119TH CONGRESS
1ST SESSION

S. _____

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

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

A BILL

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

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 ''Skin Substitute Access and Payment Reform Act of 2025''.

SEC. 2. FINDINGS.

Congress finds the following:

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

ulcers. Each year, more than 10,500,000 Medicare beneficiaries will require medical care for treatment of a wound. By improving healing rates and reducing the rate of lower limb amputation, skin substitute products improve the health and wellness of Medicare beneficiaries.

(2) These treatments vary in makeup and source material, including human tissue-derived products, non-human, animal-derived products, and synthetic products. Studies show that different skin substitute products are similarly safe and effective in treating chronic wounds, and Medicare coverage does not currently differentiate between different types of lawfully marketed skin substitutes. Healthcare providers are well-informed about alternative skin substitute products and are in the best position to determine which specific product would best suit each specific patient based on the patient's specific needs and the provider's knowledge and experience.

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

tainty and significant price differences among these products.

(4) The Medicare payment systems in place at the date of enactment of this Act incentivize use of more expensive products and continued price increases while failing to recognize the similar clinical effects of skin substitute products. Medicare expenditures for skin substitute products rose significantly in 2024 and 2025.

(5) It is therefore necessary to reform the Medicare payment and coverage rules for skin substitute products to appropriately recognize the well-established and known clinical value of these treatments while containing costs.

SEC. 3. PAYMENT REFORM FOR SKIN SUBSTITUTE PRODUCTS.

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

(1) in paragraph (1)—

(A) subparagraph (B), by striking ''or'' at the end;

(B) in subparagraph (C), by striking the period at the end and inserting ''; or''; and

(C) 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

(2) by adding at the end the following new paragraph:

"(9) SKIN SUBSTITUTE PRODUCTS.—

"(A) IN GENERAL.—Beginning on January 1, 2026, for any skin substitute product (as defined in subsection (c)(6)), the amount specified in this paragraph is the volume-weighted average of the payment allowance limit calculated under subparagraph (B).

"(B) VOLUME-WEIGHTED AVERAGE PAYMENT LIMIT.—The volume-weighted average of the payment allowance limit of a skin substitute product under this paragraph is determined by—

"(i) calculating the sum of the products of—

"(I) the published payment allowance limit for each billing and payment code listed in the ASP Pricing File published by the Secretary for the fourth calendar quarter of 2023 for each skin substitute product; and

''(II) the total number of units, as specified under paragraph (2), for each billing and payment code described in subclause (I), billed with dates of service from October 1, 2023, to December 31, 2023, and listed in the Integrated Data Repository for Part B claims data; and

''(ii) dividing the sum calculated under clause (i) by the total number of units under subclause (II).

''(C) UPDATES TO PAYMENT AMOUNTS.—For 2027 and each subsequent year, the amount specified in this paragraph shall be adjusted for the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year.''.

(b) DEFINITION AND OTHER RULES FOR SKIN SUBSTITUTE PRODUCTS.—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 new subparagraph:

''(J) SKIN SUBSTITUTE PRODUCTS.—

''(i) IN GENERAL.—The term 'skin substitute product' —

"(I) means a cellular, biological or synthetic material or tissue applied to a wound and intended to remain within the wound bed, including a product approved, cleared, or authorized to section 510(k), 513(f)(2), or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 260c(f)(2), 360e) or section 361 of the Public Health Service Act (42 U.S.C. 264), and their implementing regulations; and

"(II) does not include—

"(aa) any product that is intended to temporarily protect or cover the wound bed and be removed before complete resorption, such as a dressing;

"(bb) any liquid, gel, powder, or other similarly constituted item; or

"(cc) any product that would otherwise meet the requirements of subclause (I), but is approved under section 505 of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or licensed under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

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

''(iii) SPECIAL RULES.—Beginning on January 1, 2026, the following rules shall apply:

''(I) Each skin substitute product shall be subject to the same criteria when determining whether such skin substitute product is reasonable and necessary for the diagnosis or treatment of illness or injury under section 1862(a)(1)(A), unless determined by the Secretary that such product is unsafe based on evidence of contamination, serious infectious disease, or serious adverse reactions caused by such product.

''(II) The Secretary may not determine that a skin substitute product is not considered reasonable and necessary for the diagnosis or treatment of illness or injury under section 1862(a)(1)(A) based solely on analysis of any clinical evidence relating to such product.

''(III) A manufacturer of a skin substitute product shall not be required to report the average sales price for such product under section 1927(b)(3)(A)(iii) or subsection (f)(2).''.