

# SB0222S02 compared with SB0222

~~{Omitted text}~~ shows text that was in SB0222 but was omitted in SB0222S02

inserted text shows text that was not in SB0222 but was inserted into SB0222S02

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## Right to Try Amendments

2026 GENERAL SESSION

STATE OF UTAH

**Chief Sponsor: Chris H. Wilson**

House Sponsor: Tyler Clancy

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### LONG TITLE

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#### General Description:

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

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#### Highlighted Provisions:

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This bill:

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▶ allows a patient to obtain an investigational drug or device in additional circumstances;

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▶ ~~{removes the requirement that a patient have a terminal illness to access an investigational drug; and}~~

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▶ amends the definition regarding the forms a medicine may take~~{-}~~ ; and

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▶ creates a reporting requirement for manufacturers.

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#### Money Appropriated in this Bill:

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None

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#### Other Special Clauses:

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None

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#### Utah Code Sections Affected:

SB0222

## SB0222 compared with SB0222S02

17 AMENDS:

18 **58-85-102** , as last amended by Laws of Utah 2025, Chapter 114

19 ENACTS:

20 **58-85-107 , Utah Code Annotated 1953**

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

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

24 **58-85-102. Definitions.**

As used in this chapter:

25 (1) "Eligible illness" means a condition of a patient that ~~{, as determined by a physician }~~ :

26 (a) ~~{ is likely to pose a significant risk to the patient when compared to the }~~ as determined by a  
physician, presents a substantial and severely debilitating or life-threatening risk ~~{ posed }~~ to the  
patient ~~{ by treatment with an investigational drug or investigational device }~~ ; and

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

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

33 ~~{(2)}~~ (3) "Insurer" means the same as that term is defined in Section 31A-1-301.

34 ~~{(3)}~~ (4) "Investigational device" means a device that:

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

36 (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

39 (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.

38 ~~{(4)}~~ (5) "Investigational drug" means a drug that:

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

40 (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

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(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.

42 [(5)] (6) "Medicinal dosage form" means:

43 (a) a tablet;

44 (b) a capsule;

45 (c) a concentrated oil;

46 (d) a ~~{[liquid]}~~ [suspension] formulation;

47 (e) a transdermal preparation; or

48 (f) a sublingual preparation.

49 [(6)] (7) "Physician" means an individual who is licensed under:

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

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

52 [(7)] (8) {"Terminal illness" means a condition of a patient that:}

53 {(a)}

(i) {as determined by a physician:}

54 {(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}

56 {(ii)} (B) {will inevitably lead to the patient's death; } [and]

57 {(b)} } or

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

65 (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. { }

68 Section 2. Section 2 is enacted to read:

69 **58-85-107. Report.**

70 (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.

75 (2) The report shall include the following information:

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- 76 (a) the number of patients that received an investigational drug or investigational device to treat an  
eligible illness;
- 78 (b) each eligible illness being treated;
- 79 (c) adverse outcomes likely attributable to the investigational drug or investigational device; and
- 81 (d) any other information the manufacturer determines relevant.
- 82 (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.

85 Section 3. **Effective date.**

Effective Date.

This bill takes effect on May 6, 2026.

2-23-26 9:55 AM