UPDATED VERSION*

OHIO LEGISLATIVE SERVICE COMMISSION

Final Analysis Matthew Magner

Sub. H.B. 290

131st General Assembly
(As Passed by the General Assembly)

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, Balderson, Beagle, Burke, Cafaro, Coley, Eklund, Faber, Gardner, Hite, Hughes, Jones, Jordan, LaRose, Lehner, Manning, Obhof, Oelslager, Patton, Peterson, Sawyer, Schiavoni, Seitz, Skindell, Thomas, Uecker

Effective date: April 6, 2017

ACT SUMMARY

Treatment with investigational drugs, products, and devices

- Permits the use of a drug, product, or device that is under clinical investigation, but has not been approved by the U.S. Food and Drug Administration (FDA), 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 act.
- 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, and provides qualified immunity to the manufacturer.
- Provides that the act does not require a health care insurer, government health care program, or any other entity that offers health care benefits to provide coverage for costs incurred from the use of an investigational drug, product, or device.

* This version updates the effective date.

- Prohibits a state official, employee, or agent from preventing or attempting to prevent an eligible patient or treating physician from accessing an investigational drug, product, or device in accordance with the act, solely because it is not FDA approved.

County home superintendent or administrator

- Permits a board of county commissioners to contract for selection by another entity of a county home superintendent or administrator.

- 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.

CONTENT AND OPERATION

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

The act permits an eligible patient who is suffering from a terminal condition to be treated with an investigational drug, product, or device. For this purpose, an "investigational drug, product, or device" is a drug, biological product, or medical device that has successfully completed the first phase of clinical trials required by the U.S. 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, such as heroin, for which there is no legal use).[1]

Eligibility for treatment

Terminal condition

To be eligible for treatment with an investigational drug, product, or device under the act, a patient must have a terminal condition, as determined by the treating physician and by one other physician who has examined the patient.[2] "Terminal condition" is any of the following conditions, if irreversible, incurable, and untreatable through a method of treatment approved by the FDA:

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

[2] 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 does not exceed 12 months.[3]

Eligible patient

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

(1) **Treatment options and risks considered** – The treating physician has determined that the patient 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 condition;

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

(3) **Physician documentation** – The treating physician documents in the patient's medical record that the preceding conditions have been met.[4]

Access to clinical trials

A patient who meets the requirements specified above is, nonetheless, not eligible if a clinical trial using the investigational drug, product, or device is actively being conducted within 100 miles of the patient's residence, unless the patient applied but was denied access to that clinical trial.[5]

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

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

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

Treating physician

The act authorizes only a treating physician to treat an eligible patient with an investigational drug, product, or device. The "treating physician" is the physician primarily responsible for providing medical care and treating an eligible patient's terminal condition. "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.[6]

The treating physician must be a physician who is authorized to practice medicine and surgery or osteopathic medicine and surgery in Ohio.[7]

Informed consent

To treat an eligible patient, the act requires the treating physician to secure the patient's informed consent in a signed statement. If the patient is a minor or lacks capacity to consent, informed consent must be obtained from a parent, guardian, or other person legally responsible for the patient.[8]

The consent form must be based on a template created by the State Medical Board. The template must be created as soon as practicable after the act's effective date, and the Board must make it available to physicians and hospitals.[9]

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;

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

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

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

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

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

(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.[10]

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.[11]

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.[12]

Qualified immunity for physicians

The act 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 act 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 act states that its provisions do not create a new cause of action or substantive legal right against a treating physician or hospital related to a physician's not recommending the use of an investigational drug, product, or device.[13]

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

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

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

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

The act also exempts a physician acting under it from a provision of law authorizing 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.[14]

Drug labeling

Continuing 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 rules and regulations. The act creates an exception to this requirement when an investigational drug, product, or device is provided in accordance with the act.[15]

Alternative medical treatments

The act provides that treatment with an investigational drug, product, or device does not constitute "alternative medical treatment" under continuing law that permits a physician to use alternative medical treatment that is complementary to or different from conventional medical care.[16]

Restrictions on possession, purchase, distribution, and sale

The act applies to investigational drugs and products provisions of continuing law that restrict the possession, purchase, distribution, and sale of dangerous drugs, which include prescription drugs and certain other drugs. Generally, under these provisions, a person must be licensed by the state to possess, purchase, distribute, or sell investigational drugs or products, unless an exception applies.[17]

Manufacturer provision of investigational drugs, products, and devices

The act authorizes, but specifies that it does not require,[18] 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

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

[15] R.C. 4729.291.

[16] R.C. 4731.227.

[17] R.C. 4729.51.

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

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.[19]

Qualified immunity for manufacturers and terminal distributors

The act 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 act is not liable for or subject to damages in a civil action or prosecution in a criminal proceeding for actions or omissions related to providing or distributing the drug, product, or device.[20]

Charges not covered by insurance or estate

The act 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.[21]

However, the act 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.[22]

State interference prohibited

The act 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 act.[23]

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

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

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

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

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

Assisted suicide not authorized

The act provides that it does not condone, authorize, or approve of assisted suicide, or any action that is considered mercy killing or euthanasia.[24]

County home superintendent or administrator

Selection and appointment

The act modifies a board of county commissioners' authority to appoint a county home superintendent or administrator. Prior law required a board of county commissioners to appoint a county home superintendent. The superintendent was in the unclassified civil service and was authorized to use the title "administrator."[25]

Under the act, 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.[26] A superintendent or administrator selected pursuant to such a contract must be selected with the advice and consent of the board of county commissioners and is not a public employee due to either the selection or the performance of the duties of the position.[27]

Appointing authority

The act specifies which individual or entity serves as a county home's appointing authority and 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, the superintendent or administrator is the county home's appointing authority. If not, the board of county commissioners is the appointing authority for any public employees of the home, but the superintendent or administrator may make recommendations regarding employment or removal of any public employee. The act specifies that the board of county commissioners is not the appointing authority for any county home employee who is not a public employee.[28]

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

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

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

[27] R.C. 5155.012.

[28] R.C. 5155.01.

Continuing education for volunteer health care services

The act 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 act, 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;

(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.[29]

Licensing agencies must permit licensees to satisfy up to one-third of their 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.[30]

The licensing agencies subject to the act are:

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

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

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

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.[31]

These licensing agencies must adopt rules to implement the continuing education provisions.[32]

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.[33] The act states that receiving continuing education credit is not compensation or remuneration and does not make the health care professional ineligible for the immunity.[34]

HISTORY

ACTION	DATE
Introduced	07-16-15
Reported, H. Health & Aging	01-26-16
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Reported, S. Health & Human Services	11-30-16
Passed Senate (31-0)	12-06-16
House concurred in Senate amendments (89-0)	12-08-16

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

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

[33] R.C. 2305.234, not in the act.

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