



# OHIO LEGISLATIVE SERVICE COMMISSION

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## Fiscal Note & Local Impact Statement

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**Bill:** H.B. 290 of the 131st G.A.

**Date:** December 8, 2016

**Status:** As Enacted

**Sponsor:** Reps. Sprague and Anielski

**Local Impact Statement Procedure Required:** No

**Contents:** To permit a patient with a terminal condition to be treated with a drug, product, or device not approved by the United States Food and Drug Administration

### State Fiscal Highlights

- The bill specifies that only a licensed terminal distributor of dangerous drugs or a registered wholesale distributor of dangerous drugs can distribute an investigational drug or product. There could be a minimal increase in costs to the State of Ohio Board of Pharmacy if additional entities would need licensure and oversight by the Board.
- The bill requires the State Medical Board to create a template of the form to be used by a treating physician to secure a patient's informed consent for an investigational drug, product, or device. There could be minimal administrative costs to the State Medical Board to create this form and to make it available.
- The bill requires specified state licensing agencies to permit licensees to satisfy certain continuing education requirements by providing volunteer health care services. The bill requires these agencies to adopt rules. As such, specified state licensing agencies could realize a minimal increase in costs to promulgate rules.

### Local Fiscal Highlights

- The bill permits a treating physician to use an investigational drug, product, or device that is still in clinical trials and has not been approved for general use by the United States Food and Drug Administration to treat an eligible patient suffering from a terminal condition. There could be a cost to public hospitals if a hospital elects to acquire and provide this medication, product, or device to a patient with a terminal condition. Costs to public hospitals would depend on whether the patient's insurance would cover the medication, product, or device.

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## Detailed Fiscal Analysis

### Drugs, products, and devices

The bill permits a treating physician to use an investigational drug, product, or device that is still under clinical investigation, and has not been approved for general use by the United States Food and Drug Administration, to treat an eligible patient suffering from a terminal condition. In addition, the bill requires a treating physician providing an investigational drug, product, or device to secure the patient's informed consent. The bill provides qualified immunity to a physician who recommends or treats an eligible patient with an investigational drug, product, or device as authorized by the bill. The bill authorizes, but does not require, a manufacturer to provide an investigational drug, product, or device to an eligible patient or the patient's treating physician. According to the Ohio Hospital Association, there could be a cost to public hospitals if a hospital elects to acquire and provide this medication, product, or device to a patient with a terminal condition. Costs to public hospitals would depend on whether the patient's insurance would cover the medication, product, or device.

The bill requires the State Medical Board, as soon as practicable after the bill's effective date, to create a template of the form to be used by a treating physician to secure a patient's informed consent. There could be minimal administrative costs to the State Medical Board to create this form and to make it available.

The bill specifies that only a licensed terminal distributor of dangerous drugs or a registered wholesale distributor of dangerous drugs can distribute an investigational drug or product. There could be a minimal increase in costs to the State of Ohio Board of Pharmacy if additional entities would need licensure and oversight by the Board.

### County home

The bill modifies a board of county commissioner's authority to appoint a county home superintendent or administrator. Currently, a county board is required to appoint a county home superintendent. Under the bill, a county board may either appoint the superintendent or enter into a contract with a public or private entity that agrees to select a superintendent or administrator. The provision is permissive, so a county board could choose to enter into a contract or continue to appoint the superintendent.

### Continuing education for volunteer health care services

The bill requires licensing agencies to permit licensees to satisfy up to one-third of the licensee's continuing education requirement by providing volunteer health care services to indigent and uninsured persons. The bill specifies which licensing agencies this applies to and requires the licensing agencies to adopt rules. As such, specified state licensing agencies could realize a minimal increase in costs to promulgate rules.