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Key Legislative Developments Affecting Your Human Resources US

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“Right to Try” Legislation Enacted – No Impact on Benefit Plans Expected

President Trump signed the Right to Try Act, which allows terminally ill patients to use certain experimental drugs that have not been approved by the FDA. However, the legislation does not require pharmaceutical companies to provide these drugs or employer-sponsored plans to cover them.

Law Aims to Expand Access to Experimental Drugs for Terminally Ill

On May 30, 2018, President Trump signed into law the [Right to Try Act](#), which removes specified Food and Drug Administration (FDA) restrictions “on the provision of certain unapproved, investigational drugs to a terminally ill patient who has exhausted approved treatment options and is unable to participate in a clinical trial involving the drugs.” The bill requires the manufacturer or sponsor of such drug to report annually to the FDA on the use of the drug pursuant to this legislation, and limits the liability of a sponsor, manufacturer, prescriber, or dispenser that provides, or declines to provide, an investigational drug under this law. In his [remarks](#) accompanying the signing, the president said that the law “offers new hope for those who either don’t qualify for clinical trials or who have exhausted all available treatment options.”

Critics maintain that the new law changes very little. While it allows patients to try experimental drugs under certain circumstances, it does not require pharmaceutical companies to provide them. Additionally, they argue, the FDA’s [“compassionate use”](#) program already allows terminally ill patients expanded access to experimental drugs, and most states already have similar laws in place.

No Expected Changes for Employer-Sponsored Plans

The legislation does not mandate employer-sponsored plan coverage of drugs the FDA characterizes as investigational or experimental drugs. Indeed, most employer plans explicitly exclude those drugs from coverage.



Additionally, even if a plan sponsor wanted to offer this type of coverage, doing so would pose administrative challenges. Prescription drugs must have FDA approval in order to have a national drug code (NDC), which is necessary for a pharmacy benefit manager or a pharmacy to process a claim.

In Closing

Plan sponsors need not make any coverage, administrative, or other changes in response to the newly enacted Right to Try law.

Authors

Julia Zuckerman, JD
Richard Stover, FSA, MAAA

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