Right to Try Amendments

2026 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Chris H. Wilson

House Sponsor: Tyler Clancy

LONG TITLE

General Description:

This bill amends provisions related to when a patient may obtain and use investigational drugs and devices to treat an illness.

Highlighted Provisions:

This bill:

- allows a patient to obtain an investigational drug or device in additional circumstances;
- amends the definition regarding the forms a medicine may take; and
- creates a reporting requirement for manufacturers.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-85-102, as last amended by Laws of Utah 2025, Chapter 114

ENACTS:

58-85-107, Utah Code Annotated 1953

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **58-85-102** is amended to read:

58-85-102 . Definitions.

As used in this chapter:

(1) "Eligible illness" means a condition of a patient that:

(a) as determined by a physician, presents a substantial and severely debilitating or life-threatening risk to the patient; and

(b) presents the patient, after the patient has explored conventional therapy options, with no treatment option that is satisfactory or comparable to treatment with an investigational drug or investigational device.

(2) "Eligible patient" means an individual who has been diagnosed with a terminal illness or eligible illness by a physician.

[~~(2)~~] (3) "Insurer" means the same as that term is defined in Section 31A-1-301.

[~~(3)~~] (4) "Investigational device" means a device that:

(a) meets the definition of "investigational device" in 21 C.F.R. Sec. 812.3;[~~and~~]

(b) has successfully completed the United States Food and Drug Administration Phase 1 testing for an investigational device described in 21 C.F.R. Part 812[~~.~~] ; and

(c) if used to treat an eligible illness, is currently undergoing an investigation, as defined in 21 C.F.R. Sec. 812.3, that complies with all applicable requirements for the investigation in accordance with 21 C.F.R. Part 812.

[~~(4)~~] (5) "Investigational drug" means a drug that:

(a) meets the definition of "investigational new drug" in 21 C.F.R. Sec. 312.3;[~~and~~]

(b) has successfully completed the United States Food and Drug Administration Phase 1 testing for an investigational new drug described in 21 C.F.R. Part 312[~~.~~] ; and

(c) if used to treat an eligible illness, is currently undergoing a clinical investigation, as defined in 21 C.F.R. Sec. 312.3, that complies with all applicable requirements for the clinical investigation in accordance with 21 C.F.R. Part 312.

[~~(5)~~] (6) "Medicinal dosage form" means:

(a) a tablet;

(b) a capsule;

(c) a concentrated oil;

(d) a liquid [~~suspension~~] formulation;

(e) a transdermal preparation; or

(f) a sublingual preparation.

[~~(6)~~] (7) "Physician" means an individual who is licensed under:

(a) Title 58, Chapter 67, Utah Medical Practice Act; or

(b) Title 58, Chapter 68, Utah Osteopathic Medical Practice Act.

[~~(7)~~] (8) "Terminal illness" means a condition of a patient that:

(a)(i) as determined by a physician:

[~~(i)~~] (A) is likely to pose a greater risk to the patient than the risk posed to the patient by treatment with an investigational drug or investigational device; and

[~~(ii)~~] (B) will inevitably lead to the patient's death; [~~and~~] or

(ii) as determined by a physician who is a board certified oncologist, is cancer; and

(b) presents the patient, after the patient has explored conventional therapy options, with no treatment option that is satisfactory or comparable to treatment with an investigational drug or device.

Section 2. Section **58-85-107** is enacted to read:

58-85-107 . Report.

(1) If a manufacturer of an investigational drug or investigational device provides an investigational drug or investigational device to a patient located in the state to treat an eligible illness, the manufacturer shall report the information described in Subsection (2) to the Health and Human Services Interim Committee before the November 1 that follows the day the drug or device was provided to the patient.

(2) The report shall include the following information:

(a) the number of patients that received an investigational drug or investigational device to treat an eligible illness;

(b) each eligible illness being treated;

(c) adverse outcomes likely attributable to the investigational drug or investigational device; and

(d) any other information the manufacturer determines relevant.

(3) Subsection (1) does not apply if the patient receiving the device or drug was part of an investigation conducted under 21 C.F.R. Part 812 or a clinical investigation conducted under 21 C.F.R. Part 312.

Section 3. **Effective Date.**

This bill takes effect on May 6, 2026.