F I S C A L I M P A C T R E P O R T

SPONSOR Powdrell-Culbert **ORIGINAL DATE** 2/8/17 **LAST UPDATED** 2/15/17 **HB** 263/ec

SHORT TITLE Right to Try Act **SB**

ANALYST Chilton

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY17	FY18	FY19	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
Start-up	$50.0			$50.0	Nonrecurring	General Fund
Fixed	$18.6	$95.5	$95.5	$209.6	Recurring	General Fund
Total	$68.6	$95.5	$95.5	$259.6	Mixed	General Fund

(Parenthesis ( ) Indicate Expenditure Decreases)

Relates to, and slightly conflicts with, House Bill 228.

SOURCES OF INFORMATION
LFC Files

Responses Received From
Office of the Attorney General's (OAG)
Office of the Superintendent of Insurance (OSI)
Board of Nursing (BN)
Department of Health (DOH)

SUMMARY

Synopsis of Bill

House Bill 263 would establish a pathway by which patients with "advanced illnesses" would be able to avail themselves of new medications prior to full Federal Drug Administration (FDA) approval.

Patients with "terminal illnesses" would be eligible if they had considered all fully-approved medications, were residents of New Mexico over 18 years of age, were unable to be part of a clinical trial for the yet-to-be-approved drug, had had a physician recommendation for the desired drug, and had signed informed consent for the drug.

Components of the required informed consent are specified, to include

- A dated, written statement from the patient's physician stating the diagnosis and terminal nature of the illness
- Currently approved drugs and treatments that could be used
- The investigational drug, biologic product or device desired
- Disclosure of applicable clinical trials within 100 miles
- Designation of a supervising physician and specification of the treatment plan
- Disclosure of any financial relationships between the physician and the manufacturer
- Acknowledgement that the patient may be required to pay all costs related to the medication and the treatment surrounding its use
- A statement that in-home health care may be withdrawn
- Advice that the patient and his/her estate may be liable for expenses related to use of the desired product
- Waiver of liability in favor of a supervising or treating physician arising from recommendation or use of the investigational product

Treating and supervising physicians would be required to report adverse effects of the investigational product to DOH.

Manufacturers of such drugs are permitted but not required to provide the drug to the patient, and the legislation specifically states that the manufacturer may choose whether or not to provide the medication without charge.

Insurance companies would not be obliged to cover the cost of the drug or the care surrounding its use.

An emergency clause is included.

FISCAL IMPLICATIONS

No fiscal impact is suggested other than upon the Department of Health if it were to be required to take reports of adverse reactions to investigational drugs, a part of this bill but not of House Bill 228. Those costs, related in the table above, are calculated by DOH on the following basis:

> HB263 would require NMDOH to monitor and respond to reports of adverse or suspected adverse events stemming from the provisions of HB263. This would require a new data collection system and at least one FTE to collect, analyze, and report data. The FTE should preferably be an Epidemiologist-A, at a projected yearly cost of $75,553 (Epidemiologist-A mid-point @ $54,355 x 39% indirect = $75,553). The data collection system would be new and would need to be housed on a HIPAA and HITECH compliant web-based platform to ensure privacy and security of Protected Health Information. The initial Information Technology (IT) set-up cost could be $50,000 with an ongoing maintenance cost of $20,000 per year.

SIGNIFICANT ISSUES

DOH makes note of several problems:

- A requirement that an eligible patient be at least 18 years of age. This does not provide an option for a parent or legal guardian to provide written, informed consent for treatment of a terminally ill minor.
- A requirement that an eligible patient cannot be an inpatient in a hospital or other licensed health care facility. Given that eligible patients must be terminally ill, their care and treatment, even with an investigational product, may need to be overseen in a hospital or other licensed health care facility.
- A warning that hospice care eligibility will be available to a patient while undergoing treatment with an investigational product. Hospice care and drug treatment are not mutually exclusive.

According to the Right To Try organization's website (righttotry.org), "Right To Try laws are already in place in 33 states and counting: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois , Indiana, Louisiana, Maine, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, West Virginia and Wyoming. Seventeen additional states are considering the law this year."
The National Conference of State Legislatures (NCSL) prepared a summary of information about Right To Try legislation in 2015. It notes that the model legislation for "Right to Try" was designed by the Goldwater Institute in Arizona. NCSL cites advantages and disadvantages of the laws as follows:

> **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.
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> **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."

The FDA already has a mechanism in place for what is called "compassionate use" for patients desiring the use of a drug that has passed Phase I (safety) trials. The means for achieving permission for compassionate use has been greatly simplified in the last several years, and often can be completed in days or even hours.

OSI notes "Since we may soon have new federal statutes regarding health insurance, it is very hard to say what the consequences of enacting or not enacting this bill will be in any changed upcoming regulatory environment. Currently, health insurance companies do sometimes change their formularies in the middle of the plan year. They also drop providers in the middle of the

plan year; however, we do already have regulations in place to ensure that health care insurance companies do meet New Mexico's network adequacy provider requirements."

PERFORMANCE IMPLICATIONS

DOH states that it does not at this point take reports of adverse reactions to medications, as would be required by this bill. DOH has made an estimate of the costs (see Fiscal Impact above) for receiving reports of adverse reactions, but states that taking such reports is more likely the function of other state or federal agencies.

RELATIONSHIP with House Bill 228, which also enacts a "Right to Try Act," but differs in small as well as in more significant ways. Minors would not be able to participate under HB 228's "Right to Try Act," and participants would have to have an "advanced disease or condition," not necessarily "a terminal condition.

OTHER SUBSTANTIVE ISSUES

As noted by DOH, "Given that there may be many uncovered costs associated with accessing an investigational drug through the provisions of HB228, it is anticipated that individuals with lower incomes and lower household wealth would be less likely to benefit from the bill."

WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL

Patients wishing to use an investigational drug would continue to be required to avail themselves of the FDA's "Compassionate Use" procedure, or go without the desired medication.

LAC/jle