Effective 4/22/2020

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