

State of South Dakota

SEVENTY-FIFTH SESSION
LEGISLATIVE ASSEMBLY, 2000

391D0364

HOUSE BILL NO. 1133

Introduced by: Representatives Roe, Cutler, Eccarius, Fischer-Clemens, Koehn, Michels, and Peterson and Senators Everist, Brown (Arnold), Dunn (Jim), Flowers, Madden, Munson (David), and Shoener

1 FOR AN ACT ENTITLED, An Act to provide insurance coverage for off-label uses of
2 prescription drugs used for the treatment of cancer or life threatening conditions.

3 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF SOUTH DAKOTA:

4 Section 1. Terms used in this Act mean:

5 (1) "FDA," the federal Food and Drug Administration;

6 (2) "Health insurer," any person who provides health insurance in this state. The term
7 includes a licensed insurance company, a prepaid hospital or medical service plan, a
8 health maintenance organization, a multiple employer welfare arrangement, or any
9 person providing a plan of health insurance subject to state insurance regulation;

10 (3) "Medical literature," published scientific studies published in at least one article from
11 major peer reviewed medical journals that present data supporting the proposed off-
12 label use or uses as generally safe and effective unless there is clear and convincing
13 contradictory evidence presented in a major peer reviewed medical journal;

14 (4) "Standard reference compendia," one of the following:

15 (a) The United States Pharmacopeia Drug Information;

16 (b) DRUGDEX; or

1 (c) The American Hospital Formulary Service Drug Information;

2 (5) "Off-label," the use of an FDA approved drug for an indication that is not included in
3 the approved labeling.

4 Section 2. No health insurer issuing a policy which provides coverage for prescription drugs
5 may exclude coverage of any drug used for the treatment of cancer or life threatening conditions
6 on the grounds that the drug has not been approved by the FDA for that indication if that drug
7 is recognized for treatment of such indication in one of the standard reference compendia or in
8 the medical literature. The prescribing physician shall submit documentation supporting the
9 proposed off-label use or uses to the insurer, if requested. Any coverage of a drug that serves
10 as the primary treatment required by this Act shall also include medically necessary services
11 associated with the administration of the drug.

12 Section 3. No coverage is required under this Act for the following:

- 13 (1) Any drug that has not been fully licensed or approved by the FDA;
14 (2) The use of any drug if the FDA has determined that use to be contraindicated; or
15 (3) Any experimental drug not otherwise approved for any indication by the FDA.

16 Section 4. The provisions of this Act apply to drugs used in the treatment for cancer or life
17 threatening diseases only, and nothing in this Act may be construed to create, impair, alter, limit,
18 modify, enlarge, abrogate, or prohibit reimbursement for medications used in the treatment of
19 any other disease or condition.

20 Section 5. Nothing in this Act may be construed to prevent the application of contractual
21 deductibles or copayment provisions or managed care review.

22 Section 6. Any person seeking to refer a dispute to the director of insurance shall do so in
23 writing within thirty days of the denial of coverage of the drug.

24 Section 7. This Act may not be used to reduce or limit coverage for off-label use of drugs
25 otherwise required by law or contract.