

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 5372
OFFERED BY M . _____**

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE.

2 This Act may be cited as the “Expanding Seniors’
3 Access to Lower Cost Medications Act of 2023”.

**4 SEC. 2. FACILITATING MIDYEAR FORMULARY CHANGES
5 FOR BIOSIMILARS.**

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

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

15 “(A) IN GENERAL.—For plan year 2025,
16 and subsequent plan years, in the case of a cov-
17 ered part D drug that is the reference biological
18 product (as defined in section 351(i) of the

1 Public Health Service Act) with respect to a
2 biosimilar biological product (defined as a bio-
3 logical product licensed under section 351(k) of
4 such Act), the PDP sponsor may, with respect
5 to a formulary, at any time after the first 60
6 days of the plan year, subject to paragraph
7 (3)(E), change the preferred or tiered cost-shar-
8 ing status of such reference biological product
9 if such PDP sponsor adds, before or at the
10 same time, to such formulary such biosimilar
11 biological product at the same or a higher pre-
12 ferred status, or to the same or lower cost-shar-
13 ing tier, as that of such reference biological
14 product immediately prior to such change.

15 “(B) REQUEST FOR APPROVAL OF
16 CHANGE.—Prior to making a change described
17 in subparagraph (A), the PDP sponsor shall
18 submit to the Secretary a request to make such
19 change. If the Secretary approves the request
20 or has not provided a decision to the PDP
21 sponsor regarding such request within 30 days
22 of receiving such request, such PDP sponsor
23 may make such change.”.

24 (b) ADMINISTRATION.—

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

6 (2) NON-APPLICATION OF THE PAPERWORK RE-
7 DUCATION ACT.—Chapter 35 of title 44, United
8 States Code (commonly referred to as the “Paper-
9 work Reduction Act of 1995”), shall not apply to the
10 implementation of the amendment made by sub-
11 section (a).

