State of Minnesota

HOUSE OF REPRESENTATIVES

NINETY-THIRD SESSION **H. F. No.** **2261**

02/27/2023   Authored by Schomacker
    The bill was read for the first time and referred to the Committee on Health Finance and Policy

1.1   A bill for an act

1.2   relating to human services; requiring the commissioner to adhere to Food and Drug
1.3   Administration label requirements when making coverage and access determinations
1.4   related to qualified drugs or biologic products; amending Minnesota Statutes 2022,
1.5   section 256B.0625, by adding a subdivision.

1.6   BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

1.7   Section 1. Minnesota Statutes 2022, section 256B.0625, is amended by adding a subdivision

1.8   to read:

1.9   Subd. 13k. **Coverage and access determinations.** (a) The commissioner, when adopting

1.10   and implementing a preferred drug list and prior authorization requirements and making

1.11   other decisions related to drug coverage and enrollee access to drugs, shall not make

1.12   determinations or recommendations related to qualified drugs or biologic products that are

1.13   more restrictive than the indications and usage section of the label approved by the Food

1.14   and Drug Administration. The determinations and recommendations must also be consistent

1.15   with the medically accepted indication of the drug or biologic product.

1.16   (b) For purposes of this subdivision, "qualified drugs or biologic products" means:

1.17   (1) drugs and biologic products for rare diseases, as defined in the federal Orphan Drug

1.18   Act of 1983, Public Law 97-414; and

1.19   (2) drugs or biologic products designated or approved through any of the following

1.20   expedited pathways established by the Food and Drug Administration for treatment of a

1.21   serious or life-threatening illness: (i) breakthrough designation, (ii) fast track designation,

1.22   (iii) accelerated approval pathway, (iv) priority review, or (v) regenerative medicine advanced

1.23   therapy designation.