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

SPONSOR HHHC **ORIGINAL DATE** 2/16/17 **LAST UPDATED** 3/10/17 **HB** CS/228 & 263/aHHHCS/aHJC/a HFl#1

SHORT TITLE Right to Try Act **SB**

ANALYST Chilton/Daly

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	Emergency Declaration FY 17	FY 18	FY 19	FY 20	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
Start up	$50.0				$50.0	Nonrecurring	General
Fixed	$18.6	$95.5	$95.5	$95.5	$305.1	Recurring	General
Total	$68.8	$95.5	$95.5	$95.5	**$355.3**	Mixed	General

Combines similar House Bills 228 and 263

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 HFl#1

The House Floor Amendment #1 to House Health and Human Services Committee Substitute for House Bills 228 and 263 as substituted and amended provides the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with investigational drugs, biological products or devices and may be reinstated if this treatment ends and the patient still meets hospice eligibility requirements. It further removes the clause that an entity responsible for Medicare certification shall not take action solely on the health care provider's recommendation for a patients access to an investigational drug, biological product or device.

Synopsis of HJC Amendment

The House Judiciary Committee amendment to the House Health and Human Services Committee Substitute for House Bills 228 and 263 strikes the good faith requirement from the section providing manufacturers' immunity from civil liability (but leaves in place the exercise of reasonable care requirement).

Synopsis of Original Bill

The House Health and Human Services Committee Substitute for House Bills 228 and 263 would establish a pathway by which patients with "terminal illnesses" would be able to avail themselves of new medications prior to full Federal Drug Administration (FDA) approval.

"Terminal illness" is defined in the bill 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" with fully approved FDA remedies and will soon result in death.

Patients with "terminal illnesses" would be eligible if they had considered all fully-approved medications, 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

- Currently approved drugs and treatments that could be used
- Physician and patient concurrence that approved treatments would not prolong life
- Description of the best and worst outcomes of using the medication
- A statement that health care coverage may exclude payment for the medication
- A statement that the availability of hospice care will not be affected
- Acknowledgement that the patient may be required to pay all costs related to the medication and the treatment surrounding its use.

Parents would sign the informed consent in the case of a minor with advanced disease.

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. However, if the patient were to die while being treated with an investigational drug, his/her heirs would not be liable for outstanding debts related to use of that drug.

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

Physicians recommending an investigational drug to a patient would not be subject to licensing or disciplinary action based on that recommendation.

Treating and supervising physicians would be required to report adverse reactions to the investigational drug or device to the Department of Health.

FISCAL IMPLICATIONS

DOH states "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

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.

Appropriately, the bill does not define the term "soon" as in "'terminal illness' means…that will soon result in death." It is difficult for health care providers to prognosticate with certainty the remaining time permitted to a patient with an incurable terminal disease.

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."

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 [this bill], 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/sb/al