118TH CONGRESS 1ST SESSION

To amend title XVIII of the Social Security Act to require PDP sponsors of a prescription drug plan and Medicare Advantage organizations offering an MA–PD plan under part D of the Medicare program that use a formulary to include certain generic drugs and biosimilar biological products on such formulary, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. LANKFORD (for himself and Mr. MENENDEZ) 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 require PDP sponsors of a prescription drug plan and Medicare Advantage organizations offering an MA–PD plan under part D of the Medicare program that use a formulary to include certain generic drugs and biosimilar biological products on such formulary, and for other purposes.
 - 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 "Ensuring Access to

5 Lower-Cost Medicines for Seniors Act".

1	SEC. 2. REQUIREMENTS FOR PDP SPONSORS OF PRESCRIP-
2	TION DRUG PLANS AND MEDICARE ADVAN-
3	TAGE ORGANIZATIONS OFFERING MA-PD
4	PLANS UNDER PART D OF THE MEDICARE
5	PROGRAM THAT USE FORMULARIES.
6	(a) IN GENERAL.—Section 1860D–4(b)(3) of the So-
7	cial Security Act (42 U.S.C. 1395w-104(b)(3)) is amend-
8	ed by adding at the end the following new subparagraphs:
9	"(J) REQUIRED INCLUSION OF CERTAIN
10	GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL
11	PRODUCTS.—
12	"(i) IN GENERAL.—Subject to the
13	succeeding provisions of this subparagraph,
14	with respect to a plan year beginning on or
15	after January 1, 2025, the following rules
16	shall apply:
17	"(I) If the formulary includes a
18	part D reference drug, the formulary
19	shall include each part D generic drug
20	of such part D reference drug for
21	which the wholesale acquisition cost is
22	less than the wholesale acquisition
23	cost of such part D reference drug.
24	"(II) If the formulary includes a
25	part D reference biological product,
26	the formulary shall include at least

1	one part D biosimilar biological of
2	such part D reference biological prod-
3	uct for which the wholesale acquisition
4	cost is less than the wholesale acquisi-
5	tion cost of such part D reference bio-
6	logical product (if one or more such
7	part D biosimilar biologicals is avail-
8	able).
9	"(ii) Determinations and imple-
10	MENTATION.—Determinations of part D
11	generic drugs and part D biosimilar bio-
12	logical products described in subclauses (I)
13	and (II) of clause (i) and implementation
14	of formulary requirements under clause (i)
15	shall be made by PDP sponsors offering
16	prescription drug plans in accordance with
17	uniform requirements established by the
18	Secretary (by program instruction or oth-
19	erwise), which shall provide for such deter-
20	minations to be made as of specified dates
21	(in the case of determinations during a
22	plan year, on a quarterly basis), and for
23	any associated formulary changes to be im-
24	plemented promptly thereafter (in accord-
25	ance with timeframes specified by the Sec-

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1 retary). Such uniform requirements shall 2 also specify circumstances under which a 3 part D generic drug or part D biosimilar biological product shall be deemed for pur-4 5 poses of subclauses (I) and (II) of clause 6 (i) to have a lower wholesale acquisition 7 cost than its part D reference drug or part 8 D reference biological product (so as to re-9 quire its inclusion on formularies), includ-10 ing where no wholesale acquisition cost is 11 published for such part D reference drug 12 or part D reference biological product or 13 the part D reference drug or part D ref-14 erence biological product is not available 15 for purchase by the PDP sponsor (or its 16 network pharmacies) from its manufac-17 turer at the published wholesale acquisition 18 cost. 19 "(iii) PROHIBITION ON CERTAIN LIM-20 ITS ON ACCESS.—The PDP sponsor offer-21 ing the prescription drug plan may not im-22 pose limits on access to a part D generic 23 drug required to be included on the for-24 mulary under clause (i)(I) or a part D bio-

similar biological product required to be in-

1	cluded on the formulary under clause
2	(i)(II), including through prior authoriza-
3	tion, utilization management, or step ther-
4	apy, that are more restrictive than any
5	such limits imposed on access to the part
6	D reference drug of such part D generic
7	drug or part D reference biological product
8	of such part D biosimilar biological prod-
9	uct, respectively, or that otherwise have
10	the effect of giving preferred status to such
11	part D reference drug or part D reference
12	biological product over such part D generic
13	drug or part D biosimilar biological prod-
14	uct, respectively.
15	"(iv) Definitions.—In this subpara-
16	graph and subparagraph (K):
17	"(I) PART D BIOSIMILAR BIO-
18	LOGICAL PRODUCT.—The term 'part
19	D biosimilar biological product' means
20	a covered part D drug that is a bio-
21	similar biological product (as defined
22	in section $1847A(c)(6)(H)$).
23	"(II) PART D GENERIC DRUG.—
24	The term 'part D generic drug' means
25	a covered part D drug that is ap-

1	proved under section $505(j)$ of the
2	Federal Food, Drug, and Cosmetic
3	Act.
4	"(III) PART D REFERENCE BIO-
5	LOGICAL PRODUCT.—The term 'part
6	D reference biological product' means
7	a covered part D drug that is a ref-
8	erence biological product (as defined
9	in section $1847A(c)(6)(I)$.
10	"(IV) PART D REFERENCE
11	DRUG.—The term 'part D reference
12	drug' means, with respect to a part D
13	generic drug, a covered part D drug
14	that is the listed drug (as described in
15	clause (i) of section $505(j)(2)(A)$ of
16	the Federal Food, Drug, and Cos-
17	metic Act) that is referred to in the
18	abbreviated application for such part
19	D generic drug under such section.
20	"(V) WHOLESALE ACQUISITION
21	COST.—The term 'wholesale acquisi-
22	tion cost' has the meaning given such
23	term in section $1847A(c)(6)(B)$.
24	"(K) Cost-sharing tiering require-
25	MENTS WITH RESPECT TO PART D GENERIC

2PRODUCTS.—3"(i) GENERIC DRUG AND BIOSIMILAR4BIOLOGICAL PRODUCT COST-SHARING5TIER.—With respect to a plan year begins6ning on or after January 1, 2025, if the7PDP sponsor offering the prescription8drug plan applies tiered cost-sharing9(through copayment or coinsurance tiers)10to covered part D drugs on a formulary11the PDP sponsor shall—12"(I) have at least one cost-sharing13ing tier on the formulary that only in14cludes part D generic drugs and part15D biosimilar biological products; and16"(II) with respect to each cost17sharing tier described in subclause (I)	SIMILAR BIOLOGICAL
4BIOLOGICALPRODUCTCOST-SHARING5TIER.—With respect to a plan year begin6ning on or after January 1, 2025, if the7PDP sponsor offering the prescription8drug plan applies tiered cost-sharing9(through copayment or coinsurance tiers)10to covered part D drugs on a formulary11the PDP sponsor shall—12"(I) have at least one cost-sharing13ing tier on the formulary that only in-14cludes part D generic drugs and part15D biosimilar biological products; and16"(II) with respect to each cost	
5TIER.—With respect to a plan year begin6ning on or after January 1, 2025, if the7PDP sponsor offering the prescription8drug plan applies tiered cost-sharing9(through copayment or coinsurance tiers)10to covered part D drugs on a formulary11the PDP sponsor shall—12"(I) have at least one cost-sharing13ing tier on the formulary that only in-14cludes part D generic drugs and part15D biosimilar biological products; and16"(II) with respect to each cost	RUG AND BIOSIMILAR
6ning on or after January 1, 2025, if the7PDP sponsor offering the prescription8drug plan applies tiered cost-sharing9(through copayment or coinsurance tiers)10to covered part D drugs on a formulary11the PDP sponsor shall—12"(I) have at least one cost-sharing13ing tier on the formulary that only in-14cludes part D generic drugs and part15D biosimilar biological products; and16"(II) with respect to each cost	UCT COST-SHARING
7PDP sponsor offering the prescription8drug plan applies tiered cost-sharing9(through copayment or coinsurance tiers)10to covered part D drugs on a formulary11the PDP sponsor shall—12"(I) have at least one cost-sharing13ing tier on the formulary that only in-14cludes part D generic drugs and part15D biosimilar biological products; and16"(II) with respect to each cost-	to a plan year begin-
8drug plan applies tiered cost-sharing9(through copayment or coinsurance tiers)10to covered part D drugs on a formulary11the PDP sponsor shall—12"(I) have at least one cost-sharing13ing tier on the formulary that only in-14cludes part D generic drugs and part15D biosimilar biological products; and16"(II) with respect to each cost-	uary 1, 2025, if the
9 (through copayment or coinsurance tiers) 10 to covered part D drugs on a formulary 11 the PDP sponsor shall— 12 "(I) have at least one cost-shar- 13 ing tier on the formulary that only in- 14 cludes part D generic drugs and part 15 D biosimilar biological products; and 16 "(II) with respect to each cost-	ing the prescription
10to covered part D drugs on a formulary11the PDP sponsor shall—12"(I) have at least one cost-shar-13ing tier on the formulary that only in-14cludes part D generic drugs and part15D biosimilar biological products; and16"(II) with respect to each cost-	tiered cost-sharing
11the PDP sponsor shall—12"(I) have at least one cost-sharming tier on the formulary that only interpret on the formulary that only interpret drugs and part 1414cludes part D generic drugs and part 1515D biosimilar biological products; and 1616"(II) with respect to each cost	or coinsurance tiers)
12 "(I) have at least one cost-shar- 13 ing tier on the formulary that only in- 14 cludes part D generic drugs and part 15 D biosimilar biological products; and 16 "(II) with respect to each cost	rugs on a formulary,
 ing tier on the formulary that only in cludes part D generic drugs and part D biosimilar biological products; and "(II) with respect to each cost 	l—
14cludes part D generic drugs and part15D biosimilar biological products; and16"(II) with respect to each cost	t least one cost-shar-
15D biosimilar biological products; and16"(II) with respect to each cost	ormulary that only in-
16 "(II) with respect to each cost	eneric drugs and part
	ogical products; and
17 sharing tier described in subclause (I)	respect to each cost-
	ribed in subclause (I)
18 on the formulary, either apply no	ry, either apply no
19 cost-sharing requirement or a copay-	nirement or a copay-
20 ment that is—	
21 "(aa) in the case where the	n the case where the
22 lowest branded drug tier of such	ded drug tier of such
23 formulary bases cost-sharing on a	ases cost-sharing on a
24 copayment amount, an amount at	amount, an amount at
least \$20 lower than the copay-	ower than the copay-

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ment for such lowest branded drug tier (but in no case may such copayment amount be less than zero); or

"(bb) in the case where the 5 6 lowest branded drug tier of such 7 formulary bases cost-sharing on a 8 coinsurance percentage, an 9 amount at least \$20 lower than 10 the actuarially expected average 11 cost-sharing amount payable for 12 the covered part D drugs in-13 cluded on such lowest branded 14 drug tier, determined using proc-15 esses and methods established 16 under section 1860D-11(c) (but 17 in no case may such copayment 18 amount be less than zero). 19 "(ii) Specialty generic drug and

BIOSIMILAR BIOLOGICAL PRODUCT COSTSHARING TIER.—With respect to a plan
year beginning on or after January 1,
2025, if the PDP sponsor offering the prescription drug plan has a specialty tier, the
PDP sponsor shall—

1	"(I) have a second specialty tier
2	on such formulary that only includes
3	part D generic drugs and part D bio-
4	similar biological products—
5	"(aa) for which the cost (as
6	defined by the Secretary) is
7	greater than a cost threshold
8	specified by the Secretary; and
9	"(bb) with respect to which
10	the part D reference drug for
11	such a part D generic drug or
12	the part D reference biological
13	product for such a part D bio-
14	similar biological product is ei-
15	ther included on a cost-sharing
16	tier on such formulary with a
17	cost-sharing requirement that is
18	greater than the cost-sharing re-
19	quirement applied under sub-
20	clause (II), or excluded from
21	such formulary; and
22	"(II) apply a coinsurance cost-
23	sharing requirement with respect to
24	the cost-sharing tier required for the
25	formulary under subclause (I) that is

1	at least 5 percentage points lower
2	than the coinsurance percentage appli-
3	cable to any other specialty tier of the
4	formulary.
5	"(iii) Placement of certain ge-
6	NERIC DRUGS AND BIOSIMILAR BIOLOGI-
7	CAL PRODUCTS.—Each part D generic
8	drug and each part D biosimilar biological
9	product required to be included on the for-
10	mulary under subparagraph (J)(i) shall be
11	included either on a cost-sharing tier de-
12	scribed in clause (i)(I) or, if applicable, the
13	cost-sharing tier required for the formulary
14	under clause (ii)(I).
15	"(iv) Application.—
16	"(I) IN GENERAL.—The require-
17	ments under clause (i) through (iii)
18	shall, subject to the requirements
19	under section 1860D–14, apply after
20	the individual has satisfied any de-
21	ductible under subsections $(a)(2)(A)(i)$
22	or (b)(1) of section 1860D–2.
23	"(II) LIMITATION.—The Sec-
24	retary shall not approve any benefit
25	design for a prescription drug plan or

1	an MA–PD plan to which the require-
2	ments of this subparagraph apply if
3	such benefit design has any deductible
4	applicable to any part D generic drug
5	or part D biosimilar biological product
6	unless such deductible, or a greater
7	deductible, also applies to all other
8	covered part D drugs on the for-
9	mulary of such plan (subject to the
10	requirements under section 1860D–
11	14), except for lesser or zero
12	deductibles applicable only to par-
13	ticular types of covered part D drugs
14	which the Secretary determines war-
15	rant favorable cost-sharing when such
16	lesser or zero deductibles are also ap-
17	plicable to part D generic drugs and
18	part D biosimilar biological products
19	of the given type.
20	"(v) DEFINITIONS.—In this subpara-
21	graph:
22	"(I) BRAND DRUG.—The term
23	'brand drug' means a covered part D
24	drug that is approved under section
25	505(c) of the Federal Food, Drug,

1	and Cosmetic Act or licensed under
2	section 351(a) of the Public Health
3	Service Act.
4	"(II) LOWEST BRANDED DRUG
5	TIER.—The term 'lowest branded
6	drug tier' means the cost-sharing tier
7	of a formulary which includes at least
8	1 brand drug and provides for the
9	lowest level of cost sharing applicable
10	to any such tier, as determined by the
11	Secretary.
12	"(III) Specialty tier.—The
13	term 'specialty tier' means a cost-
14	sharing tier consisting only of covered
15	part D drugs that have a cost (as de-
16	fined by the Secretary) which equals
17	or exceeds an applicable cost threshold
18	established by the Secretary for high
19	cost covered part D drugs to be eligi-
20	ble for inclusion on such cost-sharing
21	tier.".
22	(b) Conforming Amendments.—Section 1860D–2
23	of the Social Security Act (42 U.S.C. 1395w–102) is
24	amended—
25	(1) In subsection $(b)(2)$ —

1	(A) in subparagraph (A), by striking "and
2	paragraphs (8) and (9)" and inserting ", para-
3	graphs (8) and (9) , and section $1860D-$
4	4(b)(3)(K)"; and
5	(B) in subparagraph (B), by inserting be-
6	fore the period the following: "and section
7	1860D–4(b)(3)(K)";
8	(2) in subsection (c), by adding at the end the
9	following new paragraph:
10	"(7) TREATMENT OF COST-SHARING FOR PART
11	D GENERIC DRUGS AND PART D BIOSIMILAR BIO-
12	LOGICAL PRODUCTS.—The coverage is provided in
13	accordance with section 1860D–4(b)(3)(K).".