F I S C A L I M P A C T R E P O R T

SPONSOR Feldman **ORIGINAL DATE** 01/30/09 **LAST UPDATED** 03/19/09 **HB**

SHORT TITLE Cancer Clinical Trial Insurance Coverage **SB** 42/aSPAC/aHBIC

ANALYST Lucero

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY09	FY10	FY11	3 Year Total Cost	Recurring or Non-Rec	Fund Affected
Total		Indeterminate but possibly moderately high	Indeterminate but possibly moderately high	Indeterminate but possibly moderately high	Recurring	General Fund

(Parenthesis ( ) Indicate Expenditure Decreases)

SOURCES OF INFORMATION
LFC Files

Responses Received From
Public Regulation Commission (PRC)
Human Services Department (HSD)
Department of Health (DOH)
Aging and Long-Term Services Department (ALTSD)
Health Policy Commission (HPC)

SUMMARY

Synopsis of HBIC Amendment

The House Business and Industry Committee (HBIC) amendment to SB42 as amended adds the required coverage of patient costs incurred in cancer clinical trials (Section 59A-22-43) to other health insurance sections of the statute including:

1. the Health Care Purchasing Act
2. Section 59A-23-4 NMSA 1978 the statute regarding group health insurance contracts and blanket health insurance contracts;
3. Section 59A-46-30 NMSA 1978 the statute regarding Health Maintenance Organizations;
4. Section 59A-47-33 NMSA 1978 the statute regarding nonprofit health care plans;

Synopsis of SPAC Amendment

The Senate Public Affairs Committee (SPAC) amendment removes reference to the phases of clinical trials and restores language allowing that there would be coverage so long as "the clinical trial is not designed exclusively to test toxicity or disease pathophysiology and it has a therapeutic intent".

Synopsis of Original Bill

Senate Bill 42 (SB42) proposes to amend and repeal sections of the New Mexico Insurance Code, Section 59A-22-43 NMSA 1978 Chapter 27, Section 1, which relates to coverage of cancer clinical trials. SB42 proposes to require a health plan 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.

This bill proposes to repeal the existing exclusion of health plan coverage for clinical trials designed solely to test toxicity or disease pathophysiology. In order for a clinical trial to qualify as applicable, the bill would require that "there is a reasonable expectation based on clinical data that the medical treatment provided in the clinical trial will be at least as effective as any other medical treatment." The bill adds language to specify that a health plan shall not be responsible for out-of-state costs for phase I trials or trials undertaken for the prevention of, or the prevention of recurrence of, cancer.

The Section 59A-22-43 NMSA 1978 is slated for repeal effective July 1, 2009.

FISCAL IMPLICATIONS

The HBIC amendment adds the proposed insurance coverage for the cancer clinical trials to the Health Care Purchasing Act which may increase public employee insurance costs including General Services Risk Management, Retiree Health Care, and Public Schools Insurance Authority. Without additional data, it is difficult to estimate the amount of the increase.

The Veteran's Services Department (VSD) reports, this bill does not appear to have a fiscal impact to the early cancer screen trail now being developed under the administration of New Mexico Tech. The medical component will be covered by the VA Medical Center in Albuquerque so there would be no cost to the veteran.

SIGNIFICANT ISSUES

The SPAC amendment expand coverage for participation in cancer clinical trials to all cancer clinical trials rather than limiting the coverage to participation in certain phases of clinical trials. Existing law limits coverage of participation in cancer clinical trials to Phase II, III or IV cancer clinical trials.

VSD has signed an MOU with New Mexico Tech to develop and administer an early cancer screening test that uses technology developed in New Mexico for early diagnosis of cancer. This trail is targeted at veterans who may have cancer that has not been diagnosed. This trail uses a technology that would use sputum sample to screen for early signs of cancer.

DOH reports:

> Clinical trials are research studies designed to translate basic scientific research results into better ways to prevent, diagnose, or treat cancer. Routine patient care costs associated with participation are paid for either by the patient or by his/her health plan. These include the usual costs of medical care, such as doctor visits, hospital stays, clinical laboratory tests, x-rays, and treatment of any negative effects of the experimental regimen.
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> For eligible cancer patients, the experimental procedures available only through cancer clinical treatment trials may increase survival or improve quality of life compared to standard treatment. However, for many reasons, only about five percent of adult cancer patients participate in cancer clinical treatment trials. Health plan coverage of routine patient care costs for cancer clinical trials may expand access to such trials and encourage more New Mexicans to participate in cancer research. For example, when Congress mandated a change in Medicare policy in 2000 to require the coverage of routine patient care for participants in phase II through IV cancer clinical treatment trials, evidence indicates that the change may have led to increased participation by older patients who have Medicare combined with supplemental private insurance (National Cancer Institute - Supported Clinical Trials: Facts and Figures, www.cancer.gov/clinicaltrials/facts-and-figures)
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> Enrollment in cancer clinical trials is low for all patient groups. Racial and ethnic minorities, women, and the elderly are less likely to enroll in cancer trials than whites, men, and younger patients, respectively. The proportion of trial participants who are black has declined in recent years (Journal of the American Medical Association, vol. 291 #22, 2004).

TECHNICAL ISSUES

The PRC notes that the statute loosely uses the term "health plan," when it would be more accurate throughout Section 59A-22-43 NMSA 1978 to better define the types of individuals who are affected by this mandate. Current practice in the Insurance Division is to construe this legislation as mandating this coverage solely for individual health insurance policies, based on the general scope of Article 22 of the Insurance Code. Notably, most recent mandates found in Part 22 specifically include both the individual and group markets, and apply their mandate as follows: "An individual or group health insurance policy, health care plan or certificate of health insurance that is delivered, issued for delivery or renewed in the state shall provide coverage for…".

OTHER SUBSTANTIVE ISSUES

DOH provides that:

> Clinical cancer treatment trials provide access to either the best available standard treatment or a promising new treatment for patients with cancer. Advances in cancer care and the development of cancer therapeutics depends largely upon an effective clinical trial process. Currently, the NM Insurance Code requires health plan coverage for routine care costs associated with Phase II, III and IV cancer clinical treatment trials.

SB42 proposes to add requirements for health plan coverage of routine patient care costs associated with phase I clinical cancer treatment trials. Phase I trials are designed to determine the highest possible treatment dose and the best method of giving the treatment without causing serious side effects.

Private health insurers are often reluctant to reimburse for routine care costs for patients enrolled in clinical treatment trials due to a perception that costs are significantly higher for patients in trials than for those receiving standard treatment. (NCI, www.cancer.gov/clinicaltrials/developments/notcostly0603) According to a study published in the Journal of the American Medical Association (6/11/03), routine care costs were only slightly higher (3.5%) for patients in Phase III clinical treatment trials versus those on standard care. The cost differentials were larger for phase I and II treatment trials (12.8% higher) compared to standard care.
(NCI, www.cancer.gov/clinicaltrials/developments/notcostly0603)

Unlike clinical cancer treatment trials, clinical prevention trials are not designed to answer questions about curing or increasing survival time for people who currently have cancer. Rather, these trials look for the best ways to prevent cancer in people who have never had cancer or to prevent cancer from coming back or a new cancer occurring in people who have already had cancer. Clinical cancer prevention trials test new approaches, such as medicines, vitamins, minerals, or other supplements that doctors believe may lower the risk of developing a certain type of cancer. Clinical prevention trials tend to enroll larger numbers of participants than treatment trials, cost tens of millions of dollars and require many years of combined intervention and follow-up, and years of investigator and sponsoring agency time to measure the outcomes of interest. Usually, these are studies that will never be repeated (*CA: A Cancer Journal for Clinicians*, 2003). It is not clear what the magnitude of routine health care costs for participants in clinical prevention trials might be. However, even if costs are relatively low per participant, the large number of participants required for many of these trials could potentially result in significant costs. Of note, the NM Insurance Code already requires health plans to cover routine care costs associated with clinical trials for the prevention of reoccurrence of cancer. SB42 proposes to expand this requirement to also include clinical trials for the primary prevention of cancer.

The National Cancer Institute provides information regarding state requirements for coverage of cancer clinical trials costs (http://www.cancer.gov/clinicaltrials/ctlaws-home). According to this site (last updated 12/1/2008), it appears that at least 14 states already require coverage of patient care costs for all phases (I through IV) of clinical cancer treatment trials. There is no clear indication that health plan coverage is required in any state for patient care costs associated with clinical trials for the primary prevention of cancer.

Health plan coverage mandates such as those included in SB42 could lead to increased costs that would likely be passed on to purchasers (i.e., employers and covered individuals). As noted above, there is a published estimate of a 12.8% increase in health care costs for participants in Phase I treatment trials. Of note, Phase I treatment trials typically enroll relatively small numbers of very ill individuals. It is not clear what magnitude of patient care costs might be associated with clinical trials for the primary prevention of cancer, which typically enroll large numbers of healthy individuals.

The Health Policy Commission notes:

> The National Cancer Institute indicates that clinical trials contribute to knowledge of and progress against cancer. Many of today's most effective cancer treatments are based on previous study results. Because of progress made through clinical trials, many people treated for cancer are now living longer.
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> The more people who participate in clinical trials, the faster critical research questions can be answered that will lead to better treatment and prevention options for all cancers.
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> Substantial improvements in treating childhood cancer have come about as the direct result of clinical trials; more than 60% of U.S. children with cancer participate in clinical trials. In 2000, more than 70% of children with cancer were alive five years after diagnosis, compared to only 55% in the mid-1970s. In contrast, only 3% of U.S. adults with cancer participate in clinical trials.
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> According to a 2000 survey, most people with cancer were either unaware or unsure that participation in clinical trials was an option for their treatment, and most of them said they would have been willing to enroll had they known it was possible.
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> The National Cancer Institute reports that each year in the United States:
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> - About 555,550 people die of cancer-more than 1,500 people a day
> - Cancer is the second leading cause of death, exceeded only by heart disease
> - 1 of every 4 deaths are caused by cancer
> - About 1,284,900 new cancer cases are diagnosed
> - According to the Department of Health, cancer remains the second leading cause of death among New Mexico children age one through 14 years.
> - A newborn baby's risk of being diagnosed with cancer before age 20 is about 0.35% or one in 285.
> - Between 1993 and 2002, cancer was diagnosed in almost 800 New Mexican children, adolescents, and young people under the age of 20.
> - The number of newly diagnosed cases has exceeded 100 every year since 2001.
> - Leukemia and brain tumors are common cancers across all ages under 20 years.
> - Some of the cancers occur almost exclusively in the youngest (0-4 years) age group, and the cancers of epithelial origin usually occur in the oldest (15-19 years) age group.
> - Survival rates have improved over the last three decades for most childhood cancers. 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.

ALTERNATIVES

SB42 could require health plan coverage of routine patient care costs for Phase I clinical cancer treatment trials without requiring such coverage for clinical trials for the primary prevention of cancer.

DL/svb