[~118H6465]

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(Original Signature of Member)

119TH CONGRESS
1ST SESSION

H. R. _____

To amend title XVIII of the Social Security Act to provide a phase-in for plasma-derived products under the manufacturer discount program.

IN THE HOUSE OF REPRESENTATIVES

Mr. HUDSON introduced the following bill; which was referred to the Committee on _____

A BILL

To amend title XVIII of the Social Security Act to provide a phase-in for plasma-derived products under the manufacturer discount 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 ''Preserving Life-saving Access to Specialty Medicines in America Act'' or the ''PLASMA Act''.

SEC. 2. PHASE-IN FOR PLASMA-DERIVED PRODUCTS UNDER MANUFACTURER DISCOUNT PROGRAM.

Section 1860D–14C(g)(4) of the Social Security Act (42 U.S.C. 1395w–114c(g)(4)) is amended—

(1) in subparagraph (A), in the matter preceding clause (i), by striking ''and (C)'' and inserting '', (C), and (D)'';

(2) by redesignating subparagraphs (D) and (E) as subparagraphs (E) and (F), respectively; and

(3) by inserting after subparagraph (C) the following:

''(D) PHASE-IN FOR PLASMA-DERIVED PRODUCTS.—

''(i) IN GENERAL.—For 2026 and subsequent years, subject to clause (iv), in the case of an applicable drug of a manufacturer that is a plasma-derived product (as defined in clause (ii)), and that is marketed as of August 16, 2022, and dispensed for an applicable beneficiary, the term 'discounted price' means the specified plasma-derived product percent (as defined in clause (iii)) of the negotiated price of the applicable drug of the manufacturer.

''(ii) PLASMA-DERIVED PRODUCT.—In this subparagraph, the term 'plasma-de-

rived product' means an applicable drug that is a biological product that is derived from human whole blood or plasma.

"(iii) SPECIFIED PLASMA-DERIVED PRODUCT PERCENT.—In this subparagraph, the term 'specified plasma-derived product percent' means, with respect to a year—

"(I) for an applicable drug that is a plasma-derived product dispensed for an applicable beneficiary who has not incurred costs, as determined in accordance with section 1860D–2(b)(4)(C), for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) for the year—

"(aa) for 2026, 99 percent;

"(bb) for 2027, 98 percent;

"(cc) for 2028, 95 percent;

"(dd) for 2029, 92 percent; and

"(ee) for 2030 and each subsequent year, 90 percent; and

''(II) for an applicable drug that is a plasma-derived product dispensed for an applicable beneficiary who has incurred costs, as determined in accordance with section 1860D–2(b)(4)(C), for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) for the year—

''(aa) for 2026, 99 percent;

''(bb) for 2027, 98 percent;

''(cc) for 2028, 95 percent;

''(dd) for 2029, 92 percent;

''(ee) for 2030, 90 percent;

''(ff) for 2031, 85 percent; and

''(gg) for 2032 and each subsequent year, 80 percent.

''(iv) LIMITATIONS.—This subparagraph shall not apply with respect to the following:

''(I) CERTAIN DRUGS DISPENSED TO LIS BENEFICIARIES.—An applica-

ble drug described in subparagraph (B)(i).

''(II) SPECIFIED SMALL MANUFACTURERS.—An applicable drug described in subparagraph (C)(i).''.