ARIZONA HOUSE OF REPRESENTATIVES

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Senate: HHS DPA 6-2-0-0 | 3rd Read 16-11-3-0
House: HHS DP 7-2-0-0 | 3rd Read 39-18-3-0

SB 1163: individualized investigational treatment; availability; prohibitions
Sponsor: Senator Barto, LD 15
Transmitted to the Governor

Overview

Permits a manufacturer operating within an eligible facility to make an individualized investigational treatment available to an eligible patient with a life-threatening or severely debilitating illness.

History

Arizona voters approved the Terminal Patient's Right to Try Act (Act) in 2014, which allows a manufacturer of an investigational drug, biological product or device to make the investigational drug, biological product or device available to eligible patients. The Act outlines various rules and restrictions relating to investigational drugs, biological products or devices.

An *Investigational drug, biological product or device* is a drug, biological product or device that has successfully completed phase one of a clinical trial but has not been approved for general use by the United States Food and Drug Administration (FDA) and remains under investigation in a clinical trial (A.R.S. § 36-1311).

An *eligible patient* means a person who:

1) Has a terminal illness as determined by their physician and a consulting physician;
2) Has had their physician determine that they have no comparable or satisfactory FDA approved treatment options available to diagnose, monitor or treat the disease or condition involved and that the probable risk to the person from the investigational drug, biological product or device is not greater than the probable risk from the condition or disease;
3) Has received a prescription or recommendation from their physician for an investigational drug, biological product or device;
4) Has given written informed consent for the use of the investigational drug, biological product or device or if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian has given written informed consent on the patient's behalf; and
5) Has documentation from their physician that they meet all of the stated requirements (A.R.S. § 36-1311).

Provisions

1. Allows a manufacturer operating within an eligible facility according to all applicable federalwide assurance regulations to make an individualized investigational treatment available to an eligible patient. (Sec. 1)

2. Stipulates that an eligible patient's physician may request an individualized investigational drug, biological product or device from an eligible facility or manufacturer operating within the eligible facility. (Sec. 1)

☐ Prop 105 (45 votes)	☐ Prop 108 (40 votes)	☐ Emergency (40 votes)	☐ Fiscal Note

3. Clarifies that these provisions do not require the manufacturer to make an individualized investigational drug, biological product or device available to an eligible patient. (Sec. 1)

4. States that an eligible facility or manufacturer operating within an eligible facility may:
   a) Provide an individualized investigational drug, biological product or device to an eligible patient without receiving compensation; and
   b) Require an eligible patient to pay the costs of, or the cost associated with the manufacture of the individualized investigational drug, biological product or device. (Sec. 1)

5. Allows, but does not require, a health plan, third-party administrator or other third-party payor to provide coverage for the cost of an individualized investigational drug, biological product or device or the costs of the services related to the use of an individualized investigational drug, biological product or device. (Sec. 1)

6. Asserts that these provisions do not require a hospital or other licensed health care institution to provide new or additional services unless approved by the hospital or health care institution. (Sec. 1)

7. States that notwithstanding any other law, if a patient dies while being treated with an individualized investigational drug, biological product or device, the patient's heirs are not liable for any outstanding debt related to the treatment. (Sec. 1)

8. Prohibits an official, employee or agent of this state from blocking or attempting to block an eligible patient's access to an individualized investigational drug, biological product or device. (Sec. 1)

9. Stipulates that counseling, advice or a recommendation consistent with a licensed physician's medical standards of care is not considered blocking a patient's access to individualized investigational treatment. (Sec. 1)

10. Stipulates that this act does not create a private cause of action against a manufacturer of an individualized investigational drug, biological product or device or against any other person or entity involved in the care of an eligible patient using the individualized investigational drug, biological product or device for any harm done to the eligible patient resulting from the individualized investigational drug, biological product or device if the manufacturer or other person or entity complied in good faith and has exercised reasonable care. (Sec. 1)

11. Defines terms. (Sec. 1)