AN ACT AUTHORIZING ACCESS TO AND THE USE OF EXPERIMENTAL TREATMENTS FOR A TERMINAL ILLNESS; ESTABLISHING CONDITIONS FOR THE USE OF EXPERIMENTAL TREATMENTS; PROHIBITING SANCTIONS OF HEALTH CARE PROVIDERS; CLARIFYING THE DUTIES OF HEALTH INSURERS REGARDING EXPERIMENTAL TREATMENTS; PROHIBITING CERTAIN ACTIONS BY STATE OFFICIALS; PROVIDING IMMUNITY; AND PROVIDING AN IMMEDIATE EFFECTIVE DATE.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

**Section 1. Short title.** [Sections 1 through 10] may be cited as the "Right to Try Act".

**Section 2. Definitions.** As used in [sections 1 through 10], the following definitions apply:

(1) "Eligible patient" means an individual who meets the requirements of [section 4];

(2) "Health care facility" has the meaning provided in 50-5-101.

(3) "Health care provider" means any of the following individuals licensed pursuant to Title 37:

(a) a physician;

(b) an advanced practice registered nurse authorized by the board of nursing to prescribe medicine; and

(c) a physician assistant whose duties and delegation agreement allows the physician assistant to undertake the activities allowed under [sections 1 through 10].

(4) "Investigational drug, biological product, or device" means a drug, biological product, or device that:

(a) has successfully completed phase 1 of a clinical trial but has not yet been approved for general use by the United States food and drug administration; and

(b) remains under investigation in a United States food and drug administration-approved clinical trial.

(5) "Terminal illness" means a progressive disease or medical or surgical condition that:

(a) entails significant functional impairment;

(b) is not considered by a treating health care provider to be reversible even with administration of a treatment currently approved by the United States food and drug administration; and

(c) without life-sustaining procedures, will result in death.

(6) "Written informed consent" means a written document that meets the requirements of [section 5].

**Section 3. Availability of experimental drugs.** (1) A manufacturer of an investigational drug, biological product, or device may make the drug, product, or device available to an eligible patient who has requested the drug, product, or device pursuant to [sections 1 through 10].

(2) The manufacturer may:

(a) provide an investigational drug, biological product, or device to an eligible patient without receiving compensation; or

(b) require an eligible patient to pay the costs of or the costs associated with the manufacture of the investigational drug, biological product, or device.

(3) A manufacturer is not required to make an investigational drug, biological product, or device available to an eligible patient.

**Section 4. Eligible patient -- requirements.** A patient is eligible for treatment with an investigational drug, biological product, or device if the patient has:

(1) a terminal illness that is attested to by the patient's treating health care provider;

(2) considered all other treatment options currently approved by the United States food and drug administration;

(3) received a recommendation from the patient's treating health care provider for an investigational drug, biological product, or device;

(4) given written informed consent for the use of the investigational drug, biological product, or device; and

(5) documentation from the treating health care provider that the patient meets the requirements of this section.

**Section 5. Written informed consent required.** (1) A patient or a patient's legal guardian must provide written informed consent for treatment with an investigational drug, biological product, or device.

(2) At a minimum, the written informed consent must include:

(a) an explanation of the currently approved products and treatments for the disease or condition from which the patient suffers;

(b) an attestation that the patient concurs with the treating health care provider in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life;

(c) clear identification of the specific investigational drug, biological product, or device that the patient is seeking to use;

(d) a description of the potentially best and worst outcomes of using the investigational drug, biological product, or device and a realistic description of the most likely outcome;

(e) a statement that the patient's health plan or third-party administrator and provider are not obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device unless they are specifically required to do so by law or contract;

(f) a statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the investigational drug, biological product, or device and that hospice care may be reinstated if the treatment ends and the patient meets hospice eligibility requirements; and

(g) a statement that the patient understands that the patient is liable for all expenses related to the use of the investigational drug, biological product, or device and that the liability for expenses extends to the patient's estate, unless a contract between the patient and the manufacturer of the drug, biological product, or device states otherwise.

(3) The description of potential outcomes required under subsection (2)(d) must:

(a) include the possibility that new, unanticipated, different, or worse symptoms might result and that the proposed treatment could hasten death; and

(b) be based on the treating health care provider's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition.

(4) The written informed consent must be:

(a) signed by:

(i) the patient;

(ii) a parent or legal guardian, if the patient is a minor; or

(iii) a legal guardian, if a guardian has been appointed pursuant to Title 72, chapter 5; and

(b) attested to by the patient's treating health care provider and a witness.

**Section 6. Effect on insurance coverage and health care services.** (1) [Sections 1 through 10] do not:

(a) expand the coverage required of an insurer under Title 33 or of the state or a local government under Title 2 or Title 53;

(b) affect the requirements for insurance coverage of routine patient costs for patients involved in approved cancer clinical trials pursuant to 2-18-704, 33-22-101, 33-22-153, 33-31-111, 33-35-306, 53-4-1005, or 53-6-101;

(c) require a health plan, third-party administrator, or governmental agency to pay costs associated with the use, care, or treatment of an eligible patient with an investigational drug, biological product, or device; or

(d) require a health care facility to provide new or additional services.

(2) A health plan, third-party administrator, or governmental agency may provide coverage for the cost of an investigational drug, biological product, or device or the cost of services related to the use of an investigational drug, biological product, or device under [sections 1 through 10].

(3) A health care facility may approve the use of an investigational drug, biological product, or device in the health care facility.

**Section 7. Heirs not liable for payments.** If an eligible patient dies while being treated with an investigational drug, biological product, or device, the patient's heirs are not liable for any outstanding debt related to the treatment or to a lack of insurance as a result of the treatment.

**Section 8. Disciplinary action prohibited.** (1) A licensing board may not revoke, fail to renew, suspend, or take any action against a license issued under Title 37 to a health care provider based solely on the health care provider's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device.

(2) The department of public health and human services may not take action against a health care provider's medicare certification based solely on the health care provider's recommendation that a patient have access to an investigational drug, biological product, or device.

**Section 9. State action prohibited.** (1) An official, employee, or agent of the state of Montana may not block or attempt to block an eligible patient's access to an investigational drug, biological product, or device.

(2) Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this section.

**Section 10. Immunity from suit.** A manufacturer of an investigational drug, biological product, or device, a pharmacist, a health care facility, a health care provider, or a person or entity involved in the care of an eligible patient using an investigational drug, biological product, or device is immune from suit for any harm done to the eligible patient resulting from the investigational drug, biological product, or device if the manufacturer, pharmacist, health care facility, health care provider, or other person or entity is complying in good faith with the terms of this act and has exercised reasonable care.

**Section 11. Codification instruction.** [Sections 1 through 10] are intended to be codified as an integral part of Title 50, chapter 9, and the provisions of Title 50, chapter 9, apply to [sections 1 through 10].

**Section 12. Severability.** If a part of [this act] is invalid, all valid parts that are severable from the invalid part remain in effect. If a part of [this act] is invalid in one or more of its applications, the part remains in effect in all valid applications that are severable from the invalid applications.

**Section 13. Two-thirds vote required.** Because [section 10] limits governmental liability, Article II, section 18, of the Montana constitution requires a vote of two-thirds of the members of each house of the legislature for passage.

**Section 14. Effective date.** [This act] is effective on passage and approval.

- END -

I hereby certify that the within bill,

SB 0142, originated in the Senate.

Secretary of the Senate

President of the Senate

Signed this _____ day

of _____, 2015.

Speaker of the House

Signed this _____ day

of _____, 2015.

SENATE BILL NO. 142

INTRODUCED BY C. SMITH, N. BALLANCE, DEBBY BARRETT, G. BENNETT, S. BERGLEE, M. BLASDEL, J. BRENDEN, B. BROWN, D. BROWN, T. BROWN, C. CLARK, J. COHENOUR, R. COOK, A. DOANE, R. DRISCOLL, R. EHLI, J. FIELDER, S. FITZPATRICK, K. FLYNN, F. GARNER, C. GLIMM, E. GREEF, D. HAGSTROM, B. HAMLETT, K. HANSEN, G. HERTZ, S. HESS, J. HINKLE, D. HOWARD, D. JONES, L. JONES, D. KARY, J. KEANE, B. KEENAN, A. KNUDSEN, D. LAMM, M. LANG, S. LASZLOFFY, S. LAVIN, F. MANDEVILLE, T. MANZELLA, E. MCCLAFFERTY, W. MCKAMEY, M. MCNALLY, M. MILLER, M. MONFORTON, D. MOORE, F. MOORE, D. MORTENSEN, A. OLSZEWSKI, R. OSMUNDSON, R. PINOCCI, L. RANDALL, A. REDFIELD, K. REGIER, V. RICCI, T. RICHMOND, R. RIPLEY, M. ROSENDALE, D. SANDS, N. SCHWADERER, S. STAFFANSON, N. SWANDAL, J. TAYLOR, F. THOMAS, B. TSCHIDA, G. VANCE, C. VINCENT, R. WEBB, D. ZOLNIKOV

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