Ohio Legislative Service Commission

Bill Analysis

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Sub. H.B. 290

131st General Assembly
(As Reported by S. Health and Human Services)

Reps. Sprague and Anielski, Blessing, Dever, Grossman, Hackett, Henne, Rezabek, Romanchuk, Thompson, Huffman, Antonio, Barnes, Bishoff, Brown, Butler, T. Johnson, Kuhns, LaTourette, Sykes, Antani, Arndt, Baker, Boccieri, Boose, Boyd, Burkley, Clyde, Dovilla, Fedor, Ginter, Green, Hagan, Hall, Hambley, G. Johnson, Lepore-Hagan, Maag, Manning, McClain, M. O'Brien, S. O'Brien, Patterson, Perales, Ramos, Reineke, Roegner, Ruhl, Ryan, Schuring, Sheehy, Young

Sens. Brown, Tavares

BILL SUMMARY

Treatment with investigational drugs, products, and devices

- Permits the use of 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.

- 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.

- Authorizes, but does not require, the manufacturer to provide an investigational drug, product, or device to an eligible patient or the patient's treating physician.

- Provides qualified immunity to a manufacturer or terminal distributor of dangerous drugs that provides or distributes an investigational drug, product, or device as authorized by the bill.

- Restricts the possession, purchase, distribution, and sale of investigational drugs and products by wholesale distributors of dangerous drugs and licensed terminal distributors of dangerous drugs.

- Provides that the bill does not require a health care insurer, the Medicaid program or any other government health care program, or any other entity that offers health

care benefits, to provide coverage for the costs incurred from the use of an investigational drug, product, or device.

County home superintendent or administrator

- Permits a board of county commissioners to contract with an entity that agrees to select a county home superintendent or administrator with the county board's advice and consent.

- Specifies who serves as a county home's appointing authority.

Continuing education for volunteer health care services

- Permits certain health care professionals to satisfy a portion of their continuing education requirements by providing health care services without compensation to indigent and uninsured persons.

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CONTENT AND OPERATION

Drugs, products, and devices that have not completed clinical trials

The bill permits an eligible patient who is suffering from a terminal condition to be treated with an investigational drug, product, or device. It defines "investigational drug, product, or device" as a drug, biological product, or medical device that has successfully completed the first phase of clinical trials required by the United States Food and Drug Administration (FDA) and remains under clinical investigation but has not been approved for general use by the FDA. This does not include a schedule I controlled substance (a drug for which there is no legal use).[1]

Generally, clinical trials consist of three phases. Phase 1 trials use a small number (between 20 and 80) of healthy volunteers to try to determine dosing, document how a drug is metabolized and excreted, and identify acute side effects.

Phase 2 trials include more participants (about 100-300) who have the disease or condition that the product could treat. In Phase 2 trials, researchers seek to gather additional safety data and preliminary evidence of the drug's beneficial effects. If the Phase 2 trials indicate that the drug may be effective, and the risks are considered acceptable, the drug moves to Phase 3.

In Phase 3 trials, the drug is studied in a larger number of people with the disease (approximately 1,000-3,000). This phase further tests the product's effectiveness, monitors side effects and may compare the product's effects to a standard treatment, if one is already available.[2]

Eligibility for treatment with an investigational drug, product, or device

Terminal condition

The bill provides that to be eligible for treatment with an investigational drug, product, or device, a patient must have a terminal condition, as determined by the individual's treating physician and by one other physician who has examined the individual.[3] "Terminal condition" is defined as the following conditions, if irreversible, incurable, and untreatable through a method of treatment approved by the FDA:

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[1] R.C. 4731.97(A)(1); R.C. 3719.41, not in the bill.

[2] U.S. Department of Health and Human Services, U.S. Food and Drug Administration, *Inside Clinical Trials: Testing Medical Products in People*, available at: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143531.htm (last visited December 2, 2016).

[3] R.C. 4731.97(B)(1)(a).

(1) A progressive form of cancer;

(2) A progressive neurological disorder;

(3) A progressive musculoskeletal disorder;

(4) A condition that, based on reasonable medical standards and a reasonable degree of medical certainty, appears likely to cause death within a period of time that is relatively short but does not exceed 12 months.[4]

Eligible patient

In addition to having a terminal condition, for an individual to be an eligible patient the following conditions must be met:

(1) **Treatment options and risks considered** – The treating physician has determined that the individual has considered all approved treatment options and determined that there is no satisfactory or comparable approved treatment and that the risk from the investigational drug, product, or device is no greater than the probable risk from not treating the terminal condition;

(2) **Physician recommendation** – The treating physician recommends use of the investigational drug, product, or device as a last option available for the individual, attests that it represents the individual's best chance at survival, and agrees to either administer or personally furnish it or has issued a prescription to the individual;

(3) **Physician documentation** – The treating physician documents in the individual's medical record that all of the preceding conditions have been met.[5]

Access to clinical trials

The bill contains an exception to prohibit certain otherwise eligible patients from being eligible under the bill. An individual who meets the requirements specified above is not an eligible patient if a clinical trial using the investigational drug, product, or device is actively being conducted within 100 miles of the individual's residence, unless the individual applied for participation but was denied access to that clinical trial.[6]

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[4] R.C. 4731.97(A)(6).

[5] R.C. 4731.97(B)(1).

[6] R.C. 4731.97(B)(2).

Treating physician

The bill authorizes only a treating physician to treat an eligible patient with an investigational drug, product, or device. "Treating physician" is defined as the physician primarily responsible for providing medical care and treating an eligible patient's terminal condition. The bill specifies that "treating physician" does not include the patient's primary care physician, unless no other physician is primarily responsible for treating the terminal condition. A patient may have more than one treating physician.[7]

The bill defines "physician" as an individual authorized by Ohio law to practice medicine and surgery or osteopathic medicine and surgery.[8]

Informed consent

To treat an eligible patient, the bill requires the treating physician to secure the patient's informed consent in a signed statement. If the patient is a minor or lacks the capacity to consent, the informed consent must be obtained from a parent, guardian, or other person legally responsible for the patient.[9]

The consent form must be based on a template to be created by the State Medical Board under the bill. The template must be created as soon as practicable after the bill's effective date and the Board must make it available to physicians and hospitals.[10]

The treating physician must record all of the following on the form:

(1) An explanation of the approved treatment options for the patient's terminal condition;

(2) The specific proposed investigational drug, product, or device;

(3) The potentially best and worst outcomes of using the investigational drug, product, or device with a realistic description of the most likely outcome, including that there is no proof of efficacy and that it is possible that new, unanticipated, different, or worse symptoms might result and death may be hastened;

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[7] R.C. 4731.97(A)(7).

[8] R.C. 4731.97(A)(5).

[9] R.C. 4731.97(C)(1).

[10] R.C. 4731.97(I).

(4) An explanation that the investigational drug, product, or device manufacturer may hold the patient liable for all expenses that arise from the patient's use of the investigational drug, product, or device;

(5) An explanation that any health insurance or government program that covers the individual may not include coverage of any charges by the treating physician or another health care provider for any care or treatment resulting from the patient's use of the investigational drug, product, or device;

(6) A statement explaining that the drug manufacturer, the pharmacy or other distributor, and the patient's treating physician or administering hospital are not liable for civil damages or subject to criminal prosecution or professional disciplinary action related to providing, distributing, or treating with an investigational drug, product, or device, unless there is willful or wanton misconduct.[11]

The individual giving consent must sign the form in the conscious presence of a competent witness. The witness must also sign the form and attest that the individual giving consent appeared to (1) concur with the treating physician in believing that approved treatment options would be unlikely to prolong the patient's life, (2) understand the risks involved, and (3) willingly desire to use the investigational drug, product, or device to treat the terminal condition.[12]

The bill provides that the eligible patient, or the patient's parent, guardian, or other person legally responsible for the patient, may revoke consent to treatment with an investigational drug, product, or device at any time and in any manner that communicates the revocation.[13]

Qualified immunity for physicians

The bill provides that, except for actions constituting willful or wanton misconduct, a treating physician who recommends or treats an eligible patient with an investigational drug, product, or device in accordance with the bill is not liable for, or subject to, damages in a civil action, prosecution in a criminal action, or professional disciplinary action for an act or omission related to treatment with an investigational drug, product, or device. Further, the bill states that its provisions do not create a new cause of action or substantive legal right against a treating physician or hospital related

[11] R.C. 4731.97(2)(a).

[12] R.C. 4731.97(C)(2)(b) and (c).

[13] R.C. 4731.97(C)(3).

to a physician's not recommending the use of an investigational drug, product, or device.[14]

The bill also exempts a physician acting under the bill from current law that authorizes the State Medical Board to take disciplinary action for selling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes, or for violation of federal or state law regulating the possession, distribution, or use of any drug.[15]

Drug labeling

Current law generally requires a health professional who personally furnishes drugs to a patient to ensure that the drugs are labeled and packaged in accordance with state and federal drug laws and any applicable rules and regulations. The bill creates an exception to this requirement when an investigational drug, product, or device is provided in accordance with the bill.[16]

Alternative medical treatments

The bill provides that treatment with an investigational drug, product, or device does not constitute "alternative medical treatment" under existing law that permits a physician to use alternative medical treatment that is complementary to or different from conventional medical care.[17]

Restrictions on the possession, purchase, distribution, and sale of investigational drugs and products

The bill applies to investigational drugs and products current law that restricts the possession, purchase, distribution, and sale of dangerous drugs. Effectively, this means that a person must be licensed by the state to possess, purchase, distribute, or sell investigational drugs or products, unless the person meets one of the exceptions in existing law applicable to the possession, purchase, distribution, and sale of dangerous drugs.

Subject to numerous exceptions, current law prohibits a person other than a registered wholesale distributor of dangerous drugs from possessing for sale, selling, distributing, or delivering, at wholesale, dangerous drugs. The bill extends that

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[14] R.C. 4731.97(D).

[15] R.C. 4731.22(B)(3).

[16] R.C. 4729.291.

[17] R.C. 4731.227.

prohibition to investigational drugs and products.[18] Current law also restricts a wholesale distributor of dangerous drugs' ability to possess for sale, or sell, at wholesale, dangerous drugs. The bill extends that restriction to investigational drugs or products.[19]

Regarding terminal distributors of dangerous drugs, which are licensed under current law and include pharmacies, hospitals, nursing homes, and other entities that sell or provide dangerous drugs directly to patients, current law generally prohibits them from purchasing dangerous drugs for the purpose of resale from any person other than a registered wholesale distributor. The bill extends that prohibition to investigational drugs and products.[20] Current law also generally prohibits terminal distributors from selling or distributing dangerous drugs at retail or possessing or controlling them other than for the distributor's personal consumption. The bill extends that prohibition to investigational drugs and products.[21]

Manufacturer provision of investigational drugs, products, and devices

The bill authorizes, but specifies that it does not require,[22] the manufacturer of a dangerous drug to provide an investigational drug, product, or device to an eligible patient or the patient's treating physician. The investigational drug, product, or device may be provided directly to the patient or physician or provided through a terminal distributor of dangerous drugs. A manufacturer may provide the investigational drug, product, or device with or without charge for the costs associated with manufacturing and providing it. A manufacturer may require the patient to participate in data collection regarding use of the drug, product, or device.[23]

Qualified immunity for manufacturers and terminal distributors

The bill provides that, except for willful or wanton misconduct, a manufacturer or terminal distributor that provides or distributes an investigational drug, product, or device as authorized by the bill is not liable for or subject to damages in a civil action or

[18] R.C. 4729.51(A)(1).

[19] R.C. 4729.51(B)(1).

[20] R.C. 4729.51(D).

[21] R.C. 4729.51(E).

[22] R.C. 4729.89(D).

[23] R.C. 4729.89(B).

prosecution in a criminal proceeding for actions or omissions related to providing or distributing the drug, product, or device.[24]

Charges not covered by insurance or estate

The bill provides that its provisions authorizing a treating physician to treat an eligible patient with an investigational drug, product, or device do not require any health care insurer, the Medicaid program or any other government health care program, or any other entity that offers health care benefits to provide coverage for costs incurred from the use of any investigational drug, product, or device.[25]

However, the bill provides that if an eligible patient dies while being treated with the drug, product, or device and there are any outstanding costs related to treating the patient, the patient's estate, devisees, and heirs cannot be held liable by any person or government entity for those costs.[26]

State interference prohibited

The bill prohibits an official, employee, or agent of the state from preventing or attempting to prevent, solely because an investigational drug, product, or device has not been approved for general use by the FDA, an eligible patient or treating physician from accessing an investigational drug, product, or device in accordance with the bill.[27]

Assisted suicide not authorized

The bill provides that it does not condone, authorize, or approve of assisted suicide, or any action that is considered mercy killing or euthanasia.[28]

County home superintendent or administrator

Selection and appointment

The bill modifies a board of county commissioners' authority to appoint a county home superintendent or administrator. Current law requires a county board to appoint

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[24] R.C. 4729.89(C).

[25] R.C. 4731.97(G).

[26] R.C. 4731.97(F).

[27] R.C. 4731.97(E).

[28] R.C. 4731.97(H).

a county home superintendent. That superintendent is in the unclassified civil service and is authorized to use the title "administrator."[29]

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.[30] A superintendent or administrator selected pursuant to such a contract must be selected with the advice and consent of the county board and is not a public employee due to either the selection or the performance of the duties of the position.[31]

Appointing authority

The bill specifies which individual or entity serves as a county home's appointing authority (the appointing authority has the power of appointment to, and removal from, positions in the county home). If a county home superintendent or administrator is a public employee, then the superintendent or administrator is the county home's appointing authority.

If the superintendent or administrator is not a public employee, then the county board is the appointing authority for any public employees of the home; the superintendent or administrator may make recommendations to the county board regarding the employment or removal of any public employee of the county home. The bill specifies that the county board is not the appointing authority for any county home employee who is not a public employee.[32]

Continuing education for volunteer health care services

The bill permits certain health care professionals to satisfy a portion of their continuing education requirements by providing health care services without compensation to indigent and uninsured persons. Under the bill, a licensing agency that licenses health care professionals must apply toward the satisfaction of a licensee's continuing education requirements the provision of volunteer health care services if the following conditions are satisfied:

(1) The licensing agency requires licensees to complete continuing education as a condition of license renewal;

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[29] R.C. 5155.03(A) and (C).

[30] R.C. 5155.03(A)(2).

[31] R.C. 5155.012.

[32] R.C. 5155.01.

(2) The health services are provided to an indigent and uninsured person;

(3) The licensee provides the health services as a volunteer;

(4) The licensee satisfies the requirements to qualify for immunity from liability for providing volunteer health care services to indigent and uninsured persons;

(5) The health services provided are within the licensee's scope of authority.[33]

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. A licensing agency must permit licensees to earn continuing education at a rate of one credit hour for each sixty minutes spent providing volunteer health care services.[34]

The bill specifies that these continuing education requirements apply to the following licensing agencies:

State Dental Board	Board of Speech-language Pathology and Audiology
Board of Nursing	Ohio Occupational Therapy, Physical Therapy, and Athletic Trainers Board
State Board of Optometry	Counselor, Social Worker, and Marriage and Family Therapist Board
Ohio Optical Dispensers Board	Chemical Dependency Professionals Board
State Board of Pharmacy	Ohio Board of Dietetics
State Medical Board	Ohio Respiratory Care Board;
State Board of Psychology	State Board of Emergency Medical Services
State Chiropractic Board	State Board of Orthotics, Prosthetics, and Pedorthics
Hearing Aid Dealers and Fitters Licensing Board	Any other licensing agency that considers its licensees to be health care professionals.[35]

[33] R.C. 4745.04(B).

[34] R.C. 4745.04(C).

[35] R.C. 4745.04(A).

The bill requires these licensing agencies to adopt rules to implement the continuing education provisions.[36]

Continuing law gives health care professionals qualified immunity from liability for providing volunteer health care services to indigent and uninsured persons. To qualify as a volunteer, the health care professional must provide the services without receiving or expecting to receive any compensation or other form of remuneration.[37] The bill expressly states that receiving continuing education credit is not compensation or remuneration and does not make the health care professional ineligible for the immunity.[38]

COMMENT

Federal law provides that no person may introduce or deliver for introduction into interstate commerce any new drug that is not approved by the FDA;[39] however, there is a procedure under which the FDA on a case-by-case basis may permit drugs that are still in clinical trial to be provided to patients.[40] The bill attempts to create a broad exception to the federal law for Ohio patients with terminal conditions. In general, when state and federal law conflict, federal law will displace, or preempt, state law.[41]

HISTORY

ACTION	DATE
Introduced	07-16-15
Reported, H. Health & Aging	01-26-16
Passed House (96-1)	02-23-16
Reported, S. Health & Human Services	11-30-16

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[36] R.C. 4745.04(D).

[37] R.C. 2305.234, not in the bill.

[38] R.C. 4745.04(E).

[39] 21 United States Code 355(a).

[40] 21 Code of Federal Regulations 312.300.

[41] U.S. Constitution Article VI, section 2 (Supremacy Clause).