



GOVERNOR'S OFFICE OF  
BUDGET AND PROGRAM PLANNING

## Fiscal Note 2009 Biennium

<b>Bill #</b>	SB0428	<b>Title:</b>	Assurance coverage of routine costs of clinical trials
<b>Primary Sponsor:</b>	Kaufmann, Christine	<b>Status:</b>	As Amended in House Committee

- |  |  |  |
|--|--|--|
| <input checked="" type="checkbox"/> Significant Local Gov Impact | <input type="checkbox"/> Needs to be included in HB 2  | <input checked="" type="checkbox"/> Technical Concerns   |
| <input type="checkbox"/> Included in the Executive Budget        | <input type="checkbox"/> Significant Long-Term Impacts | <input type="checkbox"/> Dedicated Revenue Form Attached |

### FISCAL SUMMARY

	<u>FY 2008</u> <u>Difference</u>	<u>FY 2009</u> <u>Difference</u>	<u>FY 2010</u> <u>Difference</u>	<u>FY 2011</u> <u>Difference</u>
<b>Expenditures:</b>				
General Fund	Unknown	Unknown	Unknown	Unknown
State Special Revenue	Unknown	Unknown	Unknown	Unknown
Federal Special Revenue	Unknown	Unknown	Unknown	Unknown
Other	Unknown	Unknown	Unknown	Unknown
<b>Revenue:</b>				
General Fund	\$0	\$0	\$0	\$0
State Special Revenue	\$0	\$0	\$0	\$0
Federal Special Revenue	\$0	\$0	\$0	\$0
Other	Unknown	Unknown	Unknown	Unknown
<b>Net Impact-General Fund Balance</b>	<u>Unknown</u>	<u>Unknown</u>	<u>Unknown</u>	<u>Unknown</u>

### Description of fiscal impact:

This bill requires insurance coverage of routine patient costs for patients participating in a cancer clinical trial. Routine patient care costs means the cost of a medical item or service that would normally be covered under a person's insurance contract, as if the person had not enrolled or participated in the clinical trial, including the administration of the drug or item under evaluation in the clinical trial.

The bill applies to the state group insurance program, the university system employee group insurance program, and any group insurance plan program of a city, town, school district, or other political subdivision of the state, any self funded multiple employer welfare arrangement that is not regulated by the Employee Retirement Income Security Act, and the Children's Health Insurance Program (CHIP).

## FISCAL ANALYSIS

### Assumptions:

#### Department of Administration – State Health Insurance Plan

1. It is not possible to project the costs which the State of Montana health insurance plan could potentially incur or avert with passage of SB 428 which will require insurance coverage of routine patient care costs for patients participating in a cancer clinical trial.
2. Currently there is no mechanism for patients or providers to report to insurers when a patient is participating or enrolled in a clinical trial. This bill would provide the ability for notification and permit health plans to adjudicate claims to ensure that routine costs of care are covered as provided under the member's medical contract while permitting the costs associated with the clinical trial to be covered by the appropriate party(ies).
3. The State Employee Health Plan is unable to determine true incidence rates for participation in clinical trials within its population at this point in time. (Due to lack of information/notification.) Therefore, we are unable to determine what the change from current payments for impacted members would be under this bill.

#### Montana University System (MUS) Group Insurance Plan

4. The fiscal impact to the MUS Group Insurance Plan is unknown. Similar to the State Health Insurance Plan, it is not possible to determine the incidence rates for plan members or the net impact to costs to the plan at this time. To the extent that costs increase, these additional costs would have to be covered by additional state contributions or additional employee's contributions.

#### Department of Public Health and Human Services – Children's Health Insurance Program

5. Under the definitions provided in Section 1, it is difficult to gather data for routine patient care costs for cancer clinical trials. Also, there are many forms of cancer, making it more difficult to gather data to statically project costs for clinical trials.
6. Medicaid coverage would not be expanded under this bill, but Children's Health Insurance Program (CHIP) coverage would be increased.
7. For this fiscal note, the Department of Public Health and Human Services (DPHHS) looked at 5 individual Medicaid cases involving children which were treated by the Denver Children's Hospital for cancer. DPHHS looked at these 5 patients due to the type of specialized treatments they were receiving, and considered the possibility that they could be potential candidates for clinical trials.
8. For the 5 cancer cases that were analyzed, the hospital cost for each patient averaged \$413,730. The total medical expenditures were \$2,068,650.
9. Children with high costs may move to Medicaid depending on their eligibility status.
10. Under this bill, the department assumes it would have 2 new (CHIP) cases treated in a hospital for clinical trials.
11. Using statistical data from the National Center for Biotechnical Information article "Incremental treatment costs in national cancer institute-sponsored clinical trials", the incremental costs of direct care in clinical trials were approximately 6.5 percent higher for trial participants than non-participants.
  - a. Average costs for the 5 participants \$413,730 x 6.5 percent increase clinical trial = \$26,892
  - b. Additional costs for clinical trial participants - \$26,892 x 2 = \$53,784
12. The costs begin on January 1, 2008 and are estimated to increase at 2.5 percent in FY 2009, FY 2010, and FY 2011.
13. The table below shows the costs estimated per fiscal year and the CHIP Federal Medical Assistance Percentage (FMAP):

	Avg. Costs	No. of cases	Total costs	
<b>Avg. Total</b>	<b>26,892</b>	<b>2.00</b>	<b>53,784</b>	
		FMAP Rates	Gen Fund	Federal
FY 2008 Jan.1	26,892	0.2193	5,897	20,995
FY 2009	55,129	0.2211	12,189	42,940
FY 2010	56,507	0.2211	12,494	44,013
FY 2011	57,920	0.2211	12,806	45,114

	<u>FY 2008 Difference</u>	<u>FY 2009 Difference</u>	<u>FY 2010 Difference</u>	<u>FY 2011 Difference</u>
<b><u>Fiscal Impact:</u></b>				
<b><u>Expenditures:</u></b>				
Personal Services	Unknown	Unknown	Unknown	Unknown
Benefits	Unknown	Unknown	Unknown	Unknown
<b>TOTAL Expenditures</b>	<b>Unknown</b>	<b>Unknown</b>	<b>Unknown</b>	<b>Unknown</b>
<b><u>Funding of Expenditures:</u></b>				
General Fund (01)	Unknown	Unknown	Unknown	Unknown
State Special Revenue (02)	Unknown	Unknown	Unknown	Unknown
Federal Special Revenue (03)	Unknown	Unknown	Unknown	Unknown
Other (06) (Group & MUS Plans)	Unknown	Unknown	Unknown	Unknown
<b>TOTAL Funding of Exp.</b>	<b>Unknown</b>	<b>Unknown</b>	<b>Unknown</b>	<b>Unknown</b>
<b><u>Revenues:</u></b>				
General Fund (01)	\$0	\$0	\$0	\$0
State Special Revenue (02)	\$0	\$0	\$0	\$0
Federal Special Revenue (03)	\$0	\$0	\$0	\$0
Other (06) (Group & MUS Plans)	Unknown	Unknown	Unknown	Unknown
<b>TOTAL Revenues</b>	<b>Unknown</b>	<b>Unknown</b>	<b>Unknown</b>	<b>Unknown</b>
<b><u>Net Impact to Fund Balance (Revenue minus Funding of Expenditures):</u></b>				
General Fund (01)	Unknown	Unknown	Unknown	Unknown
State Special Revenue (02)	Unknown	Unknown	Unknown	Unknown
Federal Special Revenue (03)	Unknown	Unknown	Unknown	Unknown
Other (06) (Group & MUS Plans)	Unknown	Unknown	Unknown	Unknown

**Effect on County or Other Local Revenues or Expenditures:**

This bill could result in higher medical insurance premiums to group insurance plan programs of a city, town, school district, or other political subdivision of the state and any self-funded multiple employer welfare arrangement that is not regulated by the Employee Retirement Income Security Act. Some of these groups re-insure. They will need to work with re-insurers to provide coverage under this change in law or determine if they will need to absorb any changes in cost if re-insurers increase premiums.

**Technical Notes:**

Department of Administration - State Health Insurance Plan

1. Under 33-1-102(7), MCA, the State Employee Group Insurance Program is exempted from provisions of Title 33. SB 428 amends Title 33 and under Section 1 includes the state employee group insurance program as a covered entity for purposes of this legislation. These two sections of statute appear to be in conflict.

Montana University System (MUS) Health Insurance Plan

2. Under 20-25-130 3(2), MCA, the MUS Group Insurance Program is exempted from provisions of Title 33. SB428 amends Title 33 and under Section 1 includes the MUS employee group insurance program as a covered entity for purposes of this legislation. These two sections of statute appear to be in conflict.

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*Sponsor's Initials*

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*Date*

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*Budget Director's Initials*

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*Date*