EMERGENCY HEALTH CARE ACCESS AND IMMUNITY AMENDMENTS

2020 THIRD SPECIAL SESSION

STATE OF UTAH

Chief Sponsor: Evan J. Vickers

House Sponsor: Val L. Peterson

LONG TITLE

General Description:

This bill expands access to certain treatments and creates limited immunity for certain actions during a declared major public health emergency.

Highlighted Provisions:

This bill:

- defines terms;
- provides limited immunity for health care, including the use of certain treatments, provided during a major public health emergency;
- amends the Utah Right to Try Act to permit the use of certain investigational drugs and devices during a major public health emergency; and
- creates limited immunity for health care providers who provide an investigational drug or device to a patient during a major public health emergency.

Money Appropriated in this Bill:

None

Other Special Clauses:

This bill provides a special effective date.

Utah Code Sections Affected:

ENACTS:

58-13-2.7, Utah Code Annotated 1953

58-85-106, Utah Code Annotated 1953

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

Section 1. Section **58-13-2.7** is enacted to read:

58-13-2.7. Limited immunity during a declared major public health emergency.

(1) As used in this section:

(a) "Declared major public health emergency" means the same as that term is defined in Section 58-85-106.

(b) "Health care" means the same as that term is defined in Section 78B-3-403.

(c) "Health care provider" means the same as that term is defined in Section 78B-3-403.

(d) "Prescription device" means the same as that term is defined in Section 58-17b-102.

(e) "Prescription drug" means the same as that term is defined in Section 58-17b-102.

(f) "Qualified treatment" means the use of a prescription drug or prescription device:

(i) during a declared major public health emergency;

(ii) to treat a patient who has been diagnosed with the illness or condition that resulted in the declared major public health emergency; and

(iii) that has been approved for sale but not indicated by the United States Food and Drug Administration to treat the illness or condition described in Subsection (1)(f)(ii).

(2) (a) A health care provider is immune from civil liability for any harm resulting from any act or omission in the course of providing health care during a declared major public health emergency if:

(i) (A) the health care is provided in good faith to treat a patient for the illness or condition that resulted in the declared major public health emergency; or

(B) the act or omission was the direct result of providing health care to a patient for the illness or condition that resulted in the declared major public health emergency; and

(ii) the acts or omissions of the health care provider were not:

(A) grossly negligent; or

(B) intentional or malicious misconduct.

(b) The immunity in Subsection (2)(a) applies:

(i) even if the health care provider has a duty to respond or an expectation of payment or remuneration; and

(ii) in addition to any immunity protections that may apply under state or federal law.

(c) During a declared major public health emergency, it is not a breach of the applicable standard of care for a health care provider to provide health care that is not within the health care provider's education, training, or experience, if:

(i) the health care is within the applicable scope of practice for the type of license issued to the health care provider;

(ii) (A) the health care is provided in good faith to treat a patient for the illness or condition that resulted in the declared major public health emergency; or

(B) there is an urgent shortage of health care providers as a direct result of the declared major public health emergency; and

(iii) providing the health care is not:

(A) grossly negligent; or

(B) intentional or malicious misconduct.

(3) (a) A health care provider is not subject to civil liability, criminal liability, or sanctions against the health care provider's license for providing a qualified treatment to a patient if:

(i) the qualified treatment is within the scope of the health care provider's license;

(ii) if written recommendations have been issued by a federal government agency regarding the use of the qualified treatment for treatment of the illness or condition that resulted in the declared major public health emergency, the health care provider provides the qualified treatment in accordance with the most current written recommendations issued by the federal government agency;

(iii) the health care provider:

(A) describes to the patient or the patient's representative, based on the health care provider's knowledge of the qualified treatment, the possible positive and negative outcomes the patient could experience if the health care provider treats the patient with the qualified

treatment; and

(B) documents in the patient's medical record the information provided to the patient or the patient's representative under Subsection (3)(a)(iii)(A) and whether the patient or the patient's representative consented to the treatment; and

(iv) the acts or omissions of the health care provider were not:

(A) grossly negligent; or

(B) intentional or malicious misconduct.

(b) If two or more written recommendations described in Subsection (3)(a)(ii) are issued by federal government agencies, a health care provider satisfies the requirement described in Subsection (3)(a)(ii) by providing the qualified treatment in accordance with the most current written recommendations of any one federal government agency.

Section 2. Section **58-85-106** is enacted to read:

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 76B-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.

Section 3. **Effective date.**

If approved by two-thirds of all the members elected to each house, this bill takes effect upon approval by the governor, or the day following the constitutional time limit of Utah Constitution, Article VII, Section 8, without the governor's signature, or in the case of a veto, the date of veto override.