HB14-1281

Colorado Legislative Council Staff Fiscal Note

FINAL FISCAL NOTE

Drafting Number:	LLS 14-0892	**Date:**	July 28, 2014
Prime Sponsor(s):	Rep. Ginal; Joshi Sen. Rivera; Aguilar	**Bill Status:**	Signed into Law
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SHORT TITLE: TERMINAL PATIENTS INVESTIGATIONAL DRUGS

Fiscal Impact Summary*	FY 2014-2015	FY 2015-2016
State Revenue		
State Expenditures	Minimal increase in workload and costs.	
FTE Position Change		
Appropriation Required: None.		

** This summary shows changes from current law under the bill for each fiscal year.*

Summary of Legislation

The bill creates The Right to Try Act, permitting eligible patients to use investigational drugs, biological products, or devices (investigational products) that are pending approval from the United States Food and Drug Administration (FDA).

A patient is eligible to participate if he or she has a terminal illness and has considered all other treatment options currently approved by the FDA. Eligible patients must also have been unable to participate in clinical trials previously. Eligible patients must receive a recommendation from their physician to use an investigational product. Eligible patients must also obtain written, informed consent, as defined in the bill.

Manufacturers may choose to make their investigational products available to eligible patients without receiving compensation. Manufacturers may also require eligible patients to pay any costs associated with the manufacturing of the investigational product. The bill does not impose any requirement on manufacturers to make an investigational product available to eligible patients. The bill authorizes manufacturers to charge patients for any costs associated with investigational products.

Under the bill, health insurance carriers may, but are not required to, provide coverage for eligible patients seeking an investigational product. A licensing board may not discipline or take any other action against a physician's license based solely on a physician's recommendation to an eligible patient regarding the use of investigational products, as long as recommendations are consistent with medical standards of care. An official, employee, or agent of the state cannot block or attempt to block any eligible patient's access of an eligible patient to an investigational product. Finally, the bill clarifies that it does not create a new cause of action against a manufacturer if a patient is harmed by its investigational product.

Background

State agencies such as the Department of Corrections (DOC) and the State Veterans Nursing Homes within the Department of Human Services (DHS) care for terminally ill patients. The DOC estimates having approximately 20 terminally ill patients in their care at any given time. The State Veterans Nursing Homes currently have 10 patients in Hospice Care. These are estimates based on the current number of patients and may fluctuate over time.

State Expenditures

The bill does not create new liability for state agencies to pay for the cost of investigational products. At any given time, the DOC and the DHS will have custody of only a small number of patients, if any, who are terminally ill and meet other eligibility criteria set forth in the bill. In situations where a manufacturer charges patients for the cost of investigational products, the fiscal note assumes that persons in the custody of state agencies will be able to apply financial resources, insurance, and any other similar benefit to the extent allowed by current law. State Agencies may also choose to pay for treatment if costs are comparable to other treatments and can be paid within existing appropriations. In addition, the DOC may have costs for security, transportation, and other logistics if inmates receive investigational products outside of DOC facilities.

Effective Date

The bill was signed into law by the Governor and took effect on May 17, 2014.

State and Local Government Contacts

Health Care Policy and Financing	Corrections
Higher Education	Judicial
Regulatory Agencies	Human Services