

Federal Right to Try: Questions and Answers

On May 30, 2018, President Donald Trump signed S.204, the Trickett Wendler, Frank Mongiello, Jordan McLinn and Matthew Bellina Right to Try Act. Right to Try opens a new pathway for terminally ill patients who have exhausted their government-approved options and can't get into a clinical trial to access treatments. Although 40 states have passed Right to Try laws, the signing of S.204 makes Right to Try the law of the land, creating a uniform system for terminal patients seeking access to investigational treatments.

Q: Who qualifies for Right to Try?

A: To be eligible for Right to Try a patient must meet the following conditions:

- Be diagnosed with a **life-threatening disease or condition**;
- Have exhausted **approved treatment options**;
- Be **unable to participate in a clinical trial** involving the eligible investigational drug, as certified by a doctor, who is in good standing with her licensing organization and will not be compensated directly by the manufacturer for so certifying; and
- Give written **informed consent** regarding the risks associated with taking the investigational treatment.

Q: What is a life-threatening disease or condition?

A: Federal law defines a life-threatening disease or condition as: "Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted" (21 CFR 312.81).

Q: What drugs or treatments qualify for Right to Try?

A: The treatments available under the law must meet the following conditions:

- Have **completed an FDA-approved Phase 1** clinical trial;
- Be **in an active clinical trial** intended to form the basis of an application for approval or be the subject of an application for approval that has been filed with the FDA; and
- Be in **ongoing active development or production** and not discontinued by the manufacturer or placed on clinical hold.

Q: I do not live in a state with a Right to Try law. Can I still use Right to Try?

A: Yes. S.204 makes Right to Try the law of the land. So long as a patient and treatment meet the qualifications of the federal law, Right to Try applies, regardless of whether the patient's state adopted Right to Try.

Q: Does medical cannabis qualify?

A: Right to Try only applies to treatments that have completed an FDA-approved Phase 1 clinical trial and remain under study in an active clinical trial. If there is a Phase 2 or 3 clinical trial for medical cannabis as a treatment of an underlying terminal condition, it may qualify.

Q: What can companies charge for treatments?

A: Federal law bans companies from making a profit on any drug or treatment that has not been approved by the FDA, but the law does allow companies to recover the costs that are directly related to providing an individual treatment. Existing regulations govern what can and cannot be included in the calculation for determining the direct costs that can be charged. You can read that formula here: <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm351264.pdf>. This means that a patient could be charged for the direct costs of providing their individual treatment, but the company cannot make a profit.

Q: How will payment work?

A: Just like with the FDA's existing Expanded Access program, insurance companies and taxpayer-funded healthcare programs like Medicaid or Medicare are not required to cover the cost of investigational treatments, but they may choose to do so. Some insurance companies have covered the costs of investigational treatments used by patients under state Right to Try laws, but others have not. Each patient's cost situation will be different and determined by their individual insurance company or program and their own financial resources.

Q: How do I initiate a request?

A: The patient, the patient's representative, or physician should send a letter to the drug manufacturer's director of compassionate use or other designated representative to discuss options for access. [A sample letter is provided here.](#)

Q: Where can I find a list of potential treatments?

A: If your physician is not yet aware of investigational treatments, there are several websites that can assist in locating potential treatments:

<https://clinicaltrials.gov/>

<https://platform.emergingmed.com/find-clinical-trials/cr#partnerhome>

<https://www.cancer.gov/about-cancer/treatment/clinical-trials/search>

Q: Is a drug company required to make a treatment available?

A: No. Drug companies are not required to provide treatments to patients under Right to Try laws. It would not be appropriate to force companies to provide treatments that they do not think are the right fit for a patient or if they do not have enough supply to provide the treatment outside of its clinical trial.

Q: Can I make my doctor submit a request for a treatment I want to try?

A: No. Doctors have a responsibility to ensure that patients are given treatments that they believe, in their professional opinion, could help them. A doctor who does not think a treatment will help is not obligated to make a request for the treatment. In addition, doctors who pursue treatments under Right to Try must be in good standing with their state licensing or certifying board, and they cannot be compensated for certifying that patients qualify for Right to Try.

Q: How will a company decide if they will give me the treatment?

A: Each company will develop its own process and procedures for approving Right to Try requests.

