

State of South Dakota

SEVENTY-FIFTH SESSION
LEGISLATIVE ASSEMBLY, 2000

391D0364

SENATE COMMERCE COMMITTEE
ENGROSSED NO. **HB1133** - 2/16/00

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) "Life threatening," either or both of the following:

11 (a) A disease or condition where the likelihood of death is high, unless the course
12 of the disease is interrupted; or

13 (b) A disease or condition with potentially fatal outcomes where the end point of
14 clinical intervention is survival;

15 (4) "Medical literature," a published scientific study in a journal or other publication in

1 which original manuscripts have been published only after critical review for scientific
2 accuracy, validity, and reliability by unbiased independent experts and a determination
3 by the International Committee of Medical Journal Editors that it meets the Uniform
4 Requirements for Manuscripts submitted to biomedical journals. The term, medical
5 literature, does not include a publication or a supplement to a publication that is
6 sponsored to a significant extent by a pharmaceutical manufacturing company or
7 health carrier;

8 (5) "Standard reference compendia," one of the following:

9 (a) The United States Pharmacopeia Drug Information;

10 (b) DRUGDEX; or

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

12 (6) "Off-label," the use of an FDA approved drug for an indication that is not included in
13 the approved labeling;

14 (7) "Drug," any substance prescribed by a licensed health care provider acting within the
15 scope of the provider's license and that is intended for use in the diagnosis, mitigation,
16 treatment, or prevention of disease and is taken by mouth; injected into a muscle, the
17 skin, a blood vessel, or cavity of the body; applied to the skin; or otherwise
18 assimilated by the body. The term, drug, includes only those substances that are
19 approved by the FDA for at least one indication.

20 Section 2. No health insurer issuing a policy which provides coverage for prescription drugs
21 may exclude coverage of any drug used for the treatment of cancer or life threatening conditions
22 on the grounds that the drug has not been approved by the FDA for that indication if that drug
23 is recognized for treatment of such indication in one of the standard reference compendia or in
24 the medical literature. The prescribing physician shall submit documentation supporting the
25 proposed off-label use or uses to the insurer, if requested. Any coverage of a drug that serves

1 as the primary treatment required by this Act shall also include medically necessary services
2 associated with the administration of the drug.

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

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

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

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

13 Section 6. The following drugs or services are not subject to coverage under section 2 of this
14 Act:

- 15 (1) Any drug that is used in research trials sponsored by the manufacturer of that drug or
16 a governmental entity; or
- 17 (2) Any drug or service furnished in a research trial, if the sponsor of the research trial
18 furnishes the drug or service without charge to any participant in the research trial.

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

1 **BILL HISTORY**

2 1/18/00 First read in House and referred to Commerce. H.J. 118

3 2/1/00 Scheduled for Committee hearing on this date.

4 2/1/00 Commerce Do Pass Amended, Passed, AYES 11, NAYS 0. H.J. 342

5 2/3/00 House of Representatives Deferred to another day. H.J. 401

6 2/4/00 House of Representatives Deferred to another day. H.J. 433

7 2/7/00 House of Representatives Do Pass Amended, Passed, AYES 58, NAYS 7. H.J. 444

8 2/8/00 First read in Senate and referred to Commerce. S.J. 359

9 2/15/00 Scheduled for Committee hearing on this date.

10 2/15/00 Commerce Do Pass Amended, Passed, AYES 7, NAYS 0. S.J. 493

11 2/15/00 Commerce Place on Consent Calendar.