



# OHIO LEGISLATIVE SERVICE COMMISSION

Office of Research  
and Drafting

Legislative Budget  
Office

**S.B. 170**  
**136<sup>th</sup> General Assembly**

## **Fiscal Note & Local Impact Statement**

[Click here for S.B. 170's Bill Analysis](#)

**Version:** As Introduced

**Primary Sponsors:** Sens. Huffman and Roegner

**Local Impact Statement Procedure Required:** No

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### **Highlights**

- Public health benefit plans or governmental agencies may experience costs related to a patient's individualized investigational treatment if these entities opt to provide coverage for these costs. If this occurs, costs will depend on the nature of a patient's treatment and the number of patients who undergo an individualized investigational treatment.

### **Detailed Analysis**

#### **Use of individualized investigational treatments**

The bill allows an eligible patient who is suffering from a life threatening or severely debilitating illness to be treated with an individualized investigational treatment. In addition to having a life threatening or severely debilitating disease, the bill provides additional eligibility criteria, including that the individual has received a recommendation from the treating physician for an individualized investigational treatment, based on an analysis of the individual, and that written, informed consent for the treatment has been executed. The bill allows, but does not require, health plan issuers and governmental agencies to provide coverage for the cost of individualized investigational treatments or the cost of services related to the use of such treatments. The bill specifies that its requirements are not to be construed as doing any of the following: (1) expanding the coverage required under a health benefit plan, (2) requiring any governmental agency to pay costs associated with an individualized investigational treatment, (3) requiring the hospital or facility to provide new or additional services, unless approved by the hospital or facility, (4) authorizing a health benefit plan or governmental agency to exclude coverage for a covered person receiving such treatment for services that are not related to the treatment and that are otherwise covered, and (5) negating, abrogating, or in any way affecting any mandatory coverage for participation in clinical trials, as otherwise required in law. The bill specifies that if a patient dies while being treated by an individualized investigational treatment,

the patient's heirs are not liable for any outstanding debt related to the treatment or lack of coverage due to the treatment.

Additionally, the bill authorizes, but does not require, a manufacturer that is operating within an eligible facility under a federal-wide assurance for the protection of human subjects to make an individualized investigational drug available to an eligible patient. The manufacturer may provide the treatment without receiving compensation or require the patient to pay the costs.

### **Fiscal impact**

Government-owned hospitals and public health plans should not experience costs related to a patient's individualized investigational treatment, as the bill provides that the patient's health plan issuer and provider are not obligated to pay for any care or treatment directly related to the use of an individualized investigational treatment. However, the bill permits a health benefit plan or governmental agency to provide coverage for the costs. If this occurs, costs to a public health benefit plan or governmental agency will depend on the nature of a patient's treatment and the number patients who undergo an individualized investigational treatment.

### **Immunity**

The bill prohibits the State Medical Board from taking any action against a physician's license or certificate to practice based solely on the physician's recommendations to an eligible patient regarding an individualized investigational treatment. It also specifies that, to the extent permitted under federal law, an entity responsible for Medicare certification cannot take action against a physician's Medicare certification based on the physician's recommendation.

The bill also specifies that nothing in the bill's provisions is to be construed to create a private cause of action against a manufacturer of an individualized investigational treatment or against any other person or entity involved in the care of an eligible patient using the treatment for any harm to the patient resulting from the treatment, if the manufacturer or other person or entity has complied in good faith with the bill's provisions and has exercised reasonable care.

### **Fiscal impact**

The bill's immunity provisions would limit related investigations by the State Medical Board and potential court cases.