

**Fifty-fifth Legislative Assembly, State of North Dakota, begun in the Capitol in the City of Bismarck, on Monday, the sixth day of January, one thousand nine hundred and ninety-seven**

HOUSE BILL NO. 1428  
(Representatives Henegar, Kilzer)

AN ACT to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to coverage for off-label uses of drugs.

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

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

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

1. In this section:
  - a. "Coverage of a drug" includes medically necessary services associated with the administration of the drug.
  - b. "Medical literature" means scientific studies published in a peer review national medical journal.
  - c. "Off-label use of drugs" means prescribing drugs for treatments other than those stated in the labeling approved by the federal food and drug administration.
  - d. "Standard reference compendia" means the United States pharmacopeia drug information or American hospital formulary service drug information.
2. An insurance company, nonprofit health service corporation, or health maintenance organization that provides coverage for drugs may not issue, deliver, execute, or renew any health insurance policy or health service contract on an individual, group, blanket, franchise, or association basis which excludes coverage of a drug for a particular indication on the grounds the drug has not been approved by the federal food and drug administration for that indication if the drug is recognized for treatment of the indication in one of the standard reference compendia or medical literature.
3. The commissioner of insurance may direct an insurer or contractor regulated by this section to make payments as required by this section.
4. The state health officer may appoint a panel of up to eight qualified medical experts to review off-label uses of drugs not included in the standard reference compendia or medical literature. This panel shall advise the commissioner of insurance whether a particular off-label use is medically appropriate and shall make recommendations regarding payment of off-label use.
5. This section does not alter existing law regarding provisions limiting the coverage of drugs that have not been approved by the federal food and drug administration; does not require coverage for any drug when the federal food and drug administration has determined its use to be contraindicated; and does not require coverage for experimental drugs not otherwise approved for any indication by the federal food and drug administration.

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Speaker of the House

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President of the Senate

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Chief Clerk of the House

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Secretary of the Senate

This certifies that the within bill originated in the House of Representatives of the Fifty-fifth Legislative Assembly of North Dakota and is known on the records of that body as House Bill No. 1428.

House Vote:      Yeas    93      Nays    1      Absent    3

Senate Vote:    Yeas    44      Nays    0      Absent    5

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Chief Clerk of the House

Received by the Governor at \_\_\_\_\_ M. on \_\_\_\_\_, 1997.

Approved at \_\_\_\_\_ M. on \_\_\_\_\_, 1997.

\_\_\_\_\_  
Governor

Filed in this office this \_\_\_\_\_ day of \_\_\_\_\_, 1997,

at \_\_\_\_\_ o'clock \_\_\_\_\_ M.

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Secretary of State