

Fiscal Estimate - 2021 Session

Original
 Updated
 Corrected
 Supplemental

LRB Number 21-5283/1	Introduction Number AB-0979
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Description
 right to try off-label therapies

Fiscal Effect

State:

<input type="checkbox"/> No State Fiscal Effect	<input type="checkbox"/> Increase Existing Revenues	<input checked="" type="checkbox"/> Increase Costs - May be possible to absorb within agency's budget
<input checked="" type="checkbox"/> Indeterminate	<input type="checkbox"/> Decrease Existing Revenues	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<input type="checkbox"/> Increase Existing Appropriations		<input type="checkbox"/> Decrease Costs
<input type="checkbox"/> Decrease Existing Appropriations		
<input type="checkbox"/> Create New Appropriations		

Local:

<input type="checkbox"/> No Local Government Costs	5. Types of Local Government Units Affected	
<input type="checkbox"/> Indeterminate		
1. <input type="checkbox"/> Increase Costs	3. <input type="checkbox"/> Increase Revenue	<input type="checkbox"/> Towns <input type="checkbox"/> Village <input type="checkbox"/> Cities
<input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory	<input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory	<input type="checkbox"/> Counties <input type="checkbox"/> Others
2. <input type="checkbox"/> Decrease Costs	4. <input type="checkbox"/> Decrease Revenue	<input type="checkbox"/> School Districts <input type="checkbox"/> WTCS Districts
<input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory	<input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory	

Fund Sources Affected	Affected Ch. 20 Appropriations
<input type="checkbox"/> GPR <input type="checkbox"/> FED <input checked="" type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEGS	s.20.165(1)(g)

Agency/Prepared By	Authorized Signature	Date
DSPS/ Lilian Kelly (608) 266-0958	Daniel Hereth (608) 267-2435	5/20/2022

Fiscal Estimate Narratives

DSPS 5/20/2022

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Assumptions Used in Arriving at Fiscal Estimate

Under current law, a manufacturer of an investigational drug, device, or biological product may make the investigational drug, device, or biological product available to an eligible patient. "Investigational drug, device, or biological product" is defined to mean a drug, device, or biological product that has not been approved or licensed for use by the federal Food and Drug Administration and that meets certain conditions relating to its status in clinical trials approved by the FDA.

This bill adds off-label therapies to those drugs, devices, or biological products that an eligible patient may receive. Under the bill, "off-label therapy" is defined to mean a use of a drug, device, or biological product approved by the FDA other than a use approved by the FDA. The same requirements and protections that exist under current law for investigational drugs, devices, and biological products also apply to off-label therapies.

The Department estimates that it will incur one-time costs totaling \$5,100 for staff salary, fringe, and overhead to review, update and communicate rules, modify forms and websites, and establish procedures regarding the change. This one-time cost can be absorbed in the current DSPS budget.

Long-Range Fiscal Implications

Fiscal Estimate Worksheet - 2021 Session

Detailed Estimate of Annual Fiscal Effect

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Description right to try off-label therapies			
I. One-time Costs or Revenue Impacts for State and/or Local Government (do not include in annualized fiscal effect):			
The Department estimates that it will incur one-time costs totaling \$5,100.			
II. Annualized Costs:		Annualized Fiscal Impact on funds from:	
		Increased Costs	Decreased Costs
A. State Costs by Category			
State Operations - Salaries and Fringes		\$	\$
(FTE Position Changes)			
State Operations - Other Costs			
Local Assistance			
Aids to Individuals or Organizations			
TOTAL State Costs by Category		\$	\$
B. State Costs by Source of Funds			
GPR			
FED			
PRO/PRS			
SEG/SEG-S			
III. State Revenues - Complete this only when proposal will increase or decrease state revenues (e.g., tax increase, decrease in license fee, etc.)			
		Increased Rev	Decreased Rev
GPR Taxes		\$	\$
GPR Earned			
FED			
PRO/PRS			
SEG/SEG-S			
TOTAL State Revenues		\$	\$
NET ANNUALIZED FISCAL IMPACT			
		<u>State</u>	<u>Local</u>
NET CHANGE IN COSTS		\$	\$
NET CHANGE IN REVENUE		\$	\$
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