



## 99TH GENERAL ASSEMBLY

### State of Illinois

2015 and 2016

HB1335

Introduced 2/4/2015, by Rep. Greg Harris

#### 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 08955 JLK 29128 b

CORRECTIONAL  
BUDGET AND  
IMPACT NOTE ACT  
MAY APPLY

FISCAL NOTE ACT  
MAY APPLY

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, 2015)

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, including imposing fines not to exceed  
19 \$10,000 for each violation, upon any of the following grounds:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 (12) Adverse action taken by another state or  
24 jurisdiction against a license or other authorization to  
25 practice as a medical doctor, doctor of osteopathy, doctor  
26 of osteopathic medicine or doctor of chiropractic, a

1 certified copy of the record of the action taken by the  
2 other state or jurisdiction being prima facie evidence  
3 thereof. This includes any adverse action taken by a State  
4 or federal agency that prohibits a medical doctor, doctor  
5 of osteopathy, doctor of osteopathic medicine, or doctor of  
6 chiropractic from providing services to the agency's  
7 participants.

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

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

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

20 (16) Abandonment of a patient.

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

26 (18) Promotion of the sale of drugs, devices,



1 appliances or goods provided for a patient in such manner  
2 as to exploit the patient for financial gain of the  
3 physician.

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

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

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

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

23 (23) Being named as a perpetrator in an indicated  
24 report by the Department of Children and Family Services  
25 under the Abused and Neglected Child Reporting Act, and  
26 upon proof by clear and convincing evidence that the

1 licensee has caused a child to be an abused child or  
2 neglected child as defined in the Abused and Neglected  
3 Child Reporting Act.

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

7 (25) Gross and wilful and continued overcharging for  
8 professional services, including filing false statements  
9 for collection of fees for which services are not rendered,  
10 including, but not limited to, filing such false statements  
11 for collection of monies for services not rendered from 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 (26) A pattern of practice or other behavior which  
16 demonstrates incapacity or incompetence to practice under  
17 this Act.

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

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

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

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

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

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

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

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

23          (35) Failure to report to the Department surrender of a  
24 license or authorization to practice as a medical doctor, a  
25 doctor of osteopathy, a doctor of osteopathic medicine, or  
26 doctor of chiropractic in another state or jurisdiction, or

1 surrender of membership on any medical staff or in any  
2 medical or professional association or society, while  
3 under disciplinary investigation by any of those  
4 authorities or bodies, for acts or conduct similar to acts  
5 or conduct which would constitute grounds for action as  
6 defined in this Section.

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

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

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

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

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

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

25 (42) Entering into an excessive number of written  
26 collaborative agreements with licensed advanced practice

1 nurses resulting in an inability to adequately  
2 collaborate.

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

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

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

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

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

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

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

25 The Department may refuse to issue or take disciplinary  
26 action concerning the license of any person who fails to file a

1 return, or to pay the tax, penalty or interest shown in a filed  
2 return, or to pay any final assessment of tax, penalty or  
3 interest, as required by any tax Act administered by the  
4 Illinois Department of Revenue, until such time as the  
5 requirements of any such tax Act are satisfied as determined by  
6 the Illinois Department of Revenue.

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

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

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

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

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

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

24 In enforcing this Section, the Disciplinary Board or the  
25 Licensing Board, upon a showing of a possible violation, may  
26 compel, in the case of the Disciplinary Board, any individual

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



1 Licensing Board, or the Department may order the examining  
2 physician or any member of the multidisciplinary team to  
3 provide to the Department, the Disciplinary Board, or the  
4 Licensing Board any and all records, including business  
5 records, that relate to the examination and evaluation,  
6 including any supplemental testing performed. The Disciplinary  
7 Board, the Licensing Board, or the Department may order the  
8 examining physician or any member of the multidisciplinary team  
9 to present testimony concerning this examination and  
10 evaluation of the licensee, permit holder, or applicant,  
11 including testimony concerning any supplemental testing or  
12 documents relating to the examination and evaluation. No  
13 information, report, record, or other documents in any way  
14 related to the examination and evaluation shall be excluded by  
15 reason of any common law or statutory privilege relating to  
16 communication between the licensee, permit holder, or  
17 applicant and the examining physician or any member of the  
18 multidisciplinary team. No authorization is necessary from the  
19 licensee, permit holder, or applicant ordered to undergo an  
20 evaluation and examination for the examining physician or any  
21 member of the multidisciplinary team to provide information,  
22 reports, records, or other documents or to provide any  
23 testimony regarding the examination and evaluation. The  
24 individual to be examined may have, at his or her own expense,  
25 another physician of his or her choice present during all  
26 aspects of the examination. Failure of any individual to submit

1 to mental or physical examination and evaluation, or both, when  
2 directed, shall result in an automatic suspension, without  
3 hearing, until such time as the individual submits to the  
4 examination. If the Disciplinary Board or Licensing Board finds  
5 a physician unable to practice following an examination and  
6 evaluation because of the reasons set forth in this Section,  
7 the Disciplinary Board or Licensing Board shall require such  
8 physician to submit to care, counseling, or treatment by  
9 physicians, or other health care professionals, approved or  
10 designated by the Disciplinary Board, as a condition for  
11 issued, continued, reinstated, or renewed licensure to  
12 practice. Any physician, whose license was granted pursuant to  
13 Sections 9, 17, or 19 of this Act, or, continued, reinstated,  
14 renewed, disciplined or supervised, subject to such terms,  
15 conditions or restrictions who shall fail to comply with such  
16 terms, conditions or restrictions, or to complete a required  
17 program of care, counseling, or treatment, as determined by the  
18 Chief Medical Coordinator or Deputy Medical Coordinators,  
19 shall be referred to the Secretary for a determination as to  
20 whether the licensee shall have their license suspended  
21 immediately, pending a hearing by the Disciplinary Board. In  
22 instances in which the Secretary immediately suspends a license  
23 under this Section, a hearing upon such person's license must  
24 be convened by the Disciplinary Board within 15 days after such  
25 suspension and completed without appreciable delay. The  
26 Disciplinary Board shall have the authority to review the

1 subject physician's record of treatment and counseling  
2 regarding the impairment, to the extent permitted by applicable  
3 federal statutes and regulations safeguarding the  
4 confidentiality of medical records.

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

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

18 All fines imposed under this Section shall be paid within  
19 60 days after the effective date of the order imposing the fine  
20 or in accordance with the terms set forth in the order imposing  
21 the fine.

22 (B) The Department shall revoke the license or permit  
23 issued under this Act to practice medicine or a chiropractic  
24 physician who has been convicted a second time of committing  
25 any felony under the Illinois Controlled Substances Act or the  
26 Methamphetamine Control and Community Protection Act, or who

1 has been convicted a second time of committing a Class 1 felony  
2 under Sections 8A-3 and 8A-6 of the Illinois Public Aid Code. A  
3 person whose license or permit is revoked under this subsection  
4 B shall be prohibited from practicing medicine or treating  
5 human ailments without the use of drugs and without operative  
6 surgery.

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

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

25 (Source: P.A. 97-622, eff. 11-23-11; 98-601, eff. 12-30-13;  
26 98-668, eff. 6-25-14; 98-1140, eff. 12-30-14.)