§ 90-325.31. Authorized access to and use of individualized investigational drugs, biological products, or devices.

(a) A manufacturer operating within an eligible facility and in accordance with all applicable federal law may make available to an eligible patient, and an eligible patient may request, the manufacturer's individualized investigational drug, biological product, or device from an eligible facility or manufacturer operating within an eligible facility. However, nothing in this Part shall be construed to require a manufacturer of an individualized investigational drug, biological product, or device to make such individualized investigational drug, biological product, or device available to an eligible patient.

(b) A manufacturer of an individualized investigational drug, biological product, or device may provide the individualized 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 individualized investigational drug, biological product, or device. (2024-36, s. 1.)