

**AMENDMENT**

**OFFERED BY MR. TONKO OF NEW YORK**

At the end of the bill, add the following new title  
(and update the table of contents accordingly):

1     **TITLE \_\_\_\_\_ —MISCELLANEOUS**

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

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

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

12                    “(i) IN GENERAL.—For 2021 and  
13                    subsequent years, the Secretary shall add a  
14                    new set of measures to the 5-star rating  
15                    system based on access to biosimilar bio-  
16                    logical products covered under part B and,  
17                    in the case of MA–PD plans, such prod-  
18                    ucts that are covered part D drugs. Such  
19                    measures shall assess the impact a plan’s

1 benefit structure may have on enrollees’  
2 utilization of or ability to access biosimilar  
3 biological products, including in compari-  
4 son to the reference biological product, and  
5 shall include measures, as applicable, with  
6 respect to the following:

7 “(I) COVERAGE.—Assessing  
8 whether a biosimilar biological prod-  
9 uct is on the plan formulary in lieu of  
10 or in addition to the reference biologi-  
11 cal product.

12 “(II) PREFERENCING.—Assess-  
13 ing tier placement or cost-sharing for  
14 a biosimilar biological product relative  
15 to the reference biological product.

16 “(III) UTILIZATION MANAGE-  
17 MENT TOOLS.—Assessing whether and  
18 how utilization management tools are  
19 used with respect to a biosimilar bio-  
20 logical product relative to the ref-  
21 erence biological product.

22 “(IV) UTILIZATION.—Assessing  
23 the percentage of enrollees prescribed  
24 the biosimilar biological product when

1 the reference biological product is also  
2 available.

3 “(ii) DEFINITIONS.—In this subpara-  
4 graph, the terms ‘biosimilar biological  
5 product’ and ‘reference biological product’  
6 have the meaning given those terms in sec-  
7 tion 1847A(c)(6).

8 “(iii) PROTECTING PATIENT INTER-  
9 ESTS.—In developing such measures, the  
10 Secretary shall ensure that each measure  
11 developed to address coverage,  
12 preferencing, or utilization management is  
13 constructed such that patients retain equal  
14 access to appropriate therapeutic options  
15 without undue administrative burden.”.

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

- 1 manner as such provisions apply to the 5-star rating sys-
- 2 tem under such section 1853(o)(4).

