AN ACT

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

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

Section 1. Terms used in this Act mean:

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

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

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

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

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

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

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

(a) The United States Pharmacopeia Drug Information;

(b) DRUGDEX; or

(c) The American Hospital Formulary Service Drug Information;

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

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

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

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

(1) Any drug that has not been fully licensed or approved by the FDA;

(2) The use of any drug if the FDA has determined that use to be contraindicated; or

(3) Any experimental drug not otherwise approved for any indication by the FDA.

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

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

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

(1) Any drug that is used in research trials sponsored by the manufacturer of that drug or a governmental entity; or

(2) Any drug or service furnished in a research trial, if the sponsor of the research trial furnishes the drug or service without charge to any participant in the research trial.

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

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I certify that the attached Act originated in the

HOUSE as Bill No. 1133

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Chief Clerk

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Speaker of the House

Attest:

_____
Chief Clerk

_____
President of the Senate

Attest:

_____
Secretary of the Senate

House Bill No. 1133
File No. ____
Chapter No. _____

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Received at this Executive Office this _____ day of _____ ,

20____ at _____ M.

By _____
for the Governor

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The attached Act is hereby approved this _____ day of _____ , A.D., 20___

_____
Governor

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STATE OF SOUTH DAKOTA,
ss.
Office of the Secretary of State

Filed _____ , 20___
at _____ o'clock __ M.

_____
Secretary of State

By _____
Ass. Secretary of State