

Introduced by

Representatives Henegar, Kilzer

1 A BILL for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota
2 Century Code, relating to coverage for off-label uses of drugs.

3 **BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:**

4 **SECTION 1.** A new section to chapter 26.1-36 of the North Dakota Century Code is
5 created and enacted as follows:

6 **Coverage for off-label uses of drugs.**

7 1. In this section:

8 a. "Coverage of a drug" includes medically necessary services associated with
9 the administration of the drug.

10 b. "Medical literature" means scientific studies published in a peer review
11 national medical journal.

12 c. "Off-label use of drugs" means prescribing drugs for treatments other than
13 those stated in the labeling approved by the federal food and drug
14 administration.

15 d. "Standard reference compendia" means the United States pharmacopeia drug
16 information, American medical association drug evaluation, or American
17 hospital formulary service drug information.

18 2. An insurance company, nonprofit health service corporation, or health maintenance
19 organization that provides coverage for drugs may not issue, deliver, execute, or
20 renew any health insurance policy or health service contract on an individual,
21 group, blanket, franchise, or association basis which excludes coverage of a drug
22 for a particular indication on the grounds the drug has not been approved by the
23 federal food and drug administration for that indication if the drug is recognized for

1 treatment of the indication in one of the standard reference compendia or medical
2 literature.

3 3. The commissioner of insurance may direct an insurer or contractor regulated by
4 this section to make payments as required by this section.

5 4. a. The state health officer shall appoint a panel of eight medical experts to
6 review off-label uses of drugs not included in the standard reference
7 compendia or medical literature. This panel shall advise the commissioner of
8 insurance whether a particular off-label use is medically appropriate.

9 b. The panel shall consist of three medical oncologists chosen by the state
10 medical oncology association; two specialists in the management of acquired
11 immune deficiency syndrome chosen by the state acquired immune deficiency
12 syndrome medical provider organizations; and one specialist in heart disease,
13 one physician, and one pulmonary specialist selected by the state medical
14 association. The panel shall make recommendations whenever an issue
15 regarding payment of off-label use is brought to the commissioner of
16 insurance.

17 5. This section does not alter existing law regarding provisions limiting the coverage
18 of drugs that have not been approved by the federal food and drug administration;
19 does not require coverage for any drug when the federal food and drug
20 administration has determined its use to be contradicted; and does not require
21 coverage for experimental drugs not otherwise approved for any indication by the
22 federal food and drug administration.