***Effective 5/12/2015***

# Chapter 85
# Utah Right to Try Act

**58-85-101 Title.**

This chapter is known as the "Utah Right to Try Act."

Enacted by Chapter 110, 2015 General Session

**58-85-102 Definitions.**

As used in this chapter:

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

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

(3) "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.

(4) "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.

(5) "Medicinal dosage form" means the same as that term is defined in Section 58-37-3.6.

(6) "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) "Terminal illness" means a condition of a patient that:

(a) as determined by a physician:

(i) 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) will inevitably lead to the patient's death; 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.

Amended by Chapter 1, 2018 Special Session 3

**58-85-103 Right to request investigational drug or device.**

(1) An eligible patient may obtain an investigational drug through an agreement with the investigational drug's manufacturer and the eligible patient's physician that provides:

(a) for the transfer of the investigational drug from the manufacturer to the physician; and

(b) that the physician will administer the investigational drug to the patient.

(2) An eligible patient may obtain an investigational device through an agreement with the investigational device's manufacturer and the eligible patient's physician that provides:

(a) for the transfer of the investigational device from the manufacturer to the physician; and

(b) that the physician will use the investigational device to treat the patient.

(3) An agreement described in Subsection (1) or (2), between an eligible patient, a physician, and a manufacturer, shall include an informed consent document that, based on the physician's knowledge of the relevant investigational drug or investigational device:
(a) describes the possible positive and negative outcomes the eligible patient could experience if the physician treats the eligible patient with the investigational drug or investigational device, including that the investigational drug or investigational device could increase the possibility of death;
(b) states that an insurer is not required to cover the cost of providing the investigational drug or investigational device to the patient;
(c) states that, subject to Section 58-85-105, an insurer may deny coverage for the eligible patient; and
(d) states that the patient may be liable for all expenses caused by the physician treating the patient with the investigational drug or investigational device, unless the agreement provides otherwise.
(4) A physician or an eligible patient shall notify the eligible patient's insurer of the day on which the physician treated an eligible patient with an investigational drug or investigational device, and the investigational drug or device used, under an agreement described in Subsection (1) or (2).

Enacted by Chapter 110, 2015 General Session

**58-85-104 Standard of care -- Medical practitioners not liable -- No private right of action.**
(1) It is not a breach of the applicable standard of care for a physician, other licensed health care provider, or hospital to treat an eligible patient with an investigational drug or investigational device under this chapter.
(2) A physician, other licensed health care provider, or hospital that treats an eligible patient with an investigational drug or investigational device under this chapter may not, for any harm done to the eligible patient by the investigational drug or device, be subject to:
(a) civil liability;
(b) criminal liability; or
(c) licensure sanctions under:
(i) for a physician:
(A)Chapter 67, Utah Medical Practice Act; or
(B)Chapter 68, Utah Osteopathic Medical Practice Act;
(ii) for the other licensed health care provider, the act governing the other licensed health care provider's license; or
(iii) for the hospital, Title 26B, Chapter 2, Part 2, Health Care Facility Licensing and Inspection.
(3) This chapter does not:
(a) require a manufacturer of an investigational drug or investigational device to agree to make an investigational drug or investigational device available to an eligible patient or an eligible patient's physician;
(b) require a physician to agree to:
(i) administer an investigational drug to an eligible patient under this chapter; or
(ii) treat an eligible patient with an investigational device under this chapter; or
(c) create a private right of action for an eligible patient:
(i) against a physician or hospital, for the physician's or hospital's refusal to:
(A) administer an investigational drug to an eligible patient under this chapter; or
(B) treat an eligible patient with an investigational device under this chapter; or

(ii) against a manufacturer, for the manufacturer's refusal to provide an eligible patient with an investigational drug or an investigational device under this chapter.

Amended by Chapter 329, 2023 General Session

**58-85-105 Insurance coverage.**

(1) This chapter does not:
(a) require an insurer to cover the cost of:
(i) administering an investigational drug under this chapter; or
(ii) treating a patient with an investigational device under this chapter; or
(b) prohibit an insurer from covering the cost of:
(i) administering an investigational drug under this chapter; or
(ii) treating a patient with an investigational device under this chapter.
(2) Except as described in Subsection (3), an insurer may deny coverage to an eligible patient who is treated with an investigational drug or investigational device, for harm to the eligible patient caused by the investigational drug or investigational device.
(3) An insurer may not deny coverage to an eligible patient under Subsection (2) for:
(a) the eligible patient's preexisting condition;
(b) benefits that commenced before the day on which the eligible patient is treated with the investigational drug or investigational device; or
(c) palliative or hospice care for an eligible patient that has been treated with an investigational drug or device, but is no longer receiving curative treatment with the investigational drug or device.

Amended by Chapter 1, 2018 Special Session 3

**58-85-106 Use of investigational drugs and devices during a major public health emergency -- Limitations -- Immunity.**

(1) As used in this section:
(a) "Declared major public health emergency" means a state of emergency declared by the governor under Section 53-2a-206 as the result of a major public health emergency.
(b) "Health care provider" means the same as that term is defined in Section 78B-3-403.
(c) "Insurer" means the same as that term is defined in Section 31A-22-634.
(d) "Major public health emergency" means an occurrence of imminent threat of an illness or health condition that:
(i) is believed to be caused by:
(A) bioterrorism;
(B) the appearance of a novel or previously controlled or eradicated infectious agent or biological toxin;
(C) a natural disaster;
(D) a chemical attack or accidental release; or
(E) a nuclear attack or accident; and
(ii) poses a high probability of:
(A) a large number of deaths in the affected population;
(B) a large number of serious or long-term disabilities in the affected population; or
(C) widespread exposure to an infectious or toxic agent that poses a significant risk of substantial future harm to a large number of people in the affected population.
(e) "Physician" means the same as that term is defined in Section 58-67-102.

(f) "Qualified patient" means a patient who has been diagnosed with a condition that has resulted in a declared major public health emergency.

(2)

(a) To the extent permitted under federal law, a qualified patient may obtain an investigational drug through an agreement with the investigational drug's manufacturer and the qualified patient's physician that provides:

(i) for the transfer of the investigational drug from the manufacturer to the physician; and

(ii) that the physician will administer the investigational drug to the qualified patient.

(b) To the extent permitted under federal law, a qualified patient may obtain an investigational device through an agreement with the investigational device's manufacturer and the qualified patient's physician that provides:

(i) for the transfer of the investigational device from the manufacturer to the physician; and

(ii) that the physician will use the investigational device to treat the qualified patient.

(c) The agreement described in Subsection (2)(a) or (b) shall include an informed consent document that, based on the physician's knowledge of the relevant investigational drug or investigational device:

(i) describes the possible positive and negative outcomes the qualified patient could experience if the physician treats the qualified patient with the investigational drug or investigational device;

(ii) states that an insurer is not required to cover the cost of providing the investigational drug or investigational device to the qualified patient;

(iii) states that, subject to Subsection (5), an insurer may deny coverage for the qualified patient; and

(iv) states that the qualified patient may be liable for all expenses caused by the physician treating the patient with the investigational drug or investigational device, unless the agreement provides otherwise.

(3) The physician of a qualified patient shall notify the qualified patient's insurer of:

(a) the day on which the physician treated the qualified patient with an investigational drug or investigational device; and

(b) the investigational drug or investigational device used under an agreement described in Subsection (2).

(4)

(a) It is not a breach of the applicable standard of care for a health care provider to treat a qualified patient with an investigational drug or investigational device under this section.

(b) A health care provider that treats a qualified patient with an investigational drug or investigational device in accordance with this section is not subject to civil liability, criminal liability, or sanctions against the health care provider's license for any harm to the qualified patient resulting from the qualified patient's use of the investigational drug or device.

(5)

(a) This section does not:

(i) require a manufacturer of an investigational drug or investigational device to agree to make an investigational drug or investigational device available to a qualified patient or a qualified patient's physician;

(ii) require a physician to agree to:

(A) administer an investigational drug to a qualified patient under this section; or

(B) treat a qualified patient with an investigational device under this section;

(iii) create a private right of action for a qualified patient against a health care provider for the health care provider's refusal to:

(A) administer an investigational drug to a qualified patient under this section; or
(B) treat a qualified patient with an investigational device under this section; or
(iv) create a private right of action for a qualified patient against a manufacturer for the manufacturer's refusal to provide a qualified patient with an investigational drug or an investigational device under this section.
(b) This section does not:
(i) require an insurer to cover the cost of:
(A) administering an investigational drug under this section; or
(B) treating a patient with an investigational device under this section; or
(ii) prohibit an insurer from covering the cost of:
(A) administering an investigational drug under this section; or
(B) treating a patient with an investigational device under this section.
(c) Except as described in Subsection (5)(d), an insurer may deny coverage to a qualified patient who is treated with an investigational drug or investigational device for harm to the qualified patient caused by the investigational drug or investigational device.
(d) An insurer may not deny coverage to a qualified patient under Subsection (5)(c) for:
(i) the qualified patient's preexisting condition;
(ii) benefits that commenced before the day on which the qualified patient was treated with the investigational drug or investigational device; or
(iii) palliative or hospice care for a qualified patient that has been treated with an investigational drug or investigational device but is no longer receiving curative treatment with the investigational drug or investigational device.

Enacted by Chapter 8, 2020 Special Session 3