

SB0029



99TH GENERAL ASSEMBLY

State of Illinois

2015 and 2016

SB0029

Introduced 1/15/2015, by Sen. Michael Connelly

SYNOPSIS AS INTRODUCED:

New Act
225 ILCS 60/22

from Ch. 111, par. 4400-22

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 I 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. Contains a penalty provision. Defines required terms. Contains legislative findings. 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.

LRB099 02785 JLK 22793 b

CORRECTIONAL
BUDGET AND
IMPACT NOTE ACT
MAY APPLY

FISCAL NOTE ACT
MAY APPLY

A BILL FOR

1 AN ACT concerning health.

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

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

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

1 Section 10. Definitions. For the purposes of this Act:

2 "Accident and health insurer" has the meaning given to that
3 term in Section 126.2 of the Illinois Insurance Code.

4 "Eligible patient" means a person who:

5 (1) has a terminal illness;

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

8 (3) has received a prescription or recommendation from
9 his or her physician for an investigational drug,
10 biological product, or device;

11 (4) has given his or her informed consent in writing
12 for the use of the investigational drug, biological
13 product, or device or, if he or she is a minor or lacks the
14 mental capacity to provide informed consent, a parent or
15 legal guardian has given informed consent on his or her
16 behalf; and

17 (5) has documentation from his or her physician
18 indicating that he or she has met the requirements of this
19 Act.

20 "Investigational drug, biological product, or device"
21 means a drug, biological product, or device that has
22 successfully completed Phase I of a clinical trial, but has not
23 been approved for general use by the United States Food and
24 Drug Administration.

25 "Phase I of a clinical trial" means the stage of a clinical

1 trial where an investigational drug, biological product, or
2 device that has been tested in a small group for the first time
3 to evaluate its safety, determine a safe dosage range, and
4 identify side effects.

5 "Terminal illness" means a disease that, without
6 life-sustaining measures, can reasonably be expected to result
7 in death in 24 months or less.

8 Section 15. Availability of drugs, biological products,
9 and devices.

10 (a) A manufacturer of an investigational drug, biological
11 product, or device may make available such drug, product, or
12 device to eligible patients. Nothing in this Act shall be
13 construed to require a manufacturer to make available any drug,
14 product, or device.

15 (b) A manufacturer may:

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

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

22 Section 20. Insurance coverage. An accident and health
23 insurer may choose to provide coverage for the cost of an
24 investigational drug, biological product, or device. Nothing

1 in this Act shall be construed to require an accident and
2 health insurer to provide coverage for the cost of any
3 investigational drug, biological product, or device.

4 Section 25. Penalty. Any official, employee, or agent of
5 the State who blocks or attempts to block access by an eligible
6 patient to an investigational drug, biological product, or
7 device shall be guilty of a misdemeanor, punishable by a fine
8 not to exceed \$1,500.

9 Section 30. The Medical Practice Act of 1987 is amended by
10 changing Section 22 as follows:

11 (225 ILCS 60/22) (from Ch. 111, par. 4400-22)

12 (Section scheduled to be repealed on December 31, 2014)

13 Sec. 22. Disciplinary action.

14 (A) The Department may revoke, suspend, place on probation,
15 reprimand, refuse to issue or renew, or take any other
16 disciplinary or non-disciplinary action as the Department may
17 deem proper with regard to the license or permit of any person
18 issued under this Act to practice medicine, or a chiropractic
19 physician, including imposing fines not to exceed \$10,000 for
20 each violation, upon any of the following grounds:

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

23 (a) a facility licensed pursuant to the Ambulatory

1 Surgical Treatment Center Act;

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

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

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

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

19 (2) Performance of an abortion procedure in a wilful
20 and wanton manner on a woman who was not pregnant at the
21 time the abortion procedure was performed.

22 (3) A plea of guilty or nolo contendere, finding of
23 guilt, jury verdict, or entry of judgment or sentencing,
24 including, but not limited to, convictions, preceding
25 sentences of supervision, conditional discharge, or first
26 offender probation, under the laws of any jurisdiction of

1 the United States of any crime that is a felony.

2 (4) Gross negligence in practice under this Act.

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

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

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

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

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

17 (10) Making a false or misleading statement regarding
18 their skill or the efficacy or value of the medicine,
19 treatment, or remedy prescribed by them at their direction
20 in the treatment of any disease or other condition of the
21 body or mind.

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

24 (12) Disciplinary action of another state or
25 jurisdiction against a license or other authorization to
26 practice as a medical doctor, doctor of osteopathy, doctor

1 of osteopathic medicine or doctor of chiropractic, a
2 certified copy of the record of the action taken by the
3 other state or jurisdiction being prima facie evidence
4 thereof.

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

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

12 (15) A finding by the Disciplinary Board that the
13 registrant after having his or her license placed on
14 probationary status or subjected to conditions or
15 restrictions violated the terms of the probation or failed
16 to comply with such terms or conditions.

17 (16) Abandonment of a patient.

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

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

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

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

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

15 (22) Wilful omission to file or record, or wilfully
16 impeding the filing or recording, or inducing another
17 person to omit to file or record, medical reports as
18 required by law, or wilfully failing to report an instance
19 of suspected abuse or neglect as required by law.

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

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

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

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

15 (27) Mental illness or disability which results in the
16 inability to practice under this Act with reasonable
17 judgment, skill or safety.

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

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

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

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

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

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

10 (34) Failure to report to the Department any adverse
11 final action taken against them by another licensing
12 jurisdiction (any other state or any territory of the
13 United States or any foreign state or country), by any peer
14 review body, by any health care institution, by any
15 professional society or association related to practice
16 under this Act, by any governmental agency, by any law
17 enforcement agency, or by any court for acts or conduct
18 similar to acts or conduct which would constitute grounds
19 for action as defined in this Section.

20 (35) Failure to report to the Department surrender of a
21 license or authorization to practice as a medical doctor, a
22 doctor of osteopathy, a doctor of osteopathic medicine, or
23 doctor of chiropractic in another state or jurisdiction, or
24 surrender of membership on any medical staff or in any
25 medical or professional association or society, while
26 under disciplinary investigation by any of those

1 authorities or bodies, for acts or conduct similar to acts
2 or conduct which would constitute grounds for action as
3 defined in this Section.

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

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

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

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

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

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

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

26 (43) Repeated failure to adequately collaborate with a

1 licensed advanced practice nurse.

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

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

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

10 Except for actions involving the ground numbered (26), all
11 proceedings to suspend, revoke, place on probationary status,
12 or take any other disciplinary action as the Department may
13 deem proper, with regard to a license on any of the foregoing
14 grounds, must be commenced within 5 years next after receipt by
15 the Department of a complaint alleging the commission of or
16 notice of the conviction order for any of the acts described
17 herein. Except for the grounds numbered (8), (9), (26), and
18 (29), no action shall be commenced more than 10 years after the
19 date of the incident or act alleged to have violated this
20 Section. For actions involving the ground numbered (26), a
21 pattern of practice or other behavior includes all incidents
22 alleged to be part of the pattern of practice or other behavior
23 that occurred, or a report pursuant to Section 23 of this Act
24 received, within the 10-year period preceding the filing of the
25 complaint. In the event of the settlement of any claim or cause
26 of action in favor of the claimant or the reduction to final

1 judgment of any civil action in favor of the plaintiff, such
2 claim, cause of action or civil action being grounded on the
3 allegation that a person licensed under this Act was negligent
4 in providing care, the Department shall have an additional
5 period of 2 years from the date of notification to the
6 Department under Section 23 of this Act of such settlement or
7 final judgment in which to investigate and commence formal
8 disciplinary proceedings under Section 36 of this Act, except
9 as otherwise provided by law. The time during which the holder
10 of the license was outside the State of Illinois shall not be
11 included within any period of time limiting the commencement of
12 disciplinary action by the Department.

13 The entry of an order or judgment by any circuit court
14 establishing that any person holding a license under this Act
15 is a person in need of mental treatment operates as a
16 suspension of that license. That person may resume their
17 practice only upon the entry of a Departmental order based upon
18 a finding by the Disciplinary Board that they have been
19 determined to be recovered from mental illness by the court and
20 upon the Disciplinary Board's recommendation that they be
21 permitted to resume their practice.

22 The Department may refuse to issue or take disciplinary
23 action concerning the license of any person who fails to file a
24 return, or to pay the tax, penalty or interest shown in a filed
25 return, or to pay any final assessment of tax, penalty or
26 interest, as required by any tax Act administered by the

1 Illinois Department of Revenue, until such time as the
2 requirements of any such tax Act are satisfied as determined by
3 the Illinois Department of Revenue.

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

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

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

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

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

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

21 In enforcing this Section, the Disciplinary Board or the
22 Licensing Board, upon a showing of a possible violation, may
23 compel, in the case of the Disciplinary Board, any individual
24 who is licensed to practice under this Act or holds a permit to
25 practice under this Act, or, in the case of the Licensing
26 Board, any individual who has applied for licensure or a permit

1 pursuant to this Act, to submit to a mental or physical
2 examination and evaluation, or both, which may include a
3 substance abuse or sexual offender evaluation, as required by
4 the Licensing Board or Disciplinary Board and at the expense of
5 the Department. The Disciplinary Board or Licensing Board shall
6 specifically designate the examining physician licensed to
7 practice medicine in all of its branches or, if applicable, the
8 multidisciplinary team involved in providing the mental or
9 physical examination and evaluation, or both. The
10 multidisciplinary team shall be led by a physician licensed to
11 practice medicine in all of its branches and may consist of one
12 or more or a combination of physicians licensed to practice
13 medicine in all of its branches, licensed chiropractic
14 physicians, licensed clinical psychologists, licensed clinical
15 social workers, licensed clinical professional counselors, and
16 other professional and administrative staff. Any examining
17 physician or member of the multidisciplinary team may require
18 any person ordered to submit to an examination and evaluation
19 pursuant to this Section to submit to any additional
20 supplemental testing deemed necessary to complete any
21 examination or evaluation process, including, but not limited
22 to, blood testing, urinalysis, psychological testing, or
23 neuropsychological testing. The Disciplinary Board, the
24 Licensing Board, or the Department may order the examining
25 physician or any member of the multidisciplinary team to
26 provide to the Department, the Disciplinary Board, or the

1 Licensing Board any and all records, including business
2 records, that relate to the examination and evaluation,
3 including any supplemental testing performed. The Disciplinary
4 Board, the Licensing Board, or the Department may order the
5 examining physician or any member of the multidisciplinary team
6 to present testimony concerning this examination and
7 evaluation of the licensee, permit holder, or applicant,
8 including testimony concerning any supplemental testing or
9 documents relating to the examination and evaluation. No
10 information, report, record, or other documents in any way
11 related to the examination and evaluation shall be excluded by
12 reason of any common law or statutory privilege relating to
13 communication between the licensee or applicant and the
14 examining physician or any member of the multidisciplinary
15 team. No authorization is necessary from the licensee, permit
16 holder, or applicant ordered to undergo an evaluation and
17 examination for the examining physician or any member of the
18 multidisciplinary team to provide information, reports,
19 records, or other documents or to provide any testimony
20 regarding the examination and evaluation. The individual to be
21 examined may have, at his or her own expense, another physician
22 of his or her choice present during all aspects of the
23 examination. Failure of any individual to submit to mental or
24 physical examination and evaluation, or both, when directed,
25 shall result in an automatic suspension, without hearing, until
26 such time as the individual submits to the examination. If the

1 Disciplinary Board finds a physician unable to practice because
2 of the reasons set forth in this Section, the Disciplinary
3 Board shall require such physician to submit to care,
4 counseling, or treatment by physicians approved or designated
5 by the Disciplinary Board, as a condition for continued,
6 reinstated, or renewed licensure to practice. Any physician,
7 whose license was granted pursuant to Sections 9, 17, or 19 of
8 this Act, or, continued, reinstated, renewed, disciplined or
9 supervised, subject to such terms, conditions or restrictions
10 who shall fail to comply with such terms, conditions or
11 restrictions, or to complete a required program of care,
12 counseling, or treatment, as determined by the Chief Medical
13 Coordinator or Deputy Medical Coordinators, shall be referred
14 to the Secretary for a determination as to whether the licensee
15 shall have their license suspended immediately, pending a
16 hearing by the Disciplinary Board. In instances in which the
17 Secretary immediately suspends a license under this Section, a
18 hearing upon such person's license must be convened by the
19 Disciplinary Board within 15 days after such suspension and
20 completed without appreciable delay. The Disciplinary Board
21 shall have the authority to review the subject physician's
22 record of treatment and counseling regarding the impairment, to
23 the extent permitted by applicable federal statutes and
24 regulations safeguarding the confidentiality of medical
25 records.

26 An individual licensed under this Act, affected under this

1 Section, shall be afforded an opportunity to demonstrate to the
2 Disciplinary Board that they can resume practice in compliance
3 with acceptable and prevailing standards under the provisions
4 of their license.

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

13 All fines imposed under this Section shall be paid within
14 60 days after the effective date of the order imposing the fine
15 or in accordance with the terms set forth in the order imposing
16 the fine.

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

1 surgery.

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

10 (D) ~~(C)~~ The Disciplinary Board shall recommend to the
11 Department civil penalties and any other appropriate
12 discipline in disciplinary cases when the Board finds that a
13 physician willfully performed an abortion with actual
14 knowledge that the person upon whom the abortion has been
15 performed is a minor or an incompetent person without notice as
16 required under the Parental Notice of Abortion Act of 1995.
17 Upon the Board's recommendation, the Department shall impose,
18 for the first violation, a civil penalty of \$1,000 and for a
19 second or subsequent violation, a civil penalty of \$5,000.

20 (Source: P.A. 97-622, eff. 11-23-11; 98-601, eff. 12-30-13;
21 98-668, eff. 6-25-14.)