

**STATE and LOCAL
FISCAL IMPACT**

Drafting Number: LLS 14-0892	Date: March 4, 2014
Prime Sponsor(s): Rep. Ginal; Joshi Sen. Rivera; Aguilar	Bill Status: House Health, Insurance, and Environment
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SHORT TITLE: TERMINAL PATIENTS INVESTIGATIONAL DRUGS

Fiscal Impact Summary*	FY 2014-2015	FY 2015-2016
State Revenue	Potential increase.	
State Expenditures	Potential increase.	
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, but not requiring, eligible patients to participate in clinical trials or 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 receive a prescription or recommendation from their physician to use an investigational product. 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. The Colorado Medical Board, within the Department of Regulatory Agencies, 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. If an official, employee, or agent of the state blocks access of an eligible patient to an investigational product, the individual commits a class 1 misdemeanor. 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.

Local Government Impact

The bill may increase workload and expenditures for county governments by a minimal amount. Increased efforts by county governments include district attorney caseload, caseload in the Denver county court, and demand on county jails, as discussed below.

District attorney caseload. District attorneys will investigate complaints regarding individuals who may have blocked an eligible patient's access to investigational products. The fiscal note assumes district attorneys will accommodate this workload within existing resources.

Denver county court. The Denver County Court, funded entirely by the City and County of Denver, may experience a small increase in trial caseload related to possibly criminal enforcement of the bill.

Demand on county jails. This bill impacts local governments by creating the new crime of blocking the access of an eligible patient to investigational products, which is a class 1 misdemeanor. The penalty for a class 1 misdemeanor is 6 to 18 months in a county jail, a fine of \$500 to \$5,000, or both. Because the courts have the discretion of incarceration or imposing a fine, the impact at the local level cannot be determined. The cost to house an offender in county jail varies from \$45 to \$50 per day in smaller rural jails to \$62 to \$65 per day for larger Denver-metro area jails. For the current fiscal year, the state reimburses county jails at a daily rate of \$51.45 to house state inmates. It is assumed that the impact of this bill will be minimal.

Effective Date

The bill takes effect upon signature of the Governor, or upon becoming law without his signature.

State and Local Government Contacts

Health Care Policy and Financing
Higher Education
Regulatory Agencies

Corrections
Judicial
Human Services