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FISCAL IMPACT REPORT

ORIGINAL DATE 03/13/09

SPONSOR Egolf LAST UPDATED _____ HM 102

SHORT TITLE Cancer Clinical Trial Interim Study SB _____

ANALYST Peery-Galon

APPROPRIATION (dollars in thousands)

Appropriation		Recurring or Non-Rec	Fund Affected
FY09	FY10		
	NFI		

(Parenthesis () Indicate Expenditure Decreases)

SOURCES OF INFORMATION

LFC Files

Responses Received From

Department of Health (DOH)
Public Regulation Commission (PRC)
General Services Department (GSD)

No Responses Received From

Children, Youth and Families Department
Health Policy Commission

SUMMARY

Synopsis of Bill

House Memorial 102 requests that the Legislative Council Services charge the interim legislative Health and Human Services Committee with examining the existing law pertaining to cancer clinical trials, as well as law pertaining to medical liability and parental consent for treatment of children, in light of the needs of New Mexico children who wish to have the opportunity to participate in phase one cancer clinical trials. The memorial requests the Health and Human Services Committee be charged with examining the effect of the current legal framework that affects whether sponsors and insurers will permit New Mexico children to participate in phase one cancer clinical trials. The memorial also charges the Health and Human Services Committee with making legislative recommendations to address the needs of New Mexico children who would benefit from participation in phase one cancer clinical trials, while addressing the concerns of insurers and sponsors regarding New Mexico children's participation.

SIGNIFICANT ISSUES

DOH reported phase I clinical trials are early studies of new treatments in people. The goals of a phase I trial are usually to find out whether an experimental treatment is safe in people and to establish the best dose to test in larger studies to benefit future patients. The dose is usually increased a little at a time in order to find the highest dose that does not cause harmful side effects. Because little is known about the possible risks and benefits of the treatments being tested, phase I trials usually include only a small number of patients who have not been helped by other treatments. What's more, patients who enroll in phase I trials in new cancer treatments typically have advanced disease that is no longer responding to conventional treatments. Although phase I trials are not designed to provide treatment to participants, past estimates have suggested that about 5 percent of participants demonstrate some treatment response. If the results of phase I tests are promising, a treatment will be studied further in phase II and III trials, which are designed to test whether a new treatment has an anticancer effect, whether it works against a certain type of cancer, or to compare the results of people taking a new treatment with the results of people taking the standard treatment. (www.cancer.gov/clinicaltrials/results/phase-1-safety0305)

DOH reported that although the absolute number of deaths due to cancer in children and adolescents is low relative to adults, the toll in terms of potential years of life lost is high. Cancer remains the second leading cause of death among New Mexico children ages one through 14 years. Children are often enrolled in clinical treatment trials, and much of the improvement in patient survival since 1973 can be attributed to treatment advances due to high rates of participation by children in cancer clinical trials. (www.cancernm.org/cancercouncil/facts_figures.htm)

DOH noted advances in cancer care and the development of cancer therapeutics depends largely upon an effective clinical trial process. It is important to ensure that the parents of children enrolled in cancer clinical trials understand they are participating in research that is designed to advance science for the greater good. This is particularly important for participation in phase I trials, since these studies are designed to evaluate safety and dose-finding parameters in accordance with a scientific protocol; they are not designed to provide or optimize personalized medical benefit for particular patients.

PRC reported that current law, Section 59A-22-43 NMSA 1978, requires that health plans provide coverage for routine patient care costs incurred as a result of the patient's participation in a phase II, III or IV cancer clinical trial. There is no mandate that insurers pay for routine patient care costs incurred as a result of the patient's participation in a phase I cancer clinical trial, nor is there any mandating such coverage for only children.

PRC stated that in the study, the Health and Human Services Committee will need to address whether this type of mandate will cause significant added costs in the commercial marketplace, based on per child cost, and expected change in usage of health care services and coverage compared to current usage and coverage.

PRC noted in the small group market, the cost of insuring individuals with high health care costs could be expected to drive up costs to further erode what is already an eroding market in the state of New Mexico. According to the Agency for Healthcare Research and Quality, Center for Financing, Access and Cost Trends' 2004 Medical Expenditure Panel Survey Insurance

Component., less than 35 percent of New Mexican employers offered coverage. This figure is likely lower today. New Mexico has over 29,000 small firms.

PRC reported in the individual market, persons with pre-existing conditions, such as cancer, are likely to find the type of comprehensive coverage that they need in the New Mexico Medical Insurance Pool, while preserving what have been historically affordable rates of coverage in the state's individual market. If insurers are required to issue policies of health care coverage in the individual market that include cancer treatment coverage, the cost of coverage for all policies in that market may rise, making the product less affordable for others in that market.

GSD reported Section 59A-22-43 NMSA 1978 requiring coverage of patient costs incurred in cancer clinical trials will be repealed effective July 1, 2009. Therefore, as of July 1, 2009 there will be no coverage for phase II, III, or IV clinical trials.

CONFLICT, DUPLICATION, COMPANIONSHIP, RELATIONSHIP

DOH noted that House Memorial 102 relates to:

- Senate Bill 42, which would amend and repeal sections of the New Mexico Insurance Code that relate to coverage of cancer clinical trials, requiring health plans to expand coverage for routine patient care costs incurred as a result of the patient's participation in cancer clinical trials to include phase I trials and prevention trials.
- House Bill 365, which would add new sections to the Health Care Purchasing Act; the Public Assistance Act; and Chapter 59A, Articles 22, 23, 46, 47, NMSA 1978 mandating provision of public and private health insurance coverage for any cancer therapy that is prescribed for individuals from birth to 19 years of age.

House Memorial 102 has a relationship with House Bill 369 regarding donation of cancer drugs and medical devices and House Memorial 56 "Tough Enough to Wear Pink Day" regarding the contributions of Cowboys for Cancer Research and New Mexico State University student athletes to funding cancer research.

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