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

SPONSOR HHGAC **ORIGINAL DATE** 3/03/09 **LAST UPDATED** **HB** 365/HHGACS

SHORT TITLE Insurance for Cancer Therapy for Children **SB**

ANALYST Hoffmann

APPROPRIATION (dollars in thousands)

Appropriation		Recurring or Non-Rec	Fund Affected
FY09	**FY10**		
	See Narrative		

(Parenthesis ( ) Indicate Expenditure Decreases)

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY09	FY10	FY11	3 Year Total Cost	Recurring or Non-Rec	Fund Affected
	$0.0	$45.0	$45.0	$90.0	Recurring	General Fund
	$0.0	$105.0	$105.0	$210.0	Recurring	Fed Medicaid Matching
Total	$0.0	$150.0	$150.0	$300.0	Recurring	State and Federal together

(Parenthesis ( ) Indicate Expenditure Decreases)

SOURCES OF INFORMATION

LFC Files

Responses Received From
General Services Department (GSD)
Human Services Department (HSD)
Department of Health (DOH)
Public School Insurance Authority (PSIA)
Children, Youth and Families Department (CYFD)

SUMMARY

Synopsis of HHGAC Substitute for House Bill 365

House Health and Government Affairs Committee Substitute for House Bill 365 makes the coverage requirements tighter than they were in the bill as introduced by limiting to coverage to those items with FDA approval. This also more clearly limits the benefit to drugs. It also now includes coverage of drugs for which there is an investigational new drug application.

The bill would add new sections to the Health Care Purchasing Act and several sections of the state Insurance Code (Health Insurance Contracts, Non Profit Health Care Plans; Health Maintenance Organizations, and Group and Blank Health Insurance Contracts) to health insurance coverage for any cancer therapy approved by the FDA or subject to an FDA investigational new drug application prescribed for children from birth to nineteen years of age, without regard to (1) to inclusion on any formulary; or (2) "any other limiting factor for therapies provided in accordance with the prescribing physician's best medical judgment and meeting reasonable standards of quality of care consistent with prevailing professionally recognized standards of medical practice."

The above requirement would apply to any therapy prescribed to treat the cancer, the effects of cancer, and the side effect of the treatment, as well as therapies to improve the likelihood of treatment success.

The bill would also add a new section to the Public Assistance Act such that the same requirements stated above would apply to the Medicaid Program. In addition, the bill would require HSD to apply for any federal waivers or state plan amendments necessary to ensure this cancer therapy coverage is in compliance with federal requirements.

Additional provisions for the Human Services Department are as follows:

- Does not require HSD to expend state funds when there is no reasonable expectation to receive federal matching funds.
- Requires HSD to make every effort to obtain any prescribed medications free of charge from pharmaceutical manufacturers when federal matching funds are not available.
- Requires HSD to publish quarterly a list on its web site of pharmaceutical manufacturers that agree to provide such medications free of charge and a list of those who refuse to do so.

FISCAL IMPLICATIONS

According to the HSD, House Health and Government Affairs Committee Substitute for House Bill 365 makes no appropriations, but could have a fiscal impact on the state's Medicaid costs as described below by the HSD.

The Medicaid Program already covers the great majority of clinically appropriate and medically necessary therapies that would be required by the bill.

Possible current exceptions to coverage are:

- Formularies (preferred drug lists) of the various managed care organizations and the fee-for-service Medicaid program may not cover all the items used to treat side effects.
- Non-prescription drug items such as vitamins that might be prescribed.
- Items from drug companies that have not signed federal rebate agreements with the Centers for Medicare and Medicaid Services (CMS), though this is uncommon.

The financial impact on the Medicaid Program is estimated to be approximately $150,000 annually. This figure, shown in the "ESTIMATED ADDITIONAL OPERATING BUGET IMPACT" table above, represents $100,000 for drug and therapy costs and $50,000 for the salary and benefits of half-time health professional. This individual would be needed to work with CMS, work with pharmaceutical companies, and perform other duties required in this bill.

SIGNIFICANT ISSUES

The HSD contributed the following concerns.

> The Medicaid program is generally prohibited by federal regulations from covering investigational drug items. However, the bill would not require Medicaid to pay for those items if federal funding can not be obtained. CMS would not likely approve a waiver for this program. Even for waivers, CMS approvals are restricted to the scope of services and providers allowed by the code of federal regulations.
>
> The federal Employee Retirement Income Security Act (ERISA) of 1974 exempts self-insured heath plans from such mandates as this act. ERISA covered plans are exempt from state insurance mandates. It is unclear if self-insured plans are included in this requirement. If so, because of the partial conflict with federal law, this act would create a disparity between self-insured health plans, such as the state employees' health plan, and publicly available commercial health plans.
>
> Most cancer therapies have a "protocol" that is developed for treating the specific cancer. Failure to follow these set protocols was the basis of several suits against UNM Cancer Treatment Center a few years ago. It probably would be far more valuable to require coverage of the National Cancer Institute approved protocols rather than promote deviating from the protocols because of the history of poor outcomes and suits filed after the fact.

According to the DOH, in New Mexico 870 children between the ages of 0-19 were diagnosed with cancer during the ten-year period between 1996-2005 (SEER Program, April 2008). Childhood cancers are rare, but survival has improved significantly over the past 30 years, from less than 50% before the 1970s to 80% today (American Cancer Society, 2008). Treatments may include combined therapies and are chosen based on the type and stage of cancer. Many children are enrolled in clinical trials, which provide access to either the best available standard treatment or a promising new treatment for patients with cancer.

The DOH further notes that even for patients with health care coverage, not all costs associated with cancer treatments are covered by insurers. Health insurance policies generally only pay for "covered benefits" and for services that meet their definitions of "medically necessary," which

often exclude treatments deemed "investigational or experimental." By requiring public and private insurers to provide coverage for medications that are not on the formulary, the bill would eliminate barriers for some pediatric cancer patients. The bill would also require public and private insurers to provide coverage for medications prescribed for a purpose other than that for which it was approved by the FDA (i.e., "off-label use"). Through this provision, the bill could require health plans to pay for treatments that they might otherwise deny as "not medically necessary." Of note, off-label use of pharmaceuticals is neither uncommon nor necessarily undesirable in general medical practice, since the large, expensive clinical trials required for FDA approval for a specific clinical indication often do not take place. The inclusion of non-formulary drugs and off-label use could lead to increased costs. Finally, the bill would require coverage for "therapies provided in accordance with the physician's best medical judgment and meeting reasonable standards of quality of care consistent with prevailing professionally recognized standards of medical practice." This would apply to any therapy prescribed to treat the cancer itself, its side effects, the side effects of the treatment itself, or to increase the likelihood of treatment success. Policies providing short term travel, accident only, and limited/specific disease coverage would not be included in the provisions of the bill. The second half of this provision provides some protection against idiosyncratic or non-evidence-based therapies, but it leaves the possibility of wide interpretation and requires further clarification.

The DOH Children's Medical Services (CMS) provides coordination and payment for medical care for non-Medicaid eligible children and youth with cancer from birth to 21. The new provisions contained in HB 365 would broaden coverage requirements and could increase initial treatment costs to the DOH Children's Medical Services program and other state agencies that provide care to children with cancer.

The CYFD notes the House Health and Government Affairs Committee substitute addresses the HSD concern that requiring insurance coverage for cancer treatments which had not received FDA approval would be an issue with the federal Center for Medicare and Medicaid Services by adding the language "approved by the federal food and drug administration or any cancer therapy subject to a federal food and drug administration investigational new drug application" to relevant portions of the bill.

The PRC Insurance Division reports that a significant issue in the commercial insurance market is the cost of a benefit mandate, and how to determine whether it will result in an increase in premium cost to the consumer. This bill does not appear to limit coverage through the co-payments, deductibles and limits on coverage that are contained in policies of coverage regarding other covered benefits. For instance, the mandate for hearing aid coverage for children, at Section 59A-23-7.8 NMSA 1978, includes this caveat: "*E. Coverage for hearing aids may be subject to deductibles and coinsurance consistent with those imposed on other benefits under the same policy, plan or certificate.*" House Health and Government Affairs Committee Substitute for House Bill 365 however, appears to expressly prohibit any limits. Without any limitations, the cost of the premium is likely to rise, since one way that insurers and employers keep cost increases from rising more than they already do is by placing limits on covered benefits. On the other hand, limits on coverage often cause enormous financial hardships for persons who have what otherwise appears to be adequate health care coverage. Particularly for a person with group health care coverage, there is no option to move out of the group health plan and into the New Mexico Medical Insurance Pool (NMMIP).

Referring to the DOH statistics above, the PRC comments that while the total number of cases is small, the effect on premiums may vary widely, depending on the type of coverage purchased by the consumer. The health insurance plans that would be affected by this mandate include both individual and group health plans and larger state purchasers of group health coverage. The effect of the mandate on premium costs in the individual and small-group market is likely to be greater than in a large, employer-purchased plan.

About half of all states have passed legislation requiring regular review of mandated benefits to access the cost, medical efficacy and/or the public impact. In Massachusetts, for instance, the state's Division of Health Care Finance and Policy was required by state legislation to provide a comprehensive review of the 26 mandated health benefits that were in effect on January 1, 2006. One of the mandates was the use of off-label prescription drugs for the treatment of cancer. The report noted that participating health plans did not have any additional costs, since these costs would be incurred by the plans even without the mandate in place.

The Massachusetts' study found that the 26 mandates overall comprised slightly more than 12% of the premium costs in Massachusetts.

The GSD's Risk Management Division claims that the state's Health Care plans through the appeals process would approve any prescribed drug that met prevailing recognized professional standards. However, their compliance assumes that drugs involved in clinical trial phases 1, 2 and 3 (which they DO NOT cover and which generally are provided at no costs to participants) do not meet prevailing recognized professional standards with regard to treatment.

The PSIA contributed the following comments.

> Assuming an incidence of 15 cancers per 100,000 children (from the National Cancer Institute), we assumed 75 kids will be diagnosed with cancer in NM annually. NMPSIA's medical membership represents about 3% of NM. Therefore, we would expect between 2 - 3 kids to be affected in our pool.
>
> The costs would be determined by the individual physician as to the value of the therapy in terms of the treatment of the patient. We are aware that regimens of these cancer drugs could run from $10 to $15,000 per month. Based on that, our fiscal impact could quite easily be as high as $360,000. It's impossible to predict, but it will be costly.
>
> Since no appropriation is contained in this bill, it will negatively impact PSIA's performance in maintaining premium increases within 3% of national averages.

ADMINISTRATIVE IMPLICATIONS

The HSD states that filing federal waivers, amending the state plan, working with pharmaceutical companies and CMS, and updating accurate information regarding pharmacy are all labor intensive activities.

Securing drug items free-of-charge is also administratively difficult because the pharmacy in New Mexico would still be the agent dispensing the drug items. Often a drug may be required on very short notice. It is not likely that all drug items would be arranged to be free-of-charge in advance.

CONFLICT, DUPLICATION, COMPANIONSHIP, RELATIONSHIP

The DOH comments that House Bill 365 relates to Senate Bill 42, which proposes to amend and repeal sections of the New Mexico Insurance Code that relate to coverage of cancer clinical trials. Senate Bill 42 proposes to amend Section 59A-22-43 NMSA 1978 Chapter 27, Section 1 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.

TECHNICAL ISSUES

HB 365 does not have an effective date for the new sections added to the Health Care Purchasing Act, Public Assistance Act and Chapter 59A, Articles 22,23,46,47, NMSA1978. HB 365 does not specifically identify which "department" is to administer the Cancer Coverage for Children (see page 2 line 18).

The DOH offers the following clarification of the language in House Bill 365: On Page 2, line 14: insert the word "insurance" between the words "disease" and "policies".

WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL

The HSD states that that the Medicaid Program will continue to cover virtually all medically necessary services and therapies for children with cancer.

CH/mt