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(Original Signature of Member)

117TH CONGRESS
1ST SESSION

H. R.

To amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to add a new set of measures to the 5-star rating system under the Medicare Advantage program in order to encourage increased access to biosimilar biological products.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to add a new set of measures to the 5-star rating system under the Medicare Advantage program in order to encourage increased access to biosimilar biological products.

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 “Star Rating for
5 Biosimilars Act”.

1 **SEC. 2. ADDITION OF NEW MEASURES BASED ON ACCESS**
2 **TO BIOSIMILAR BIOLOGICAL PRODUCTS TO**
3 **THE 5-STAR RATING SYSTEM UNDER MEDI-**
4 **CARE ADVANTAGE.**

5 (a) IN GENERAL.—Section 1853(o)(4) of the Social
6 Security Act (42 U.S.C. 1395w–23(o)(4)) is amended by
7 adding at the end the following new subparagraph:

8 “(E) ADDITION OF NEW MEASURES BASED
9 ON ACCESS TO BIOSIMILAR BIOLOGICAL PROD-
10 UCTS.—

11 “(i) IN GENERAL.—For 2022 and
12 subsequent years, the Secretary shall add a
13 new set of measures to the 5-star rating
14 system based on access to biosimilar bio-
15 logical products covered under part B and,
16 in the case of MA–PD plans, such prod-
17 ucts that are covered part D drugs. Such
18 measures shall assess the impact a plan’s
19 benefit structure may have on enrollees’
20 utilization of or ability to access biosimilar
21 biological products, including in compari-
22 son to the reference biological product, and
23 shall include measures, as applicable, with
24 respect to the following:

25 “(I) COVERAGE.—Assessing
26 whether a biosimilar biological prod-

1 uct is on the plan formulary in lieu of
2 or in addition to the reference biological
3 cal product.

4 “(II) PREFERENCING.—Assessing
5 ing tier placement or cost sharing for
6 a biosimilar biological product relative
7 to the reference biological product.

8 “(III) UTILIZATION MANAGEMENT TOOLS.—Assessing whether and
9 how utilization management tools are
10 used with respect to a biosimilar biological
11 product relative to the reference
12 biological product relative to the reference
13 biological product.

14 “(IV) UTILIZATION.—Assessing
15 the percentage of enrollees prescribed
16 the biosimilar biological product when
17 the reference biological product is also
18 available.

19 “(ii) DEFINITIONS.—In this subparagraph,
20 the terms ‘biosimilar biological
21 product’ and ‘reference biological product’
22 have the meaning given those terms in section
23 1847A(c)(6).

24 “(iii) PROTECTING PATIENT INTERESTS.—In developing such measures, the
25 ESTS.—In developing such measures, the

1 Secretary shall ensure that each measure
2 developed to address coverage, preferenc-
3 ing, or utilization management is con-
4 structed such that patients retain equal ac-
5 cess to appropriate therapeutic options
6 without undue administrative burden.”.

7 (b) CLARIFICATION REGARDING APPLICATION TO
8 PRESCRIPTION DRUG PLANS.—To the extent the Sec-
9 retary of Health and Human Services applies the 5-star
10 rating system under section 1853(o)(4) of the Social Secu-
11 rity Act (42 U.S.C. 1395w–23(o)(4)), or a similar system,
12 to prescription drug plans under part D of title XVIII of
13 such Act, the provisions of subparagraph (E) of such sec-
14 tion, as added by subsection (a) of this section, shall apply
15 under the system with respect to such plans in the same
16 manner as such provisions apply to the 5-star rating sys-
17 tem under such section 1853(o)(4).