HB0496

LRB09907259JLK27363b

99TH GENERAL ASSEMBLY

State of Illinois

2015 and 2016

HB0496

by Rep. Daniel V. Beiser

SYNOPSIS AS INTRODUCED:

See Index

Creates the Right to Try Act. Provides that an eligible patient with a terminal illness who has considered all other treatment options approved by the United States Food and Drug Administration may acquire from a manufacturer an investigational drug, biological product, or device that has successfully completed Phase 1 of a clinical trial, but has not been approved for general use by the United States Food and Drug Administration. Provides that a manufacturer may, but is not required to, provide an investigational drug, biological product, or device to an eligible patient, either with or without receiving compensation. Provides that an accident and health insurer may, but is not required to, provide coverage for an eligible patient seeking such a drug, product, or device. Provides that an entity responsible for Medicare certification may not take action against a health care provider's Medicare certification based solely on the health care provider's recommendation that a patient have access to an investigational drug, biological product, or device. Defines required terms. Amends the Medical Practice Act of 1987. Provides that the Department of Financial and Professional Regulation may not revoke, suspend, place on probation, reprimand, refuse to issue or renew, or take any other disciplinary or non-disciplinary action against the license or permit of a physician to practice medicine based solely on the physician's recommendation to an eligible patient regarding, or prescription for, or treatment with an investigational drug, biological product, or device. Amends the Illinois Health Statistics Act. Requires the Department of Public Health to adopt rules for the collection certain types of data from patients under the Right to Try Act.

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FISCAL NOTE ACT
MAY APPLY

A BILL FOR

AN ACT concerning health.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 1. Short title. This Act may be cited as the Right to Try Act.

Section 5. Findings. The General Assembly finds that the process of approval for investigational drugs, biological products, and devices in the United States often takes many years, and a patient with a terminal illness does not have the luxury of waiting until such drug, product, or device receives final approval from the United States Food and Drug Administration. As a result, the standards of the United States Food and Drug Administration for the use of investigational drugs, biological products, and devices may deny the benefits of potentially life-saving treatments to terminally ill patients. A patient with a terminal illness has a fundamental right to attempt to preserve his or her own life by accessing investigational drugs, biological products, and devices. Whether to use available investigational drugs, biological products, and devices is a decision that rightfully should be made by the patient with a terminal illness in consultation with his or her physician and is not a decision to be made by the government.

Section 10. Definitions. As used in this Act:

"Eligible patient" means an individual who:

(1) has an terminal illness, attested to by the patient's treating physician;

(2) has considered all other treatment options currently approved by the United States Food and Drug Administration;

(3) has received a recommendation from his or her treating 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; and

(5) has documentation from his or her treating physician that he or she meets the requirements of this Act.

"Hospital" means a hospital licensed under the Hospital Licensing Act or a hospital organized under the University of Illinois Hospital Act.

"Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed Phase 1 of a clinical trial but has not yet been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug

Administration.

"Terminal illness" means a progressive disease or medical or surgical condition that entails significant functional impairment, that is not considered by a treating physician to be reversible even with administration of current available treatments approved by the United States Food and Drug Administration, and that, without life-sustaining procedures, will soon result in death.

"Written, informed consent" means a written document that is signed by the patient, parent (if the patient is a minor), legal guardian, or health care agent designated by the patient under Article IV of the Illinois Power of Attorney Act, and attested to by the patient's physician and a witness and that, at a minimum, includes all of the following:

(i) An explanation of the currently approved products and treatments for the disease or condition from which the patient suffers.

(ii) An attestation that the patient concurs with his or her physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life.

(iii) Clear identification of the specific proposed investigational drug, biological product, or device that the patient is seeking to use.

(iv) A description of the potentially best and worst outcomes of using the investigational drug, biological

product, or device and a realistic description of the most likely outcome. The description shall include the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment. The description shall be based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition.

(v) A statement that the patient's health plan or third-party administrator and provider are not obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device, unless they are specifically required to do so by law or contract.

(vi) A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the investigational drug, biological product, or device and that care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements.

(vii) A statement that the patient understands that he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device and that this liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the drug, biological product, or device states otherwise.

Section 15. Drug manufacturers; availability of investigational drugs, biological products, or devices.

(a) A manufacturer of an investigational drug, biological product, or device may make available and an eligible patient may request the manufacturer's investigational drug, biological product, or device under this Act. This Act does not require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient.

(b) A manufacturer may:

(1) provide an investigational drug, biological product, or device to an eligible patient without receiving compensation; or

(2) require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device.

Section 20. Coverage; costs; services.

(a) This Act does not expand the coverage required of an accident and health insurer under the Illinois Insurance Code.

(b) A health plan, third-party administrator, or governmental agency may, but is not required to, provide coverage for the cost of an investigational drug, biological product, or device, or the cost of services related to the use of an investigational drug, biological product, or device under this Act.

(c) This Act does not require any governmental agency to pay costs associated with the use, care, or treatment of a patient with an investigational drug, biological product, or device.

(d) This Act does not require a hospital to provide new or additional services, unless approved by the hospital or facility.

Section 25. Death; outstanding debt. If a patient dies while being treated with an investigational drug, biological product, or device, the patient's heirs are not liable for any outstanding debt related to the treatment or lack of insurance due to the treatment.

Section 30. Action against Medicare certification. An entity responsible for Medicare certification may not take action against a health care provider's Medicare certification based solely on the health care provider's recommendation that a patient have access to an investigational drug, biological product, or device.

Section 35. Access; counseling. An official, employee, or agent of this State may not block or attempt to block an eligible patient's access to an investigational drug, biological product, or device. Counseling, advice, or a recommendation consistent with medical standards of care from a

licensed health care provider is not a violation of this Act.

Section 40. No private cause of action; health care coverage.

(a) This Act does not create a private cause of action against a manufacturer of an investigational drug, biological product, or device or against any other person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device for any harm done to the eligible patient resulting from the investigational drug, biological product, or device, if the manufacturer or other person or entity is complying in good faith with the terms of this Act and has exercised reasonable care.

(b) This Act does not affect any mandatory health care coverage for participation in clinical trials under the Illinois Insurance Code.

Section 90. The Medical Practice Act of 1987 is amended by changing Section 22 as follows:

(225 ILCS 60/22) (from Ch. 111, par. 4400-22)

(Section scheduled to be repealed on December 31, 2015)

Sec. 22. Disciplinary action.

(A) The Department may revoke, suspend, place on probation, reprimand, refuse to issue or renew, or take any other

disciplinary or non-disciplinary action as the Department may deem proper with regard to the license or permit of any person issued under this Act, including imposing fines not to exceed $10,000 for each violation, upon any of the following grounds:

(1) Performance of an elective abortion in any place, locale, facility, or institution other than:

(a) a facility licensed pursuant to the Ambulatory Surgical Treatment Center Act;

(b) an institution licensed under the Hospital Licensing Act;

(c) an ambulatory surgical treatment center or hospitalization or care facility maintained by the State or any agency thereof, where such department or agency has authority under law to establish and enforce standards for the ambulatory surgical treatment centers, hospitalization, or care facilities under its management and control;

(d) ambulatory surgical treatment centers, hospitalization or care facilities maintained by the Federal Government; or

(e) ambulatory surgical treatment centers, hospitalization or care facilities maintained by any university or college established under the laws of this State and supported principally by public funds raised by taxation.

(2) Performance of an abortion procedure in a wilful

and wanton manner on a woman who was not pregnant at the time the abortion procedure was performed.

(3) A plea of guilty or nolo contendere, finding of guilt, jury verdict, or entry of judgment or sentencing, including, but not limited to, convictions, preceding sentences of supervision, conditional discharge, or first offender probation, under the laws of any jurisdiction of the United States of any crime that is a felony.

(4) Gross negligence in practice under this Act.

(5) Engaging in dishonorable, unethical or unprofessional conduct of a character likely to deceive, defraud or harm the public.

(6) Obtaining any fee by fraud, deceit, or misrepresentation.

(7) Habitual or excessive use or abuse of drugs defined in law as controlled substances, of alcohol, or of any other substances which results in the inability to practice with reasonable judgment, skill or safety.

(8) Practicing under a false or, except as provided by law, an assumed name.

(9) Fraud or misrepresentation in applying for, or procuring, a license under this Act or in connection with applying for renewal of a license under this Act.

(10) Making a false or misleading statement regarding their skill or the efficacy or value of the medicine, treatment, or remedy prescribed by them at their direction

in the treatment of any disease or other condition of the body or mind.

(11) Allowing another person or organization to use their license, procured under this Act, to practice.

(12) Adverse action taken by another state or jurisdiction against a license or other authorization to practice as a medical doctor, doctor of osteopathy, doctor of osteopathic medicine or doctor of chiropractic, a certified copy of the record of the action taken by the other state or jurisdiction being prima facie evidence thereof. This includes any adverse action taken by a State or federal agency that prohibits a medical doctor, doctor of osteopathy, doctor of osteopathic medicine, or doctor of chiropractic from providing services to the agency's participants.

(13) Violation of any provision of this Act or of the Medical Practice Act prior to the repeal of that Act, or violation of the rules, or a final administrative action of the Secretary, after consideration of the recommendation of the Disciplinary Board.

(14) Violation of the prohibition against fee splitting in Section 22.2 of this Act.

(15) A finding by the Disciplinary Board that the registrant after having his or her license placed on probationary status or subjected to conditions or restrictions violated the terms of the probation or failed

to comply with such terms or conditions.

(16) Abandonment of a patient.

(17) Prescribing, selling, administering, distributing, giving or self-administering any drug classified as a controlled substance (designated product) or narcotic for other than medically accepted therapeutic purposes.

(18) Promotion of the sale of drugs, devices, appliances or goods provided for a patient in such manner as to exploit the patient for financial gain of the physician.

(19) Offering, undertaking or agreeing to cure or treat disease by a secret method, procedure, treatment or medicine, or the treating, operating or prescribing for any human condition by a method, means or procedure which the licensee refuses to divulge upon demand of the Department.

(20) Immoral conduct in the commission of any act including, but not limited to, commission of an act of sexual misconduct related to the licensee's practice.

(21) Wilfully making or filing false records or reports in his or her practice as a physician, including, but not limited to, false records to support claims against the medical assistance program of the Department of Healthcare and Family Services (formerly Department of Public Aid) under the Illinois Public Aid Code.

(22) Wilful omission to file or record, or wilfully

impeding the filing or recording, or inducing another person to omit to file or record, medical reports as required by law, or wilfully failing to report an instance of suspected abuse or neglect as required by law.

(23) Being named as a perpetrator in an indicated report by the Department of Children and Family Services under the Abused and Neglected Child Reporting Act, and upon proof by clear and convincing evidence that the licensee has caused a child to be an abused child or neglected child as defined in the Abused and Neglected Child Reporting Act.

(24) Solicitation of professional patronage by any corporation, agents or persons, or profiting from those representing themselves to be agents of the licensee.

(25) Gross and wilful and continued overcharging for professional services, including filing false statements for collection of fees for which services are not rendered, including, but not limited to, filing such false statements for collection of monies for services not rendered from the medical assistance program of the Department of Healthcare and Family Services (formerly Department of Public Aid) under the Illinois Public Aid Code.

(26) A pattern of practice or other behavior which demonstrates incapacity or incompetence to practice under this Act.

(27) Mental illness or disability which results in the

inability to practice under this Act with reasonable judgment, skill or safety.

(28) Physical illness, including, but not limited to, deterioration through the aging process, or loss of motor skill which results in a physician's inability to practice under this Act with reasonable judgment, skill or safety.

(29) Cheating on or attempt to subvert the licensing examinations administered under this Act.

(30) Wilfully or negligently violating the confidentiality between physician and patient except as required by law.

(31) The use of any false, fraudulent, or deceptive statement in any document connected with practice under this Act.

(32) Aiding and abetting an individual not licensed under this Act in the practice of a profession licensed under this Act.

(33) Violating state or federal laws or regulations relating to controlled substances, legend drugs, or ephedra as defined in the Ephedra Prohibition Act.

(34) Failure to report to the Department any adverse final action taken against them by another licensing jurisdiction (any other state or any territory of the United States or any foreign state or country), by any peer review body, by any health care institution, by any professional society or association related to practice

under this Act, by any governmental agency, by any law enforcement agency, or by any court for acts or conduct similar to acts or conduct which would constitute grounds for action as defined in this Section.

(35) Failure to report to the Department surrender of a license or authorization to practice as a medical doctor, a doctor of osteopathy, a doctor of osteopathic medicine, or doctor of chiropractic in another state or jurisdiction, or surrender of membership on any medical staff or in any medical or professional association or society, while under disciplinary investigation by any of those authorities or bodies, for acts or conduct similar to acts or conduct which would constitute grounds for action as defined in this Section.

(36) Failure to report to the Department any adverse judgment, settlement, or award arising from a liability claim related to acts or conduct similar to acts or conduct which would constitute grounds for action as defined in this Section.

(37) Failure to provide copies of medical records as required by law.

(38) Failure to furnish the Department, its investigators or representatives, relevant information, legally requested by the Department after consultation with the Chief Medical Coordinator or the Deputy Medical Coordinator.

(39) Violating the Health Care Worker Self-Referral Act.

(40) Willful failure to provide notice when notice is required under the Parental Notice of Abortion Act of 1995.

(41) Failure to establish and maintain records of patient care and treatment as required by this law.

(42) Entering into an excessive number of written collaborative agreements with licensed advanced practice nurses resulting in an inability to adequately collaborate.

(43) Repeated failure to adequately collaborate with a licensed advanced practice nurse.

(44) Violating the Compassionate Use of Medical Cannabis Pilot Program Act.

(45) Entering into an excessive number of written collaborative agreements with licensed prescribing psychologists resulting in an inability to adequately collaborate.

(46) Repeated failure to adequately collaborate with a licensed prescribing psychologist.

Except for actions involving the ground numbered (26), all proceedings to suspend, revoke, place on probationary status, or take any other disciplinary action as the Department may deem proper, with regard to a license on any of the foregoing grounds, must be commenced within 5 years next after receipt by the Department of a complaint alleging the commission of or

notice of the conviction order for any of the acts described herein. Except for the grounds numbered (8), (9), (26), and (29), no action shall be commenced more than 10 years after the date of the incident or act alleged to have violated this Section. For actions involving the ground numbered (26), a pattern of practice or other behavior includes all incidents alleged to be part of the pattern of practice or other behavior that occurred, or a report pursuant to Section 23 of this Act received, within the 10-year period preceding the filing of the complaint. In the event of the settlement of any claim or cause of action in favor of the claimant or the reduction to final judgment of any civil action in favor of the plaintiff, such claim, cause of action or civil action being grounded on the allegation that a person licensed under this Act was negligent in providing care, the Department shall have an additional period of 2 years from the date of notification to the Department under Section 23 of this Act of such settlement or final judgment in which to investigate and commence formal disciplinary proceedings under Section 36 of this Act, except as otherwise provided by law. The time during which the holder of the license was outside the State of Illinois shall not be included within any period of time limiting the commencement of disciplinary action by the Department.

The entry of an order or judgment by any circuit court establishing that any person holding a license under this Act is a person in need of mental treatment operates as a

suspension of that license. That person may resume their practice only upon the entry of a Departmental order based upon a finding by the Disciplinary Board that they have been determined to be recovered from mental illness by the court and upon the Disciplinary Board's recommendation that they be permitted to resume their practice.

The Department may refuse to issue or take disciplinary action concerning the license of any person who fails to file a return, or to pay the tax, penalty or interest shown in a filed return, or to pay any final assessment of tax, penalty or interest, as required by any tax Act administered by the Illinois Department of Revenue, until such time as the requirements of any such tax Act are satisfied as determined by the Illinois Department of Revenue.

The Department, upon the recommendation of the Disciplinary Board, shall adopt rules which set forth standards to be used in determining:

(a) when a person will be deemed sufficiently rehabilitated to warrant the public trust;

(b) what constitutes dishonorable, unethical or unprofessional conduct of a character likely to deceive, defraud, or harm the public;

(c) what constitutes immoral conduct in the commission of any act, including, but not limited to, commission of an act of sexual misconduct related to the licensee's practice; and

(d) what constitutes gross negligence in the practice of medicine.

However, no such rule shall be admissible into evidence in any civil action except for review of a licensing or other disciplinary action under this Act.

In enforcing this Section, the Disciplinary Board or the Licensing Board, upon a showing of a possible violation, may compel, in the case of the Disciplinary Board, any individual who is licensed to practice under this Act or holds a permit to practice under this Act, or, in the case of the Licensing Board, any individual who has applied for licensure or a permit pursuant to this Act, to submit to a mental or physical examination and evaluation, or both, which may include a substance abuse or sexual offender evaluation, as required by the Licensing Board or Disciplinary Board and at the expense of the Department. The Disciplinary Board or Licensing Board shall specifically designate the examining physician licensed to practice medicine in all of its branches or, if applicable, the multidisciplinary team involved in providing the mental or physical examination and evaluation, or both. The multidisciplinary team shall be led by a physician licensed to practice medicine in all of its branches and may consist of one or more or a combination of physicians licensed to practice medicine in all of its branches, licensed chiropractic physicians, licensed clinical psychologists, licensed clinical social workers, licensed clinical professional counselors, and

other professional and administrative staff. Any examining physician or member of the multidisciplinary team may require any person ordered to submit to an examination and evaluation pursuant to this Section to submit to any additional supplemental testing deemed necessary to complete any examination or evaluation process, including, but not limited to, blood testing, urinalysis, psychological testing, or neuropsychological testing. The Disciplinary Board, the Licensing Board, or the Department may order the examining physician or any member of the multidisciplinary team to provide to the Department, the Disciplinary Board, or the Licensing Board any and all records, including business records, that relate to the examination and evaluation, including any supplemental testing performed. The Disciplinary Board, the Licensing Board, or the Department may order the examining physician or any member of the multidisciplinary team to present testimony concerning this examination and evaluation of the licensee, permit holder, or applicant, including testimony concerning any supplemental testing or documents relating to the examination and evaluation. No information, report, record, or other documents in any way related to the examination and evaluation shall be excluded by reason of any common law or statutory privilege relating to communication between the licensee, permit holder, or applicant and the examining physician or any member of the multidisciplinary team. No authorization is necessary from the

licensee, permit holder, or applicant ordered to undergo an evaluation and examination for the examining physician or any member of the multidisciplinary team to provide information, reports, records, or other documents or to provide any testimony regarding the examination and evaluation. The individual to be examined may have, at his or her own expense, another physician of his or her choice present during all aspects of the examination. Failure of any individual to submit to mental or physical examination and evaluation, or both, when directed, shall result in an automatic suspension, without hearing, until such time as the individual submits to the examination. If the Disciplinary Board or Licensing Board finds a physician unable to practice following an examination and evaluation because of the reasons set forth in this Section, the Disciplinary Board or Licensing Board shall require such physician to submit to care, counseling, or treatment by physicians, or other health care professionals, approved or designated by the Disciplinary Board, as a condition for issued, continued, reinstated, or renewed licensure to practice. Any physician, whose license was granted pursuant to Sections 9, 17, or 19 of this Act, or, continued, reinstated, renewed, disciplined or supervised, subject to such terms, conditions or restrictions who shall fail to comply with such terms, conditions or restrictions, or to complete a required program of care, counseling, or treatment, as determined by the Chief Medical Coordinator or Deputy Medical Coordinators,

shall be referred to the Secretary for a determination as to whether the licensee shall have their license suspended immediately, pending a hearing by the Disciplinary Board. In instances in which the Secretary immediately suspends a license under this Section, a hearing upon such person's license must be convened by the Disciplinary Board within 15 days after such suspension and completed without appreciable delay. The Disciplinary Board shall have the authority to review the subject physician's record of treatment and counseling regarding the impairment, to the extent permitted by applicable federal statutes and regulations safeguarding the confidentiality of medical records.

An individual licensed under this Act, affected under this Section, shall be afforded an opportunity to demonstrate to the Disciplinary Board that they can resume practice in compliance with acceptable and prevailing standards under the provisions of their license.

The Department may promulgate rules for the imposition of fines in disciplinary cases, not to exceed $10,000 for each violation of this Act. Fines may be imposed in conjunction with other forms of disciplinary action, but shall not be the exclusive disposition of any disciplinary action arising out of conduct resulting in death or injury to a patient. Any funds collected from such fines shall be deposited in the Medical Disciplinary Fund.

All fines imposed under this Section shall be paid within

60 days after the effective date of the order imposing the fine or in accordance with the terms set forth in the order imposing the fine.

(B) The Department shall revoke the license or permit issued under this Act to practice medicine or a chiropractic physician who has been convicted a second time of committing any felony under the Illinois Controlled Substances Act or the Methamphetamine Control and Community Protection Act, or who has been convicted a second time of committing a Class 1 felony under Sections 8A-3 and 8A-6 of the Illinois Public Aid Code. A person whose license or permit is revoked under this subsection B shall be prohibited from practicing medicine or treating human ailments without the use of drugs and without operative surgery.

(C) The Department shall not revoke, suspend, place on probation, reprimand, refuse to issue or renew, or take any other disciplinary or non-disciplinary action against the license or permit issued under this Act to practice medicine to a physician based solely upon the recommendation of the physician to an eligible patient regarding, or prescription for, or treatment with, an investigational drug, biological product, or device.

(D) ~~(C)~~ The Disciplinary Board shall recommend to the Department civil penalties and any other appropriate discipline in disciplinary cases when the Board finds that a physician willfully performed an abortion with actual

knowledge that the person upon whom the abortion has been performed is a minor or an incompetent person without notice as required under the Parental Notice of Abortion Act of 1995. Upon the Board's recommendation, the Department shall impose, for the first violation, a civil penalty of $1,000 and for a second or subsequent violation, a civil penalty of $5,000. (Source: P.A. 97-622, eff. 11-23-11; 98-601, eff. 12-30-13; 98-668, eff. 6-25-14; 98-1140, eff. 12-30-14.)

Section 95. The Illinois Health Statistics Act is amended by adding Section 4.5 as follows:

(410 ILCS 520/4.5 new)

Sec. 4.5. Health and drug data under the Right to Try Act. The Department shall adopt rules for the collection, recording, storage, and protection of health and drug data for any patient receiving an investigational drug, biological product, or device under the Right to Try Act. The Department shall make this information available:

(1) for use by patients, treating physicians, medical researchers, drug manufacturers, and the United States Food and Drug Administration;

(2) in a manner consistent with any United States Food and Drug Administration requirements; and

(3) in a manner that is relevant to the requirements and needs for on-going controlled clinical trials and

clinical researchers of the investigational drugs, biological products, or devices prescribed under the Right to Try Act.

The Department shall also adopt rules regarding permissible releases of health and drug information collected under this Section to the United States Food and Drug Administration and the sponsor of the controlled clinical trial testing the investigational drug, biological product, or device.

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Statutes amended in order of appearance

New Act

225 ILCS 60/22 from Ch. 111, par. 4400-22

410 ILCS 520/4.5 new