NORTH CAROLINA GENERAL ASSEMBLY
LEGISLATIVE ACTUARIAL NOTE

BILL NUMBER: Senate Bill 781, Sections 2(a), (b), (c), (d), and 3.

SHORT TITLE: Health Insurance/Clinical Trials Coverage.

SPONSOR(S): Sen. Fountain Odom

SYSTEM OR PROGRAM AFFECTED: Teachers' and State Employees' Comprehensive Major Medical Plan.

FUNDS AFFECTED: State General Fund, State Highway Fund, Other State Employer Receipts, Premium Payments for Dependents by Active and Retired Teachers and State Employees, and Premium Payments for Coverages Selected by Eligible Former Teachers and State Employees.

BILL SUMMARY: Sections 2(a), (b), (c), and (d) of the bill provide coverage for clinical trials involving degenerative and permanently disabling medical conditions under the Plan's self-insured indemnity program. The sections also require that all covered trials have clinical and preclinical data that show a reasonable expectation, rather than clear evidence, that treatments will be at least as effective as noninvestigational alternatives. Trials approved by institutional review boards of institutions within the State that have multiple project assurance contracts approved by the National Institutes of Health, Office of Protection from Research Risks, as well as trials for all cancers, are to be specifically covered by the Plan. Another change in the program's coverage of clinical trials under the bill is that applicable trials will not be required to have approval of the U.S. Food and Drug Administration. Finally, the bill requires the program to cover all phase II trials for those clinical trials that are covered.

The Plan's health maintenance organization (HMO) alternatives to the indemnity program are required by the bill to cover the same type of clinical trials covered by the Plan's indemnity program.

EFFECTIVE DATE: January 1, 2002.

ESTIMATED IMPACT ON STATE: Clinical trials are patient research studies used to evaluate new types of medical treatment. Trials are usually divided into phases. In phase I trials, patients are given new research treatments resulting from laboratory and animal studies. Determinations of safety, harmful side effects, and dosage are the main objectives of phase I trials. Phase II trials determine the efficacy of research treatments. If phase II trials show positive results, the trials move to phase III where the research is compared to standard treatments. Successful phase III trials move to phase IV and become a part of standard treatment in medical care. Trials can last from a few months to several years. The National Institutes of Health of the U. S. Department of Health and Human Services have at least 25 components involved with clinical trials. These components are the AIDS Research Committee & AIDS Clinical Trials Group, Antiviral Study Group, Allergy, Immunology, & Transplantation Research Committee, Asthma, Allergic, & Immunologic Disease Research Centers, Center for International Disease Research, Centers for Tropical Disease Research, HIV Prevention Trials Network, Microbiology & Infectious Diseases Research Committee, National Center for Human Genome Research, National Cancer Institute, National Eye Institute, National Heart, Lung, & Blood Institute, National Institute on Aging, National Institute on Alcohol Abuse & Alcoholism, National Institute of Allergy & Infectious Diseases, National Institute of Arthritis, Musculoskeletal, & Skin Diseases, National Institute of Child Health & Human Development, National Institute of Deafness & Other Communication Disorders, National Institute of Dental Research, National Institute of Diabetes, Digestive, & Kidney Diseases, National Institute on Drug Abuse, National Institute of Mental Health, National Institute of Neurological Disorders & Strokes, and Sexually

Transmitted Diseases Research Centers. NIH trials involve over 400 different subjects in the following categories: cardiology/vascular diseases, dental/maxillofacial surgery, dermatology/plastic surgery, endocrinology, gastroenterology, hematology, immunology/infectious diseases, musculoskeletal, nephrology/urology, obstetrics/gynecology, oncology, opthalmology, otolaryngology, pediatrics/neonatology, pharmacology/toxicology, psychiatry/psychology, pulmonary/respiratory diseases, rheumatology, and trauma/emergency medicine.

The indemnity program of the Teachers' and State Employees' Comprehensive Major Medical Plan provides coverage for clinical trials when the trials involve the treatment of life-threatening medical conditions such as heart disease, cancer, cerebrovascular disease, diseases of the respiratory system, obstructive pulmonary disease, diabetes, kidney failure, and AIDS. Trials must also be approved by the National Institutes of Health (NIH), an NIH cooperative group or center, the U. S. Food and Drug Administration, the U. S. Department of Defense, the U. S. Department of Veterans Affairs, or as otherwise approved by the Plan. Trials must also be approved by applicable institutional review boards and be conducted in facilities and by personnel that maintain a high level of expertise because of their training, experience, and volume of patients. Only medically necessary costs of trials are covered by the Plan to the extent that they are not customarily funded by national agencies or by commercial manufacturers or distributors. The program does not exclude benefits for eligible trials if the proposed treatment is the only appropriate protocol for the condition being treated. Phases III and IV of eligible clinical trials are covered without prior approval of the Plan. Phase II of eligible clinical trials are covered subject to prior approval of the Plan. The Plan is required to make a decision on phase II trials within 30 days after receipt of all medical documentation required by the Plan.

Both the Plan's consulting actuary, Aon Consulting, and the consulting actuary of the General Assembly's Fiscal Research Division, Hartman & Associates, state that the cost impact on the Plan for covering all clinical trials in phases II, III, and IV for degenerative and permanently disabling medical conditions, as well as life-threatening conditions, is not determinable since no relevant experience data is available. Both actuaries however further state that the potential cost impact upon the Plan would likely be substantial. Some of the reasons given for this conclusion are that the number of Plan participants qualifying for the trials is unknown, the very nature of clinical trials inhibits a determination of usual, customary, and reasonable charges, unlimited coverage of trials by the Plan will likely lead to cost shifting from other sources to the Plan, determining average cost per participant and incidence rates for types of trials and trials participants are currently non-existent, and unlimited coverage of trials will likely increase the availability and utilization of trials which is one of the objectives of the National Institutes of Health.

ASSUMPTIONS AND METHODOLOGY: The Comprehensive Major Medical Plan for Teachers and State Employees is divided into two programs. From October, 1982, through June, 1986, the Plan only had a self-funded indemnity type of program which covered all employees, retired employees, eligible dependents of employees and retired employees, and eligible former employees and their eligible dependents authorized to continue coverage past a termination of employment other than for retirement or disability purposes. A prepaid program of coverage by health maintenance organizations (HMOs) was offered in July, 1986, as an alternative to the Plan's self-insured indemnity program. The benefits of the self-insured indemnity type of program are spelled out in Part 3 of Article 3 of Chapter 135 of the North Carolina General Statutes (i.e., $250 annual deductible, 20% coinsurance up to $1,000 annually, etc. paid by the program's members). HMOs are required to offer benefits that are comparable to those provided by the self-insured indemnity program. Beginning in July, 2000, firefighters, rescue squad workers, and members of the National Guard and their eligible dependents were allowed to voluntarily participate in the Plan on a fully contributory basis, provided they were ineligible for any other type of group health benefits and had been without such benefits for at least six months. Employer-paid non-contributory premiums are only authorized for the indemnity program's coverage for employees and retired employees. All other types of premium in the indemnity program are fully contributory. The Plan's Executive Administrator has set the premium rates for firefighters, rescue squad workers, and members of the National Guard and their families at 47% more than the comparable rates charged for employees, retired employees, and

their families. Premiums paid by employers to HMOs are limited to like amounts paid to the indemnity program with employees and retired employees paying any HMO amounts above the indemnity program's non-contributory rates. Both types of coverage continue to be available in the Plan with three HMOs currently covering about 9% of the Plan's total population in 24 of the State's 100 counties. The Plan's employees and retired employees select the type of program that they wish for themselves and their dependents during the months of August and September of each year for coverage beginning in October. The demographics of the Plan as of December 31, 2000, include:

	Self-Insured Indemnity Program	**Alternative HMOs**	**Plan Total**
Number of Participants			
Active Employees	248,518	28,822	277,340
Active Employee Dependents	134,795	17,376	152,171
Retired Employees	104,305	3,185	107,490
Retired Employee Dependents	17,936	594	18,530
Former Employees & Dependents with Continued Coverage	2,865	381	3,246
Firefighters, Rescue Squad Workers, National Guard Members & Dependents	3	-	3
Total Enrollments	508,422	50,358	558,780
Number of Contracts			
Employee Only	270,322	23,223	293,545
Employee & Child(ren)	38,775	6,006	44,781
Employee & Family	45,764	3,026	48,790
Total Contracts	354,861	32,255	387,116
Percentage of Enrollment by Age			
29 & Under	28.0%	41.6%	29.2%
30-44	20.9	26.6	21.4
45-54	21.3	19.2	21.1
55-64	14.5	9.2	14.0
65 & Over	15.4	3.4	14.3
Percentage of Enrollment by Sex			
Male	39.1%	36.9%	38.9%
Female	60.9	63.1	61.1

Assumptions for the Self-Insured Indemnity Program: For the fiscal year beginning July 1, 2000, the self-insured program started its operations with a beginning cash balance of $188 million. Receipts for the year are estimated to be $929 million from premium collections, $10 million from investment earnings, and $8 million in risk adjustment and administrative fees from HMOs, for a total of $947 million in receipts for the year. Disbursements from the self-insured program are expected to be $1.085 billion in claim payments and $31 million in administration and claims processing expenses for a total of $1.116 billion for the year beginning July 1, 2000. For the fiscal year beginning July 1, 2001, the self-insured indemnity program is expected to have an operating cash balance of only $19 million. The self-insured indemnity program is consequently assumed to be unable to carry out its operations for the 2001-2003 biennium without increases in its current premium rates or a

reduction in existing benefits or payments to health care providers or both. This assumption is further predicated upon the fact that the program's cost containment strategies (hospital DRG reimbursements, pre-admission hospital testing, pre-admission hospital inpatient certification with length-of-stay approval, hospital bill audits, required second surgical opinions, mental health case management, coordination of benefits with other payers, Medicare benefit "carve-outs", cost reduction contracts with participating physicians and other providers, prescription drug manufacturer rebates from formularies, and fraud detection) are maintained and improved where possible. Of particular note in these cost containment strategies is that the program's contract with its pharmacy benefit manager, AdvancePCS, calls for a further reduction in claim payments for outpatient prescription drugs for the 2001-03 biennium. Effective July 1, 2001, dispensing fees for pharmacies will be reduced from $4.00 to $1.50 per prescription. In addition, ingredient prices for pharmacies will be reduced from 90% to 85% of average wholesale price (AWP) for branded drugs and from maximum allowable charges (MAC) by the federal Health Care Financing Administration (HCFA) or 80% of AWP to 45% of AWP for generic drugs. Current non-contributory premium rates are $143.10 monthly for employees whose primary payer of health benefits is Medicare and $187.98 per month for employees whose primary payer of health benefits is not Medicare. Fully contributory premium amounts for employee and child(ren) contracts are $89.06 monthly for children whose primary payer of health benefits is Medicare and $117.16 monthly for other covered children, and $213.60 per month for family contracts whose dependents have Medicare as the primary payer of health benefits and $281.04 per month for other family contract dependents. Claim cost trends are expected to increase 12% annually. Total enrollment in the program is expected to increase about 3% annually over the next two years due to enrollment losses from alternative HMOs. The number of enrolled active employees is expected to show a 3% increase annually over the next two years, whereas the growth in the number of retired employees is assumed to be 5% per year. The program is expected to have an increase in the number of active employee dependents and retiree dependents of 2% per year. Investment earnings are based upon a 6% return on available cash balances. The self-insured indemnity program maintains a claim stabilization reserve for claim cost fluctuations equal to 7.5% of annual claim payments without reserving additional funds for incurred but unreported claims.

Assumptions for the Use of Clinical Trials in the Plan: None are available.

SOURCES OF DATA:

-Actuarial Note, Hartman & Associates, Senate Bill 781, Sections 2(a), (b), (c), (d), and 3, April 19, 2001, original of which is on file in the General Assembly's Fiscal Research Division.

-Actuarial Note, Aon Consulting, Senate Bill 781, Sections 2(a), (b), (c), (d), and 3, April 24, 2001, original of which is on file with the Comprehensive Major Medical Plan for Teachers and State Employees and the General Assembly's Fiscal Research Division.

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