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118TH CONGRESS
1ST SESSION

H. R. 5372

To amend Title XVIII of the Social Security Act to facilitate midyear formulary changes for biosimilars.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 8, 2023

Mr. JOYCE of Pennsylvania (for himself and Mr. PETERS) 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 facilitate midyear formulary changes for biosimilars.

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 ''Expanding Seniors' Access to Lower Cost Medicines Act of 2023''.

SEC. 2. FACILITATING MIDYEAR FORMULARY CHANGES FOR BIOSIMILARS.

(a) IN GENERAL.—Section 1860D–4(b) of the Social Security Act (42 U.S.C. 1395w–104(b)) is amended by adding at the end the following new paragraph:

"(5) MID-YEAR CHANGES IN FORMULARIES PERMITTED FOR CERTAIN BIOSIMILAR BIOLOGICAL PRODUCTS AND THE REFERENCE PRODUCT OF SUCH BIOSIMILARS.—If a PDP sponsor of a prescription drug plan uses a formulary (including the use of tiered cost-sharing), the following shall apply:

"(A) IN GENERAL.—For plan year 2025, and subsequent plan years, in the case of a covered part D drug that is the reference biological product (as defined in section 1847A(c)(6)(I)) with respect to a biosimilar biological product (as defined in section 1847A(c)(6)(H)), the PDP sponsor may, with respect to a formulary, at any time after the first 60 days of the plan year, subject to paragraph (3)(E), change the preferred or tiered cost-sharing status of such reference biological product if such PDP sponsor adds, before or at the same time, to such formulary such biosimilar biological product at the same or a higher preferred status, or to the same or lower cost-sharing tier, as that of such

reference biological product immediately prior to such change.

''(B) REQUEST FOR APPROVAL OF CHANGE.—Prior to making a change described in subparagraph (A), the PDP sponsor shall submit to the Secretary a request to make such change. If the Secretary approves the request or has not provided a decision to the PDP sponsor regarding such request within 30 days of receiving such request, such PDP sponsor may make such change.''.

(b) ADMINISTRATION.—

(1) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the amendment made by subsection (a) by program instruction or otherwise.

(2) NON-APPLICATION OF THE PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code (commonly referred to as the ''Paperwork Reduction Act of 1995''), shall not apply to the implementation of the amendment made by subsection (a).

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