AMENDMENT TO
RULES COMMITTEE PRINT 116–14
OFFERED BY MR. TONKO OF NEW YORK

Add at the end of title VIII the following (and conform the table of contents accordingly):

SEC. 812. ADDITION OF NEW MEASURES BASED ON ACCESS TO BIOSIMILAR BIOLOGICAL PRODUCTS TO THE 5-STAR RATING SYSTEM UNDER MEDICARE ADVANTAGE.

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

"(E) ADDITION OF NEW MEASURES BASED ON ACCESS TO BIOSIMILAR BIOLOGICAL PRODUCTS.—

"(i) IN GENERAL.—For 2021 and subsequent years, the Secretary shall add a new set of measures to the 5-star rating system based on access to biosimilar biological products covered under part B and, in the case of MA–PD plans, such products that are covered part D drugs. Such measures shall assess the impact a plan's

benefit structure may have on enrollees' utilization of or ability to access biosimilar biological products, including in comparison to the reference biological product, and shall include measures, as applicable, with respect to the following:

"(I) COVERAGE.—Assessing whether a biosimilar biological product is on the plan formulary in lieu of or in addition to the reference biological product.

"(II) PREFERENCING.—Assessing tier placement or cost-sharing for a biosimilar biological product relative to the reference biological product.

"(III) UTILIZATION MANAGEMENT TOOLS.—Assessing whether and how utilization management tools are used with respect to a biosimilar biological product relative to the reference biological product.

"(IV) UTILIZATION.—Assessing the percentage of enrollees prescribed the biosimilar biological product when

the reference biological product is also available.

''(ii) DEFINITIONS.—In this subparagraph, the terms 'biosimilar biological product' and 'reference biological product' have the meaning given those terms in section 1847A(c)(6).

''(iii) PROTECTING PATIENT INTERESTS.—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.''.

(b) CLARIFICATION REGARDING APPLICATION TO PRESCRIPTION DRUG PLANS.—To the extent the Secretary of Health and Human Services applies the 5-star rating system under section 1853(o)(4) of the Social Security Act (42 U.S.C. 1395w–23(o)(4)), or a similar system, 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 under the system with respect to such plans in the same

manner as such provisions apply to the 5-star rating system under such section 1853(o)(4).

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