## 117TH CONGRESS 1ST SESSION

## H. R. 2855

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

April 26, 2021

Mr. Tonko (for himself and Mr. Gibbs) 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

## 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      |
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| 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 biologi-    |
| 3  | cal product.                                |
| 4  | "(II) Preferencing.—Assess-                 |
| 5  | ing tier placement or cost sharing for      |
| 6  | a biosimilar biological product relative    |
| 7  | to the reference biological product.        |
| 8  | "(III) Utilization manage-                  |
| 9  | MENT TOOLS.—Assessing whether and           |
| 10 | how utilization management tools are        |
| 11 | used with respect to a biosimilar bio-      |
| 12 | logical product relative to the ref-        |
| 13 | erence 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 subpara-         |
| 20 | graph, the terms 'biosimilar biological     |
| 21 | product' and 'reference biological product' |
| 22 | have the meaning given those terms in sec-  |
| 23 | tion $1847A(c)(6)$ .                        |
| 24 | "(iii) Protecting patient inter-            |
| 25 | ESTS.—In developing such measures, the      |

Secretary shall ensure that each measure developed to address coverage, preferencing, or utilization management is constructed such that patients retain equal access to appropriate therapeutic options without undue administrative burden.".

7 (b) CLARIFICATION REGARDING APPLICATION TO PRESCRIPTION DRUG PLANS.—To the extent the Sec-8 retary of Health and Human Services applies the 5-star 10 rating system under section 1853(o)(4) of the Social Security 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 such Act, the provisions of subparagraph (E) of such section, as added by subsection (a) of this section, shall apply 14 15 under the system with respect to such plans in the same manner as such provisions apply to the 5-star rating sys-16 tem under such section 1853(o)(4).

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