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“Right to Try” Experimental Prescription Drugs State Laws and Legislation for 2014 & 2015

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Compiled by Richard Cauchi, NCSL Health Program, Denver

In the past 15 months there has been significantly increased activity related to how terminally ill patients can gain legal access to experimental drugs not yet approved by the U.S. Food and Drug Administration (FDA). As of March 2015 there are at least **36 states and D.C.** that have examined or will examine this burgeoning issue, with filed bills and **12 signed laws**.

The following description is excerpted from enacted measures, including language presented by supporters of such measures, and is included for general information only. As always, NCSL takes no position on these or other state pharmaceutical or legislative measures.

Update of Note:
7 states enacted new “Right to Try” laws in March 2015

The Federal FDA Role: FDA currently has a process by which patients can access experimental drugs through “expanded access” or “compassionate use.” The Agency prioritizes these requests and frequently responds within 2-4 days, but no longer than 30 days. The process requires a patient's physician to file a form with FDA. The Agency recently announced a new proposed form which will take an estimated 45 minutes to complete, compared with the old form which carried an estimate of 100 hours. Under federal regulations, a patient cannot access an experimental drug unless FDA provides permission and the company making the drug agrees to provide it.

UPDATE: On Feb. 4, 2015, the FDA publicly announced a new “streamlined process” and provided a revised [FDA webpage on expanded access](#). An FDA blog post from Associate Commissioner Dr. Peter Lurie [summarizes](#) the new policy.

To allow access to experimental drugs under state law, several state legislatures have introduced “Right to Try” bills seeking to allow patients to obtain experimental drugs without first obtaining federal approval.

The “Right to Try” [proposed model legislation](#) was designed and promoted by the Goldwater Institute, a free-market advocacy group in Arizona. Their “model legislation” typically addressed several concerns about patients’ use of experimental drugs.



- It would allow access only to medications that have passed manufacturers’ Phase I clinical trials, or the first studies in humans. Most drugs complete three phases of testing in increasingly larger patient populations before being approved by FDA.
- Access would be limited to use by terminally ill patients who have exhausted other available treatments. Example: “Terminal illness means an incurable and irreversible condition that without the administration of life-sustaining treatment will, in the opinion of the patient's physician, result in death within a relatively short time.” [Arkansas, [Act 374](#) of 2015]
- A medication would be made available only if the company manufacturing it chose to do so.

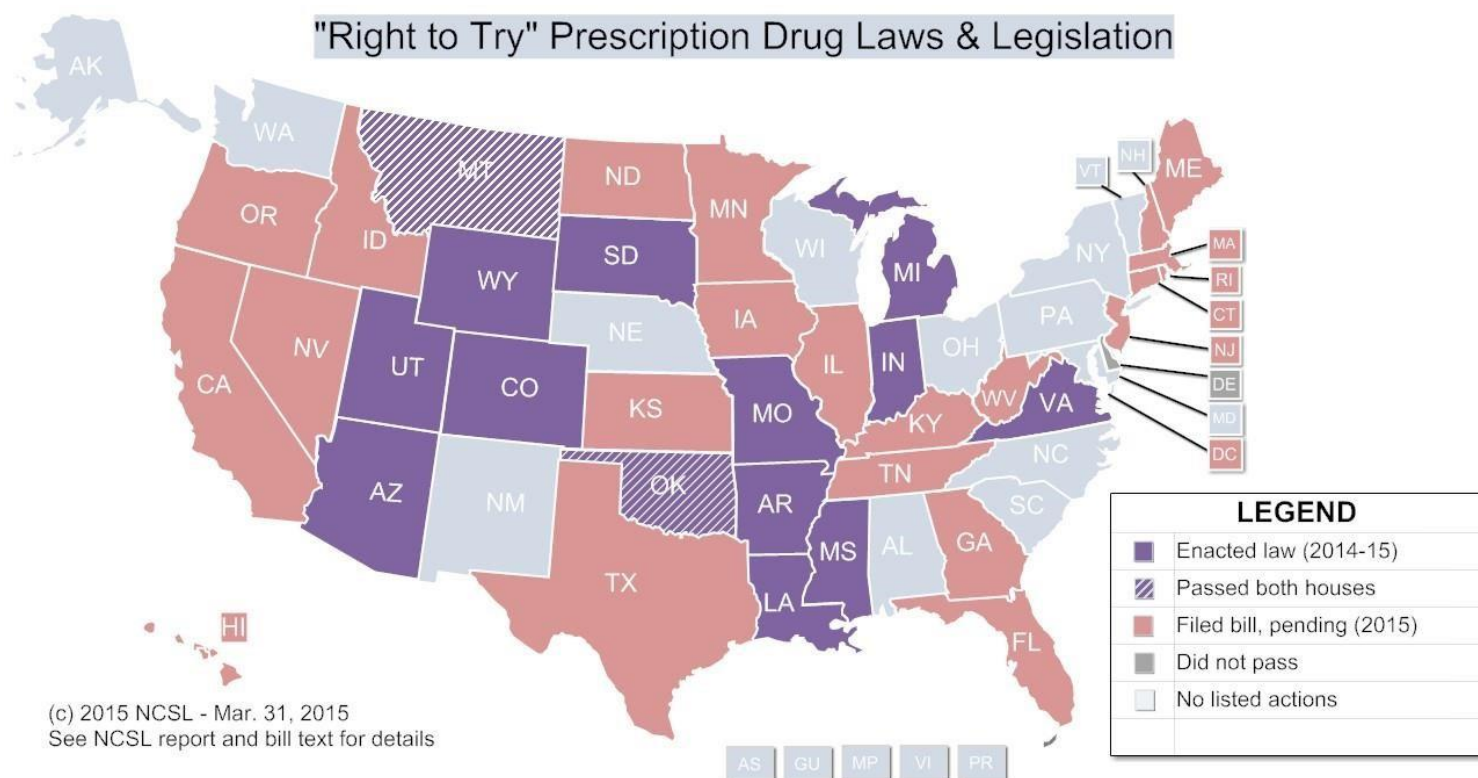
- A patient’s request for access to an experimental drug would require a doctor to diagnose a terminal disease and declare that the drug represents the patient’s best chance at survival.
- Patients would provide signed informed consent, thus limiting the legal exposure of the manufacturer of the drug.

Critics of “Right to Try” legislation note that providing experimental drugs to terminally ill patients may create a false sense of hope. There also is concern that such bills attempt to undermine FDA’s authority and medical expertise in the regulation of pharmaceutical products. They also say that patients may be exposed to the dangers of drugs with limited testing and that the best way to get drugs to patients is through widespread clinical testing—a process the “Right to Try” legislation may undermine. Other critics claim that these bills won't have an effect because they don't require the companies to provide the investigational medication to patients.

Supporters say “any hope is better than the alternative of no hope, which is inevitable when no treatments are made available for terminal patients. Patients should be free to exercise a basic freedom – attempting to preserve one’s own life. The burdens imposed on a terminal patient who fights to save his or her own life are a violation of personal liberty. Such people should have the option of accessing investigational drugs which have passed basic safety tests, provided there is a doctor’s recommendation, informed consent, and the willingness of the manufacturer of the medication to make such drugs available.”²

2014 BILL STATUS SUMMARY: Nine states considered “Right to Try” measures. As of Dec. 31, 2014, **five states—Arizona, Colorado, Louisiana, Michigan and Missouri** — had enacted laws. **Arizona** adopted a resolution to place the issue on the November 2014 ballot; it was approved and became law by a majority of voters.

2015 BILL STATUS SUMMARY: As of March 30, “Right to Try” bills have been filed in at least **32 states and D.C.**; additional measures may be filed in coming weeks. Table 2 below includes preliminary details. Specific provisions may vary. As of March 30, additional laws have been enacted in **Arkansas, Indiana, Mississippi, South Dakota, Utah, Virginia and Wyoming**.



STATE LEGISLATION, 2013-2014
Table 1

State	Bill/Act#	Status	Summary Description
Arizona	HCR2005 of 2013	Order adopted by Legislature 4/15/2014 Became law as Proposition 303 11/4/2014 Yes votes: 78.3%	A concurrent resolution enacting and ordering the submission to the people as a binding November 2014 ballot question for a state statute creating a rapid approval path for terminally ill patients to the use of investigational drugs. Allows a manufacturer to make an investigational drug, biological product or device to an eligible terminally ill patient. It exempts a patient from regulatory action based solely on the physician's recommendation of the drug, product or device to the eligible terminally ill patient and classifies, as a class 1 misdemeanor, any attempt by a state official, employee, or agent to block access of the investigational drug, biological product or device to an eligible terminally ill patient.
Colorado	HB 1281 of 2014; Ch. 220	Enrolled 5/9/2014 Signed into law 5/23/2014	Provides a state process to allow terminally ill patients to have access to investigational products that have not been approved by the federal FDA that other patients have access to when they participate in clinical trials.
Delaware	S 270 of 2014	Filed 7/1/2014 Held in Committee	Would permit terminally ill patients the right to try experimental treatments and drugs.
Louisiana	HB 891 of 2014	Enrolled; Signed into law as Act 346; 5/30/2014	Enacts the <i>Right To Try Act</i> ; authorizes access to investigational drugs, biological products, and devices for terminally ill patients; provides that a physician who prescribes such drug, biological product or device shall be immune from civil liability under medical malpractice provisions; provides that health insurers may choose to provide coverage for the cost of an investigational drug or device; requires a physician prescription.
Michigan	H 5649 of 2014 Act 346	Passed House & Senate; signed 10/17/2014	Defines the rights of terminally ill patients to access experimental medicines not yet approved by the Food and Drug Administration.
Minnesota	S 2985 of 2014	Filed, 5/13/2014 Failed- Adjourned	Would permit the use of investigational drugs, biological products, or devices by certain terminally ill eligible patients.
Missouri	HB 1685 of 2014	Passed House & Senate; Signed into law by governor 7/14/2014	Authorizes a manufacturer of an investigational drug, biological product, or devices to make the manufacturer's drug, product, or device available to eligible patients; authorizes a health care insurer to provide coverage for an investigational drug, biological product, or device; prohibits taking action against a physician's license based solely on a recommendation to an eligible patient regarding treatment with an investigational drug, biological product, or device.
New Jersey	AB 3474 SB 2186	Filed; sent to Assembly Health and Senior Services Comm. 6/26/2014 ; <i>carried over-- see 2015 bill list, below</i>	Would permit patients who are terminally ill to access investigational drugs, biological products, and devices that have not yet been approved by the United States Food and Drug Administration (FDA). To use an investigational drug, biological product, or device, the patient would be required to: have a medical condition that results in a life expectancy of less than 12 months; have consulted with a physician and considered all other treatment options currently approved by the FDA; have received a prescription or recommendation from a physician for the investigational drug, biological product, or device; and give informed, written consent to use of the investigational drug, biological product, or device. The physician would be required to document that the patient has met these requirements.

Utah	SJR 20 of 2014	Passed/enrolled 3/21/2014	This <u>non-binding</u> joint resolution of the Legislature gives the Legislative Management Committee items of study it <u>may</u> assign to the appropriate interim committee. Includes as item #89: Access to Investigational Medications, Products, and Devices - to study providing terminally ill patients with access to investigational drugs, biological products, and devices that have completed at least phase I clinical trials.
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STATE LEGISLATION, 2015			Table 2
State	Bill/Act#	Status	Summary Description (See bill text for specific provisions)
Arkansas	SB 4	Filed 1/12/2015 passed Senate/House; signed as Act 374, 3/10/2015	Permits certain terminally ill patients the right to try experimental treatments and drugs.
California	A 159 S 149 S715	Filed 1/21/2015 Filed 1/29/2015 Filed 2/27/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
Connecticut	H 6292 H 6700 H 6709 S 60	Filed 2/2/2015 " " Filed 1/13/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
Delaware	S 270 of 2014	Filed 7/1/2014 Held in Comm.	Would permit terminally ill patients the right to try experimental treatments and drugs.
District of Columbia	B 125	Filed 3/3/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
Florida	H 269 S1052	Filed 1/14/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
Georgia	H34	Filed 1/12/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
Hawaii	S 92 S 585 H 1013	Filed 1/21/2015 Filed 1/21/2015 Filed 1/21/2015	Would provide access for terminally ill patients to receive investigational drugs, biological products, and devices that have not received final FDA approval
Idaho	S 1156	Filed 3/17/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
Illinois	H 207 H 496 H 1335 H 2508 S 29	Filed 1/15/2015 Filed 1/30/2015 Filed 2/15/2015 Filed 2/27/2015 Filed 1/15/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
Indiana	H 1450 S 66	Filed 1/21/2015; passed House & Senate; signed by governor, as P.L. 2, 3/24/2015	Permits terminally ill patients the right to try experimental treatments and drugs.
Iowa	SSB 1264	Filed 13//61/02015/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
Kansas	H 2004	Filed 1/12/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
Kentucky	SB 139	Filed 2/10/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
Massachusetts	HD 2735	Filed 1/16/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.

Maine	LR 476 LR 632	Filed 1/5/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
Minnesota	H 236 S 100	Filed 1/20/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
Mississippi	S 2485 H 722 H 1042	Filed 1/21/2015; Passed Senate/House; signed by governor, 3/30/2015 Filed 1/22/2015;	Would permit terminally ill patients the right to try experimental treatments and drugs.
Missouri	H 1072	Filed 3/10/2015	Would permit terminally ill patients the right to try experimental treatments and drugs. Also see enacted law HB 1685 of 2014
Montana	S 142	Filed 1/13/2015; Passed Senate/House; sent to governor.	Would permit terminally ill patients the right to try experimental treatments and drugs.
New Hampshire	H 446	Filed 1/8/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
New Jersey	AB 3474 SB 2186	Filed 6/16/2014; pending in 2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
Nevada	A 358	Prefiled 7/16/2014; Filed 3/17/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
North Dakota	S 2259	Filed 1/19/2015; Passed Senate	Would permit terminally ill patients the right to try experimental treatments and drugs.
Oklahoma	H 1074 S 616	Filed 2/2/2015 passed House 96-0; passed Senate, 3/27/2015 Filed 2/2/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
Oregon	H 2300 S 543	Filed 2/2/2015 Filed 2/2/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
Rhode Island	H 5093	Filed 1/15/2015; held/study 2/11/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
South Dakota	H 1080	Filed 1/23/2015; Passed House/Senate; signed by governor 3/12/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
Tennessee	H 143 S 811	Filed 1/22/2015 Filed 2/11/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
Texas	H.438	Filed 1/13/2015	Would permit certain terminally ill patients to access investigational drugs, biological products, and devices in clinical trials
Utah	H 94	Filed 1/23/2015; Passed House/Senate; signed by governor 3/24/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
Virginia	S 732 H 1750	Filed 1/14/2015; Passed Senate/House; signed by governor as Ch. 655 and Ch. 656, 3/27/2015 Filed; failed to pass	Permits terminally ill patients the right to try experimental treatments and drugs.

	H 2050		
West Virginia	H 2026	Filed 1/14/2015	Would permit terminally ill patients the right to try experimental treatments and drugs.
Wyoming	S 3	Filed 1/13/2015; Passed Senate 29-1; House 58-1; signed into law 3/12/2015	Permits terminally ill patients the right to try experimental or investigational treatments and drugs.

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Additional Resources, Reports and Opinions

- [States move to give terminally ill 'right-to-try' drugs](#) - USA Today, Feb. 20, 2015
- [Quicker Access to Experimental Drugs](#) – Editorial Board, New York Times, Feb. 12, 2015
- [Bill allows experimental meds for terminal patients](#) (Delaware) – Feb. 12, 2015
- [Legislation would allow 'right-to-try' trial drugs](#) (Indiana) – USA Today, Feb. 3, 2015
- ² [Everyone Deserves the Right to Try: Empowering the Terminally Ill to Take Control of their Treatment](#) – Goldwater Institute – Feb. 11, 2015 -
- [Patients Seek “Right to Try” New Drugs](#) – New York Times, Jan. 14, 2015
- [Right-to-try for the terminally ill](#) – Pew/Stateline – June, 2014

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