**25 States Eye ‘Right-to-Try Legislation**

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Twenty more states have introduced legislation allowing terminally ill patients to gain access to investigational products. In all, 24 states are considering Right-to-Try legislation this year. Last year five states approved similar legislation.

As with the laws enacted last year, under the proposed bills manufacturers are not required to provide the investigational product and may require the patient to pay the costs of or associated with the manufacture of the product. A bill in New Hampshire adds that the manufacturer may require the patient to participate in data collection relating to the use of the product. In addition, insurance carriers are not required to provide coverage or make payment beyond the terms and conditions of the contract for medical treatment. A bill in Oregon states that the patient must be 18, a resident of the state and “has the ability to make and communicate health care decisions to health care practitioners, including the ability to communicate through individuals familiar with the patient’s manner of communicating.”

The Oregon bill also states that a health care practitioner may offer to treat a patient who has a terminal disease with a drug or device not approved by FDA only if: the health care practitioner is authorized by state laws to provide health care services or to dispense drugs, and the health care practitioner is acting within the scope of that authority; the treatment is provided free of charge to the patient; the treatment is being offered only for purposes related to the terminal disease; the patient was referred to the health care practitioner by the patient’s attending physician; and the health care practitioner refers the patient to a consulting physician to affirm the attending physician’s diagnosis and prognosis.

The states that are considering Right-to-Try legislation this year are: Arkansas, California, Connecticut, Florida, Georgia, Hawaii, Illinois, Indiana, Kansas, Minnesota, Mississippi, Montana, New Hampshire, New Jersey, North Dakota, Oklahoma, Oregon, Rhode Island, South Dakota, Tennessee, Texas, Utah, Virginia, West Virginia and Wyoming.

There are five bills under consideration in Virginia ([S.B. 732](https://leg1.state.va.us/cgi-bin/legp504.exe?151+ful+SB732), [S.B. 1149](http://lis.virginia.gov/cgi-bin/legp604.exe?151+ful+SB1149+pdf), [S.B. 1222](http://lis.virginia.gov/cgi-bin/legp604.exe?151+ful+SB1222),[H.B. 1750](http://lis.virginia.gov/cgi-bin/legp604.exe?151+ful+HB1750+pdf) and [H.B. 2050](http://lis.virginia.gov/cgi-bin/legp604.exe?151+ful+HB2050+pdf)). All the bills except H.B. 2050 require informed consent be obtained from the patient. H.B. 2050 also contains a provision that no health care provider who recommends the use of an investigational drug, biological product, or device for treatment of a patient's terminal illness in accordance with the bill will be deemed to have engaged in unprofessional conduct solely on the grounds the recommendation.

The three Senate bills — S.B. 732, prefiled by Sen. William Stanley, Jr., R-Richmond, on Dec. 15; S.B. 1149, prefiled by Sen. Richard Stuart, R-Montross, on Jan. 13; and S.B. 1149, prefiled by Sen. Bryce Reeves, R-Fredericksburg, on Jan. 14 — were referred to the Senate Committee on Education and Health and assigned to the health professions subcommittee.

The two House bills — H.B. 1750, prefiled by Rep. Margaret Ransone, R-Kinsale, on Jan. 12, and H.B. 2050, prefiled by Rep. Mark Sickles, D-Franconia, on Jan. 14  — were referred to the House Committee on Health, Welfare and Institutions.

Companion bills have been introduced in five states - llllinois ([S. 29](http://www.ilga.gov/legislation/99/SB/PDF/09900SB0029lv.pdf) and[H. 207](http://www.ilga.gov/legislation/99/HB/PDF/09900HB0207lv.pdf)), Hawaii ([H.B. 92](http://www.capitol.hawaii.gov/session2015/bills/HB92_.pdf) and [S.B. 585](http://www.capitol.hawaii.gov/session2015/bills/SB585_.pdf)), Minnesota ([SF 100](https://www.revisor.mn.gov/bills/text.php?version=latest&session=ls89&number=SF0100&session_year=2015&session_number=0) and [HF 236](http://wdoc.house.leg.state.mn.us/leg/LS89/HF0236.0.pdf)), Mississippi ([S.B. 2485](http://billstatus.ls.state.ms.us/documents/2015/pdf/SB/2400-2499/SB2485IN.pdf) and  [H.B. 722](http://billstatus.ls.state.ms.us/documents/2015/pdf/HB/0700-0799/HB0722IN.pdf) and [1042](http://billstatus.ls.state.ms.us/documents/2015/pdf/HB/1000-1099/HB1042IN.pdf)), and Oklahoma ([H.B. 1074](http://webserver1.lsb.state.ok.us/cf_pdf/2015-16%20INT/hB/HB1074%20INT.PDF) and [S.B. 616](http://webserver1.lsb.state.ok.us/cf_pdf/2015-16%20INT/SB/SB616%20INT.PDF)).

Illinois S. 29 was introduced by Sen. Michael Connelly, R-Wheaton, and Sen. Linda Holmes, D-Aurora, on Jan. 15 and referred to the Assignments Committee. Illinois H. 207 was introduced by Rep. Mary Flowers, D-Chicago, on Jan.15 and referred to the Rules Committee.

Hawaii H.B. 92 was introduced by Rep. Cindy Evans, D-North Kona, on Jan. 21 and referred to the House Health Committee and the Consumer Protection and Commerce Committee. S.B. 585 was introduced Sens. Russell Ruderman, D-Puna, Ka’u, and Will Espero, D-Ewa Beach, on Jan. 23 and referred to the Senate Health Committee and the Commerce and Consumer Protection Committee. Ruderman is a member of the Senate Health Committee.

Mississippi S.B. 2485 was introduced by Sen. Josh Harkins, R-Madison, Rankin, on Jan. 19 and referred to the Public Health and Welfare Committee. H. B. 722 and 1042 were introduced by Rep. Chris Brown, R-Lowndes, Monroe, on Jan. 19 and referred to the House Public Health and Human Services Committee. Brown is a member of that committee.

SF 100 was introduced by Sens. Branden Peterson, R-Anoka, John Hoffman, DFL-Hennepin-Anoka, Karin Housley, R-Washington, John Marty, DFL-Ramsey, and Kathy Sheran, DFL-Nicollet-Blue Earth, on Jan. 15 and referred to the Health, Human Services and Housing Committee, chaired by Sheran and upon which Hoffman and Marty serve. HF 236 was introduced by 10 representatives and referred to the Health and Human Services Reform Committee, which includes three of the sponsors.

Oklahoma H.B. 1074 was introduced by Rep. Richard Morrissette, D-Oklahoma County, on Jan. 17. S.B. 616 was introduced by Senate Majority Floor Leader Mike Schultz, R-Custer, Greer, on Jan. 22. Neither bill has received a committee assignment.

**Proposals Detailed**

Illinois S. 29 states the patient must have given informed consent in writing for the use of the investigational product but does not specify items to be included in the informed consent. It also provides that any official, employee, or agent of the state who blocks or attempts to block access by an eligible patient to an investigational product is guilty of a misdemeanor, punishable by a fine not to exceed $1,500. In addition, the state will 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 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 product.

Illinois H.B. 207 also includes a provision for patient informed consent and specifies seven statements that must be in the consent. It also states that it will not require any governmental agency to pay costs associated with the use, care, or treatment of a patient with an investigational product, nor require hospitals to provide new or additional services, unless approved by the hospital or facility.

In addition, if the patient dies while being treated with the investigational product, the patient's heirs will not liable for any outstanding debt related to the treatment or lack of insurance due to the treatment. It also 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 product. It states officials, employees or agents of the state may not block or attempt to block an eligible patient's access to an investigational product, but that counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider will not be a violation of the act.

Hawaii S.B 585 states the patient must give written informed consent for use of the investigational product and have been unable to participate in a clinical trial for the illness within 100 miles of the patient’s home or not been accepted to the clinical trial within one week of completion of the clinical trial application. The bill includes eight statements that must be in the informed consent, including that the patient understands that he or she is liable for all expenses consequent to the use of the investigational product and that the liability extends to the patient’s estate, unless a contract between the patient and manufacturer states otherwise. However, if the patient dies while being treated with the investigational product, the patient’s heirs are not liable for any outstanding debt related to the treatment or lack of insurance.

In addition, S.B. 585 states that a licensing board may not revoke, fail to renew, suspend, or take any action against a health care provider’s license based solelv on a recommendation regarding access to or treatment with an investigational product, as long as the recommendations are consistent with medical standards of care. Action against a health care provider's Medicare certification also is prohibited and no official, employee, or agent of the state can block or attempt to block an eligible patient's access to an investigational product. However, counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation.

Both Minnesota SF 100 and HF 236 provide for patient informed consent but do not make any specifications. They also prohibit licensing boards from taking action against a licensee solely based on providing a prescription or recommendation or providing treatment with an investigational product. They also impose a misdemeanor with a sentence of not more than six months in jail and a fine of up to $2,500 for state officials, employees or agents for blocking access of an eligible patient to an investigational product.

Both the Oklahoma bills provide specific statements to be included in the patient’s informed consent. The bills add governmental agencies are not required to pay costs associated with the use, care or treatment of a patient with an investigational product nor are hospitals, nursing homes, long-term care facilities or other facilities providing health care services and licensed in the state required to provide new or additional services unless approved by the hospital, nursing home, long-term care facility or other facility providing health care services under the bill.

The other bills are:

* Arkansas –[S.B. 4](http://www.arkleg.state.ar.us/assembly/2015/2015R/Bills/SB4.pdf) introduced by Sen. John Cooper, R-Jonesboro, on Dec. 5.
* California – [A.B. 159](http://www.leginfo.ca.gov/pub/15-16/bill/asm/ab_0151-0200/ab_159_bill_20150121_introduced.pdf) introduced by Assemblyman Ian Calderon, D-Whittier, on Jan. 21.
* Connecticut – [H.B. 6292](http://www.cga.ct.gov/2015/TOB/h/pdf/2015HB-06292-R00-HB.pdf) introduced by Reps. Vincent Candelora, R-Durham, and Noreen Kokoruda, R-Durham, on Jan. 22 and referred to the Joint Committee on Public Health. Candelora is a member of the committee and the deputy House Republican Leader.
* Florida – [H.B. 269](http://www.myfloridahouse.gov/Sections/Documents/loaddoc.aspx?FileName=_h0269__.docx&DocumentType=Bill&BillNumber=0269&Session=2015) introduced by Rep. Ray Pilon, R-Sarasota, Jan. 14 and referred to the Health Innovation subcommittee, the Insurance and Banking subcommittee and the Health and Human Services Committee.
* Georgia - [H.B. 34](http://www.legis.ga.gov/Legislation/en-US/display/20152016/HB/34) introduced by Rep. Mike Dudgeon, R-Johns Creek, on Jan. 5.
* Indiana – [H.B. 1065](https://iga.in.gov/legislative/2015/bills/house/1065#document-006757c1) introduced by Rep. Wes Culver, R-Elkhart County, on Jan. 6 and referred to the Public Health Committee.
* Kansas - [H.B. 2004](http://www.kslegislature.org/li/b2015_16/measures/hb2004/) prefiled by three Johnson County Republicans, Brett Hildabrand, Mike Kiegerl and Craig McPherson, on Dec. 19 and referred to the Committee on Health and Human Services.
* Montana – [S.B. 142](http://leg.mt.gov/bills/2015/billpdf/SB0142.pdf) introduced by Sen. Cary Smith, R-Billings, on Jan. 13 and referred to the Public Health, Welfare and Safety Committee.
* New Hampshire – [H.B. 446](http://www.gencourt.state.nh.us/legislation/2015/HB0446.pdf) introduced by Rep. Ted Wright, R-Moultonborough, on Jan. 8 and referred to the Judiciary Committee.
* New Jersey – [S. 2186](https://legiscan.com/NJ/text/S2186/id/1035455) was introduced by Sen. Diane Allen, R-Cinnaminson, and Joseph Vitale, D-Woodbridge, on June 16, 2014 and referred to the Senate Health, Human Services and Senior Citizens Committee, which Vitale chairs. Allen is also a member of the committee.
* North Dakota – [S.B. 2259](http://www.legis.nd.gov/assembly/64-2015/documents/15-0251-02000.pdf?20150123072019) introduced by Sens. Tim Mathern, D-Cass, Terry Wanzek, R-Stutsman, and Joan Heckaman, D-Benson, on Jan. 19 and referred to the Human Services Committee. Heckaman is the Senate Assistant Minority Leader.
* Oregon – [H.B. 2300](https://olis.leg.state.or.us/liz/2015R1/Downloads/MeasureDocument/HB2300/Introduced) was introduced at the request of the House Interim Committee on Health Care on Jan. 12 and referred to the committee.
* Rhode Island – [H.B. 5093](http://webserver.rilin.state.ri.us/BillText15/HouseText15/H5093.pdf) introduced by Reps. Joseph McNamara, D-Warwick, Cranston, K. Joseph Shekarchi, D-Warwick, Patricia Serpa, D-West Warwick, Coventry, Warwick, David Bennett, D-Warwick, Cranston, and Grace Diaz, D-Providence, on Jan. 15 and referred to the Health, Education and Welfare Committee. McNamara chairs the committee, Diaz is the deputy chair and Democratic Caucus chair, and Bennett is a member of the committee.
* South Dakota – [H.B. 1080](http://legis.sd.gov/docs/legsession/2015/Bills/HB1080P.pdf) introduced by Reps. Leslie Heinemann, R- Flandreau, Fred Deutsch, R-Florence, Steve Hickey, R-Sioux Falls, Scott Munsterman, R-Brookings, and Jim Stalzer, R-Sioux Falls, and Sen. Blake Curd, R-Sioux Falls, on Jan. 23 and referred to the House Health and Human Services Committee, which Munsterman chairs. In addition, Hickey is vice chair and Heinemann is a member of the committee.
* Tennessee –[H.B. 143](http://www.capitol.tn.gov/Bills/109/Bill/HB0143.pdf) introduced by Rep. Jon Lundberg, R-Sullivan, on Jan. 22.
* Texas – [H.B. 438](http://www.legis.state.tx.us/tlodocs/84R/billtext/html/HB00438I.htm) introduced by Rep. Terry Canales, D-Edinburg, on Dec. 3.
* Utah – [H.B. 94](http://billstatus.ls.state.ms.us/documents/2015/pdf/HB/0700-0799/HB0722IN.pdf) introduced by Rep. Gage Froerer, R-Huntsville, on Jan. 12 and referred to the House Rules Committee.
* West Virginia – [H.B. 2026](http://www.legis.state.wv.us/Bill_Text_HTML/2015_SESSIONS/RS/bills/hb2026%20intr.pdf) introduced by Rep. Gary Howell, R-Mineral, on Jan. 14 and referred to the Health and Human Services Committee.
* Wyoming – [SF 0003](http://legisweb.state.wy.us/2015/Introduced/SF0003.pdf) introduced by Sen. Bruce Burns, R-Sheridan, on Dec. 1.

**Informed Consent Required**

Bills in 13 states – California, Florida, Georgia, Indiana, Kansas, Mississippi, Montana, North Dakota, Rhode Island, South Dakota, Tennessee, Texas and West Virginia – mandate informed consent be given by the patient and provide specific statements that must be in the consent. The Hawaii and New Hampshire bills state patients must give written consent but do not make any specifications about the form or content of the informed consent.

The Mississippi bills states the patient’s written informed consent must be “at least as comprehensive as the consent used in clinical trials for the use” of the investigational product. The Mississippi bills add the informed consent also must contain a statement that the patient understands that he or she is liable for all expenses for use of the investigational product and that the liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the product states otherwise.

The Kansas bill also adds a provision that the informed consent must make clear that in-home health care also may be denied if the investigational treatment begins.

The Oregon bill states the attending physician must inform the patient: that the patient has a terminal disease; the physician’s prognosis for the patient; that the drug or device to be used is not approved by the FDA; each potential risk associated with receiving the treatment that is known to the physician; and the feasible alternatives to receiving the treatment, including palliative care, hospice care and pain control.

The Oregon bill requires the patient to sign and date a form attesting to the decision in the presence of two witnesses. The form must include: the attending physician’s diagnosis and prognosis for the patient; a statement that the drug or device is not approved by the FDA; a description of each potential risk associated with the product; a waiver of liability for any act or omission of an act related to administering the treatment that does not constitute gross negligence for: any health care practitioner who participates in administering the treatment; or any health care facility or professional organization or association involved in the administration of the treatment; a provision authorizing any information obtained during the treatment to be used: by the inventor, manufacturer or supplier of any drug or device used in treating the patient for research, analytical or marketing purposes; and by any health care practitioner who participates in administering the treatment for research or analytical purposes; and (7) a statement signed and dated by both witnesses attesting that the patient, to the best of the witnesses’ knowledge, is capable and acting voluntarily.

Of the two witnesses, one must be an individual who is not: a relative of the patient by blood, marriage or adoption; a person who, at the time the form is signed, would be entitled to any portion of the estate of the patient upon the patient’s death under any will or by operation of law; or an owner, operator or employee of a health care facility where the patient resides or receives health care services. Neither witness may be the attending physician of the patient.

Under the bills in Arkansas, California, Florida, Georgia, Hawaii, Kansas, Mississippi, Montana, New Hampshire, New Jersey, North Dakota, Rhode Island, Tennessee, Texas, West Virginia and Wyoming, state medical boards cannot revoke, suspend, sanction, fail to renew, or take any other action against a physician's license solely based on such physician's recommendation, prescription, or treatment of an eligible patient with an investigational product. The Wyoming measure adds “as long as the recommendations are consistent with medical standards of care.”

The South Dakota bill adds that a treating physician who is in compliance with the bill “may not be subject to arrest or prosecution, penalty, or denial of any right or privilege granted otherwise.”

In addition, the bills in those states, with the exception of Hawaii, Mississippi, Montana and New Hampshire, also prohibit any state official, employee, or agent from blocking or attempting to block an eligible patient's access to an investigational product. However, counseling, advice, or a recommendation for treatment consistent with medical standards of care is not construed as a violation. New Hampshire also adds that the state department of health and human services shall not take action against a licensed facility based solely on the institution’s participation in the treatment or use of an investigational product.

Unlike other bills introduced or enacted, the Georgia bill extends access to investigational products to persons with “advanced illness,” which the bill defines as “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 FDA approved and available treatments, and that, without life-sustaining procedures, will soon result in death.”

**Five Bill Require Patient Can’t Participate in Ongoing Clinical Trials**

The Arkansas, California, Kansas, Oklahoma and West Virginia bills require that the patient be unable to participate in a clinical trial for the terminal illness within 100 miles of the patient's home address, or not have been accepted to the clinical trial within one week of completion of the clinical trial application process. The Kansas bill also requires documentation from the patient’s treating physician that the patient meets the requirements.

The California, Florida, Kansas, Montana, Oklahoma, Rhode Island, South Dakota, Tennessee and West Virginia bills add that if a patient dies while being treated with an investigational product, the patient's heirs are not be liable for any outstanding debt related to the treatment or lack of insurance for the treatment.

The Indiana bill states that if the medical treatment is to be provided on an inpatient or outpatient basis at a licensed hospital then that type of treatment must have been approved by the governing board of the hospital or by a committee of the hospital authorized by the governing board to approve the types of experimental or nonconventional medical treatments that may be provided at the hospital. Under the bill, the state medical licensing board will develop protocols for medical treatments that are provided in a setting other than the inpatient or outpatient hospital setting and any physician who fails to comply with a protocol developed by the board will be subject to discipline by the board. The Florida bill states that a hospital or health care facility licensed by the state is not required to provide new or additional services unless those services are approved by the hospital or health care facility.

The Florida bill also holds 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 product.

The Mississippi bill said the state Department of Corrections or any other governmental agency is not required to provide coverage for the cost of any investigational product, nor is a licensed hospital or nursing home required to provide new or additional services, unless approved by the hospital or facility.

The Mississippi bill also states that “if the clinical trial is closed due to lack of efficacy or toxicity, the drug shall not be offered. If notice is given on a drug, product or device taken by a patient outside of a clinical trial, the pharmaceutical company or patient's physician shall notify the patient of the information from the safety committee of the clinical trial.”

The Mississippi bill adds that “except in the case of gross negligence or willful misconduct, any person who manufactures, imports, distributes, prescribes, dispenses, compounds or administers an investigational drug or device to an eligible patient with a terminal illness in accordance with this section shall not be liable in any action under state law for any loss, damage or injury arising out of, relating to, or resulting from: the design, development, clinical testing and investigation, manufacturing, labeling, distribution, sale, purchase, donation, dispensing, compounding, prescription, administration, or use of the drug or device; or the safety or effectiveness of the drug or device.”

The Georgia, Tennessee and West Virginia bills add that they do not affect the state laws on mandatory health care coverage for participation in clinical trials.

The Connecticut bill provides only that the state’s “general statutes be amended to allow terminally ill patients to request access to treatment and drugs that have passed the first clinical trial stage of development but have not received final approval by the federal Food and Drug Administration, and physicians, hospitals and manufacturers of investigational drugs, products and devices to make such treatment, drugs, products and devices available to terminally ill patients without being subject to prosecution.”

The Utah bill would amend state law to state “unprofessional conduct” by a medical practitioner does not include obtaining or administering an investigational drug or device to an eligible patient.

The Oregon bill also holds that a health care facility or health care practitioner may prohibit another health care practitioner from participating in administering an investigational treatment at the health care facility, or on premises owned or controlled by the prohibiting health care practitioner, if the health care facility or prohibiting health care practitioner adopts a written policy that clearly prohibits the administration of such treatment; and provides a printed or electronic copy of that policy to each health care practitioner who provides health care services there.