

§ 90-325.2. Authorized access to and use of investigational drugs, biological products, and devices.

(a) A manufacturer of an investigational drug, biological product, or device may make available to an eligible patient, and an eligible patient may request, the manufacturer's investigational drug, biological product, or device. However, nothing in this Part shall be construed to require a manufacturer of an investigational drug, biological product, or device to make such investigational drug, biological product, or device available to an eligible patient.

(b) A manufacturer of an investigational drug, biological product, or device may provide the investigational drug, biological product, or device to an eligible patient without receiving compensation or may require the eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device. (2015-137, s. 1; 2019-70, s. 1.)