

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
16 drug information or American hospital formulary service drug information.

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

- 1 3. The commissioner of insurance may direct an insurer or contractor regulated by
2 this section to make payments as required by this section.
- 3 4. The state health officer may appoint a panel of up to eight qualified medical
4 experts to review off-label uses of drugs not included in the standard reference
5 compendia or medical literature. This panel shall advise the commissioner of
6 insurance whether a particular off-label use is medically appropriate and shall
7 make recommendations regarding payment of off-label use.
- 8 5. This section does not alter existing law regarding provisions limiting the coverage
9 of drugs that have not been approved by the federal food and drug administration;
10 does not require coverage for any drug when the federal food and drug
11 administration has determined its use to be contraindicated; and does not require
12 coverage for experimental drugs not otherwise approved for any indication by the
13 federal food and drug administration.