should be excluded from participation in any Federal health care program under section 1128(b)(6).

"(5) SKIN SUBSTITUTE PRODUCT WASTAGE.—

"(A) With respect to skin substitute products furnished for the treatment of chronic or acute wounds, payment shall be only made for the reasonable and necessary portion of the skin substitute product used in the treatment of the wound, excluding wastage.

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

"(6) SKIN SUBSTITUTE PRODUCT DEFINED.—In this subsection, the term 'skin substitute product' has the meaning given such term in section 1847A(c)(6)(J).".

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

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

(1) conduct a comprehensive review of the approval process applied to human cellular and tissue allografts and autografts that are not subject to regulation only under section 361 of the Public Health Service Act, including those processed into liquid, gel, or powder forms;

(2) identify opportunities to streamline application requirements, review timelines, and evidentiary standards for such products while maintaining appropriate safety and efficacy oversight;

(3) consider the development of a tiered review framework based on risk assessment factors including degree of manipulation, processing methods, mode or administration, and clinical safety profile;

(4) evaluate the need for pre-market clinical evaluation and the appropriateness of leveraging existing clinical data, real-world evidence, and registry data to reduce duplicative clinical trial requirements where scientifically justified; and

(5) assess mechanisms to harmonize requirements between products currently regulated only under section 361 of the Public Health Service Act that may transition to section 351 regulation.

(b) STAKEHOLDER CONSULTATION.—In conducting the review under paragraph (1), the Secretary shall consult with—

(1) manufacturers of human tissue allografts;

(2) tissue banks and procurement organizations;

(3) clinicians specializing in wound care, surgical reconstruction, and regenerative medicine;

(4) patient advocacy organizations;

(5) health insurance payors; and

(6) relevant scientific and medical professional societies.

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

(1) appropriate modifications to Chemistry, Manufacturing, and Controls (CMC) requirements reflecting the biological nature and donor-dependent variability of human tissue;

(2) potential use of expedited review pathways, including priority review designations;

(3) opportunities for modular or staged application submissions;

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

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

(6) international regulatory approaches to similar products.

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

(e) REPORT TO CONGRESS.—Not later than 30 months after the date of enactment of this Act, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the review conducted under subsection (b), including—

(1) findings and recommendations for regulatory streamlining;

(2) any administrative actions taken or proposed;

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

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

(f) PRESERVATION OF SAFETY STANDARDS.—Nothing in this section shall be construed to reduce or eliminate safety or efficacy standards applicable to human tissue allografts or autografts subject to licensure under section 351 of the Public Health Service Act.

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