

SB21-175

HOUSE FLOOR AMENDMENT

Second Reading

BY REPRESENTATIVE McKean

1 Amend printed bill, page 23, line 10, strike "AND".

2 Page 23, line 15, strike "LIMIT." and substitute "LIMIT; AND

3 (c) MUST REQUIRE THAT AN UPPER PAYMENT LIMIT ESTABLISHED
4 FOR ANY DRUG THAT IS AN ORPHAN DRUG OR OTHERWISE IDENTIFIED AS
5 FIRST-IN-CLASS MUST BE SUPPORTED BY:

6 (I) MEANINGFUL INPUT FROM PATIENTS AND CAREGIVERS
7 AFFECTED BY THE CONDITION OR DISEASE THAT IS TREATED BY THE
8 PRESCRIPTION DRUG, INCLUDING WITHOUT LIMITATION INPUT CONCERNING
9 CAREGIVER BURDEN, THE VALUE OF TREATING PATIENTS WITH UNMET
10 MEDICAL NEEDS, THE SEVERITY OF THE DISEASE OR CONDITION THAT IS
11 TREATED BY THE PRESCRIPTION DRUG, AND ANY OTHER
12 NON-HEALTH-RELATED ISSUES INCLUDING SOCIETAL IMPACT; AND

13 (II) MEANINGFUL INPUT FROM EXTERNAL EXPERTS ON THE
14 FOLLOWING TOPICS, WITHOUT LIMITATION:

15 (A) THE IMPACT OF PARTICULAR COVERAGE, COST SHARING,
16 TIERING, UTILIZATION MANAGEMENT, PRIOR AUTHORIZATION, MEDICATION
17 THERAPY MANAGEMENT, OR OTHER UTILIZATION MANAGEMENT POLICIES
18 ON ADHERENCE BY PATIENTS TO THE PRESCRIPTION DRUG AND ON ACCESS
19 TO THE PRESCRIPTION DRUG;

20 (B) THE DEMOGRAPHICS AND THE CLINICAL DESCRIPTION OF
21 PATIENT POPULATIONS TREATED BY THE DRUG; AND

22 (C) TO THE EXTENT THE DRUG IS AN ORPHAN DRUG APPROVED FOR
23 THE TREATMENT OF A RARE DISEASE, THE SEVERITY OF AND THE UNMET
24 MEDICAL NEED ASSOCIATED WITH THE RARE DISEASE, THE BENEFITS AND
25 RISKS OF THE DRUG AS A TREATMENT FOR THE RARE DISEASE, AND
26 FACTORS THAT MAY BE LIMITING ACCESS BY PATIENTS REQUIRING
27 TREATMENT FROM OR CONSULTATION WITH A RARE DISEASE SPECIALIST.
28 FOR THE PURPOSE OF THIS SUBSECTION (4)(c)(II), "EXTERNAL EXPERT"
29 MEANS AN INDIVIDUAL WHO POSSESSES SCIENTIFIC OR MEDICAL TRAINING
30 THAT THE BOARD LACKS WITH RESPECT TO A DISEASE TREATED BY A
31 PRESCRIPTION DRUG THAT IS UNDER REVIEW BY THE BOARD OR A RELATED
32 THERAPEUTIC AREA."

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