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 SENATE OF THE UNITED STATES

Mr. Tillis (for himself and Mr. Kelly) 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 provide a phase-in for plasma-derived products under the manufacturer discount 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 "Preserving Life-saving
- 5 Access to Specialty Medicines in America Act" or the
- 6 "PLASMA Act".
- 7 SEC. 2. PHASE-IN FOR PLASMA-DERIVED PRODUCTS UNDER
- 8 MANUFACTURER DISCOUNT PROGRAM.
- 9 Section 1860D–14C(g)(4) of the Social Security Act
- 10 (42 U.S.C. 1395w-114c(g)(4)) is amended—

1	(1) in subparagraph (A), in the matter pre-					
2	ceding clause (i), by striking "and (C)" and insert-					
3	ing ", (C), and (D)";					
4	(2) by redesignating subparagraphs (D) and					
5	(E) as subparagraphs (E) and (F), respectively; and					
6	(3) by inserting after subparagraph (C) the fol-					
7	lowing:					
8	"(D) Phase-in for plasma-derived					
9	PRODUCTS.—					
10	"(i) In general.—In the case of an					
11	applicable drug that is a plasma-derived					
12	product (as defined in clause (ii)), and that					
13	is marketed as of the date of enactment of					
14	this subparagraph and dispensed for an					
15	applicable beneficiary, the term 'discounted					
16	price' means the specified plasma-derived					
17	product percent (as defined in clause (iii))					
18	of the negotiated price of the applicable					
19	drug of the manufacturer.					
20	"(ii) Plasma-derived product.—In					
21	this subparagraph, the term 'plasma-de-					
22	rived product' means an applicable drug					
23	that is a biological product that is derived					
24	from human whole blood or plasma.					

1	"(iii) Specified plasma-derived
2	PRODUCT PERCENT.—In this subpara-
3	graph, the term 'specified plasma-derived
4	product percent' means, with respect to a
5	year—
6	"(I) for an applicable drug that
7	is as a plasma-derived product dis-
8	pensed for an applicable beneficiary
9	who has not incurred costs, as deter-
10	mined in accordance with section
11	1860D-2(b)(4)(C), for covered part D
12	drugs in the year that are equal to or
13	exceed the annual out-of-pocket
14	threshold specified in section 1860D–
15	2(b)(4)(B)(i) for the year, the percent
16	specified under subparagraph
17	(B)(iii)(I) for such year; and
18	"(II) for an applicable drug that
19	is as a plasma-derived product dis-
20	pensed for an applicable beneficiary
21	who has incurred costs, as determined
22	in accordance with section 1860D-
23	2(b)(4)(C), for covered part D drugs
24	in the year that are equal to or exceed
25	the annual out-of-pocket threshold

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1	specifie	d in	section	1860D-
2	2(b)(4)	(B)(i) for	the year,	the percent
3	specifie	d un	der su	bparagraph
4	(B)(iii)	(II) for su	uch year.".	