

Effective 5/12/2015

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