REPORT OF THE
SPECIAL ADVISORY COMMISSION ON
MANDATED HEALTH INSURANCE BENEFITS

MANDATED COVERAGE FOR CLINICAL TRIALS FOR CANCER TREATMENTS

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

HOUSE DOCUMENT NO. 81

COMMONWEALTH OF VIRGINIA
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2000

COMMONWEALTH OF VIRGINIA

STEPHEN H. MARTIN
11TH SENATORIAL DISTRICT
PART OF CHESTERFIELD AND DINWIDDIE COUNTIES;
AMELIA COUNTY; CITY OF COLONIAL HEIGHTS.
POST OFFICE BOX 36147
RICHMOND, VIRGINIA 23235

COMMITTEE ASSIGNMENTS:
EDUCATION AND HEALTH
GENERAL LAWS
LOCAL GOVERNMENT
PRIVILEGES AND ELECTIONS

SENATE

January 13, 2000

To: The Honorable James S. Gilmore III
Governor of Virginia
and
The General Assembly of Virginia

The report contained herein has been prepared pursuant to §§ 9-298 and 9-299 of the Code of Virginia.

This report documents a study conducted by the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) to assess the social and financial impact and the medical efficacy of 1999 House Bill 2404 and House Bill 871 regarding mandated coverage for clinical trials for cancer treatments.

Respectfully submitted,

Stephen H. Martin
Chairman
Special Advisory Commission on
Mandated Health Insurance Benefits

SPECIAL ADVISORY COMMISSION ON
MANDATED HEALTH INSURANCE BENEFITS

Stephen H. Martin, Chairman
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Dao Huynh
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James F. McIntyre, III
Virginia Norton, Ph.D.
Fred M. Rankin, III
John L. Roper, IV
Alfred W. Gross
E. Anne Peterson, M.D., M.P.H.

TABLE OF CONTENTS

SECTION		PAGE
INTRODUCTION		1
SUMMARY OF LEGISLATION		1
CLINICAL TRIALS		3
SOCIAL IMPACT		6
FINANCIAL IMPACT		6
MEDICAL EFFICACY		6
INSURANCE COVERAGE		7
SIMILAR LEGISLATION IN OTHER STATES		8
REVIEW CRITERIA:		9
SOCIAL IMPACT		9
FINANCIAL IMPACT		11
MEDICAL EFFICACY		12
EFFECTS OF BALANCING THE SOCIAL, FINANCIAL AND MEDICAL EFFICACY CONSIDERATIONS		13
RECOMMENDATION		13
CONCLUSION		14
APPENDICES:	A - 1999 HOUSE BILL 2404	A-1
	B - 1999 HOUSE BILL 871	B-1

INTRODUCTION

House Bill 2404 was introduced in the 1999 Session of the General Assembly. The patron of the bill is Delegate Gladys B. Keating. The legislation, as introduced, required coverage for clinical trials for life-threatening diseases under policies, contracts, or plans delivered, issued for delivery, or renewed in Virginia on and after July 1, 1999. The bill was revised during the session and was incorporated into House Bill 871. The pertinent language in House Bill 871 requires coverage for clinical trials for treatment studies on cancer, including ovarian cancer trials. House Bill 871 was passed by the House and the Senate and was signed by the Governor. However, the Chairman of the Senate Committee on Commerce and Labor requested a review of the provision by the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission).

The Advisory Commission held a public hearing to receive comments on the bill on June 30, 1999, in Richmond. Three speakers provided comments in support of the bill in addition to the patron, Delegate Keating. Representatives of the American Cancer Society and the Massey Cancer Center, a physician from the University of Virginia, and a cancer patient spoke in support of the bill. Written comments in support of the bill were received from the American Cancer Society, the Massey Cancer Center at the Medical College of Virginia, and a physician from the University of Virginia Cancer Center. No one spoke in opposition to the bill.

The Advisory Commission concluded its review of the bill on July 28, 1999.

SUMMARY OF LEGISLATION

The legislation adds § 38.2-3818.8 to Title 38.2 of the Code of Virginia and requires insurers issuing individual and group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; corporations providing individual or group subscription contracts; and health maintenance organizations (HMOs) offering health care plans to provide coverage for patient costs incurred during the participation in clinical trials for treatment studies on cancer, including ovarian cancer trials. The legislation requires that the reimbursement be determined in the same manner as reimbursement is determined for other medical and surgical procedures. The coverage may not have durational limits, dollar limits, deductibles, copayments and coinsurance factors that are less favorable than for physical illness generally.

The legislation defines the term "cooperative group" as meaning a formal network of facilities that collaborate on research projects and have an

established National Institutes of Health-approved peer review program operating within the group. "Cooperative group" includes (i) the National Cancer Institute Clinical Cooperative Group and (ii) the National Cancer Institute Community Clinical Oncology Program. "Multiple project assurance contract" is defined as a contract between an institution and the Federal Department of Health and Human Services (HHS) that defines the relationship of the institution to HHS and sets out the responsibilities of the institution and the procedures that will be used to protect human subjects.

"Patient cost" is defined as "the cost of medically necessary health care service that is incurred as a result of the treatment being provided to the member (policyholder/subscriber/insured/certificate holder/their dependent) for purposes of a clinical trial. Patient cost does not include (i) the cost of non-health care services that a patient may be required to receive as a result of the treatment being provided for purposes of a clinical trial, (ii) costs associated with the clinical trial, or (iii) the cost of the investigational drug or device.

Subsection D of the bill requires that coverage for patients costs during clinical trials for treatment studies on cancer shall be provided, if the treatment is being conducted in a Phase II, III or IV clinical trial. The treatment may be provided on a case-by-case basis, if the treatment is being provided in a Phase I clinical trial.

Subsection E provides that the treatment described in subsection D shall be provided by a clinical trial approved by the National Cancer Institute (NCI); an NCI cooperative group or an NCI center; the Food and Drug Administration (FDA) in the form of an investigational new drug application, the Federal Department of Veterans Affairs; or an institutional review board of an institution in Virginia that has a multiple project assurance contract approved by the Office of Protection from Research Risks of the NCI.

The bill provides, in subsection F, that the facility and personnel providing the treatment shall be capable of doing so by virtue of their experience, training, and expertise.

The coverage under this bill applies only if (i) there is no clearly superior, noninvestigational treatment alternative and (ii) the available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the noninvestigational alternative, and (iii) the member and physician or health care provider conclude that the member's participation in the clinical trial would be appropriate pursuant to procedures established and disclosed in the policy and evidence of coverage.

The coverage requirement does not apply to short-term travel, accident-only, or contracts designed for issuance to persons eligible for coverage under

Medicare, or other similar coverage under state or governmental plans or to short-term nonrenewable policies of not more than six months' duration.

CLINICAL TRIALS

According to information from the National Institutes of Health National Cancer Institute, a clinical trial is a study conducted with cancer patients, usually to evaluate a new treatment. Each study is designed to answer scientific questions. The study is also designed to find new and better ways to help patients.

The search for cancer treatments begins with basic research in laboratory and animal studies. From the basic research, the best results are then tried in patient studies after careful laboratory study. The research shows which new methods are likely to succeed. The early research also shows how to use the treatments safely.

Clinical trials are an organized study conducted to answer specific questions about a new treatment or a different way of using an existing treatment. Each study attempts to increase medical knowledge. Clinical trials study new anti-cancer drugs and new combinations of drugs currently used. Clinical trials also study new ways of giving treatment and how changes in lifestyle can help prevent cancer or help patients who already have cancer. Other trials compare the best standard therapy with newer therapy to see which produces more cures and causes the least side effects. New cancer treatments must be proven safe and effective in scientific studies before they can be made available to all patients.

There are different kinds of clinical trials. The types of trials include prevention trials to keep cancer from developing in people who have not previously had cancer, prevention trials to prevent a new type of cancer from occurring in people who have had cancer, early detection trials to find cancer, treatment trials to test new therapies in people who have cancer, quality of life studies to improve comfort and quality of life for people who have cancer, and studies to evaluate ways of modifying cancer-causing behaviors, such as tobacco use.

Most clinical trials are conducted in steps that are known as "phases." Each phase is designed to determine different information. Patients may be eligible for studies in different phases, depending on their general condition, the type and stage of their cancer, and the therapy they may have already undergone. Patients are seen on a regular basis to determine the effects of the treatment, and if side effects become too severe, treatment is stopped.

Phase I

The purpose of a Phase I study is to find the best way to give a new treatment and how much of it can be given safely. A new treatment is given to a small number of patients, or a new drug is given in low dosage and the dosage is slowly increased as new patients enter the trial. Physicians carefully monitor patients for harmful side effects. Phase I studies are offered only to patients whose cancer cannot be helped by other known treatments. Once the best dosage is chosen, the drug is studied for its ability to shrink tumors in Phase II trials.

Phase II

Phase II studies are designed to determine if the treatment actually kills cancer cells in people. Usually, groups of 20 to 50 patients with one type of cancer receive a Phase II treatment. Patients are observed for anti-cancer effect by repeated measurement of tumor size to see if the tumor decreased in size from the beginning of the study. When a tumor decreases significantly and stays smaller for a month, the patient is said to have "responded" to the treatment. If at least one-fifth of the patients in the Phase II study respond to the treatment, it is judged "active" against their tumor type. If a treatment has shown activity against cancer in a Phase II study, it becomes part of a Phase III study.

Phase III

Phase III studies usually compare standard treatments, or the most accepted treatments, with treatments that appeared to be good in Phase II. Phase III studies require large numbers of patients; some use thousands of patients. Patients are usually "randomized" or assigned by chance to one of the treatments being studied. The group that receives the standard treatment is called the "control" group. The researchers know that a certain number of these patients will be helped by the treatment. The other patient group receives the newer therapy to see if it will help the patients more. Phase III studies look for longer life, better quality of life, fewer side effects and fewer cases of cancer returning.

Phase IV

In Phase IV studies, the research treatment becomes part of standard patient care. Some use the term "Phase IV" to include the continuing evaluation that takes place after U.S. Federal Drug Administration (FDA) approval.

Adjuvant Studies

Adjuvant studies are conducted to determine if additional therapy will improve the chance for cure in patients at risk for the return of cancer after surgical removal of all visible disease. For example, in the case of standard therapy for large bowel disease, an adjuvant study could be conducted where one group of patients would receive surgery and another group would receive surgery and then chemotherapy. If the study shows that surgery with chemotherapy is better than only surgery, surgery with chemotherapy will become the standard therapy. Adjuvant studies go through Phase I, II, and III trials, like other treatment studies.

Neoadjuvant Studies

Neoadjuvant treatment is given to attempt to reduce the cancer to a size where standard therapy is effective. Sometimes cancer in the head or neck may be too large to treat safely with surgery. Chemotherapy could be attempted to reduce a tumor to a size that can be surgically removed. Neoadjuvant studies also progress through Phase I, II, and III trials.

Supportive Care Studies

Clinical trials also try to find better ways of caring for the side effects that are caused by treatment, such as nausea and vomiting, or the side effects of the cancer, such as pain or sleeplessness. Some supportive care studies use drugs to treat side effects; others look at whether support groups assist in easing patient discomfort.

Prevention and Early Detection

People in prevention studies are often considered high-risk for developing cancer because several family members have cancer. Prevention studies generally compare a group of people who receive no special treatment to a group that is given a drug or a change in diet in an attempt to prevent cancer from starting. Participants in both groups will be followed for years, to determine if there is a lower rate of cancer in the group receiving the drug or making diet changes.

Studies in early detection analyze different methods of screening individuals for the presence of cancer. Earlier detection of cancer makes treatment of the cancer easier because it is smaller. Methods of early detection include x-rays, blood tests, and physical examinations.

Group C and Treatment Referral Center Studies

Group C and Treatment Referral studies provide drugs to cancer doctors that have been through clinical trials. These drugs have worked on some tumors and may be approved by the FDA. Patients receiving these drugs are closely monitored by their physicians.

SOCIAL IMPACT

In 1995, at least 26,437 Virginians were diagnosed with some form of cancer, according to information reported to the Virginia Cancer Registry. The 1996 figure indicates that at least 27,320 Virginians were diagnosed with cancer. These figures reflect a conservative account of cancer in Virginia because not all hospitals, outpatient facilities, and private pathology laboratories were reporting cases to the registry over the time periods covered.

FINANCIAL IMPACT

Researchers, led by a Mayo Clinic oncologist, followed 61 patients who entered clinical trials of various treatments at the Mayo Clinic from 1988 to 1994. They were compared to 61 patients who had similar tumors and who were eligible for clinical trials but chose standard therapy. The patients were followed for five years, or until they died. Hospital, physician, and related service costs were estimated from a population-based cost database that was developed by Mayo Clinic staff. One of the study findings, reported in the Journal of the National Cancer Institute, entitled, "Incremental Cost of Enrolling Cancer Patients in Clinical Trials: A Population-Based Study," was that the average total cost in 1995 inflation-adjusted dollars for patients in clinical trials was $46,424 and $44,133 for patients receiving standard treatment.

MEDICAL EFFICACY

The FDA issued regulations in 1976 that require Institutional Review Boards (IRBs) for all institutionalized subjects. The regulations were amended in 1981 to require that all studies needing a FDA research permit be reviewed and approved by an IRB before tests on humans begin. The IRB is composed of at least five people with varying backgrounds that are knowledgeable by virtue of training or experience in the research areas likely to be conducted. Racial, ethnic, and other interests must be represented; at least one member must come from a nonscientific discipline; and at least one must not be affiliated with the research institution. The IRBs review research before it is conducted to protect the rights of the participants and to safeguard their welfare.

A 1967 FDA policy statement outlined the consent process for clinical trials and required that consent be obtained, in writing, for the early stages of research. The FDA revised its regulations in 1981 to require that all studies of products obtain written informed consent.

The FDA relies on the review of responsible IRBs to ensure that research studies are not unnecessarily risky and that the studies are valid. The IRBs and the informed consent process are believed to adequately protect the welfare of participants.

INSURANCE COVERAGE

The Bureau of Insurance surveyed 50 of the largest accident and sickness insurers regarding the relevant provisions of House Bill 871. Fifteen insurers completed the survey. Nine companies indicated that they would cover participation in cancer trials after July 1, 1999 as required by the bill. Three companies responded that they did not provide the coverage prior to the bill, and three companies responded that they did provide the coverage.

According to information from the NCI, there are two types of costs connected with trials: patient care and research. The two categories of patient care costs are usual care costs and extra care costs. Usual care costs include doctor visits, hospital stays, clinical laboratory tests, x-rays, and costs that occur whether the patient is part of a trial or receiving standard treatment. The NCI indicates that these costs are usually covered by private insurance or Medicare. Extra care costs include additional tests that may not be fully covered by the clinical trial sponsor or research institution.

Research costs include data collection and management, research physician and nurse time, analysis of results, and tests performed only for research purposes. These costs are usually covered by the sponsoring organization.

In 1999, the National Institutes of Health and the American Association of Health Plans (AAHP) reached an agreement regarding clinical trials. The AAHP and its member plans will work with the NIH to develop a process that will increase participation in the NIH-sponsored clinical trials. The agreement is based on the following:

1. Clinical trials are the most effective means of generating reliable evidence relating to medical interventions.

2. The NIH is committed to supporting the conduct of this research as the means of identifying therapeutic advances that are then translated into standards of patient care.

3. Health plans have the potential to create new opportunities to increase patient accrual, conduct clinical research, disseminate research findings, and incorporate research advances into routine medical practice.

4. AAHP is committed to increasing the participation of plan members in well-designed, high quality clinical trials.

5. Plans are more likely to facilitate and encourage clinical trials and participation, if it is not markedly more expensive to the plan than standard clinical care.

There is a steering committee composed of five representatives of the NIH, five representatives of AAHP, and three patient advocates. The steering committee will oversee the research activities and evaluate the progress of the agreement on an annual basis.

SIMILAR LEGISLATION IN OTHER STATES

Information from the National Insurance Law Service and individual states indicates that at least four states require some coverage for participation in clinical trials for cancer. Legislation in Georgia requires clinical trials coverage for routine patient care costs incurred in connection with the provision of goods, services, and benefits to dependent children, in connection with approved clinical trials programs for the treatment of children's cancer.

Rhode Island requires coverage for new cancer therapies still under investigation when the treatment is being provided in connection with a Phase II, III, or IV clinical trial, approved by the NIH, in cooperation with the NCI Community oncology programs, the FDA, the Department of Veteran's Affairs, or a qualified non-governmental research entity, as identified in NCI guidelines for support grants. The provision also includes requirements that the therapy be reviewed and approved by a qualified institutional review board (IRB), the facility and personnel are capable, the patients meet all protocol requirements, there is no clearly superior, non-investigational alternative, the available clinical or preclinical data provide a reasonable expectation that the protocol treatment will be at least as efficacious as the noninvestigational alternative, and the coverage of the treatment for a Phase II trial is not required for only that part of the treatment. The parts of a Phase II trial, customarily funded by government, biotechnical and/or pharmaceutical or medical device industry, must continue. This coverage does not "supplant" other customary funding.

Maryland requires coverage for patient costs for clinical trials as a result of treatment for a life-threatening condition or prevention, early detection, and treatment studies on cancer. The Maryland legislation is very similar to the

proposal in House Bill 2404. The coverage is required, if the treatment is being conducted in a Phase I, Phase II, Phase III, or Phase IV clinical trial for cancer or a Phase II, Phase III, or Phase IV clinical trial for any other life-threatening condition. The treatment must also be in a trial approved by one of the National Institutes of Health, an NIH cooperative group, or an NIH center; the FDA in the form of an investigational new drug application; the Federal Department of Veteran's Affairs; or an institutional review with a multiple project assurance contract approved by the Office of Protection from Research Risks of the NIH. The facility and personnel providing the treatment must be capable and there must be no clearly superior, non-investigational treatment alternative and the available clinical or preclinical data must provide a reasonable expectation that the treatment will be at least as effective as the noninvestigational alternative. The coverage may be provided on a case-by-case basis for treatment in Phase I clinical trials for a life-threatening condition other than cancer. The insurer must provide coverage for patient costs for drugs and devices approved for sale by the FDA whether the FDA has approved the drug or device for the patient's particular condition.

Illinois recently passed legislation to require the offer of coverage for clinical trials for cancer treatment. Louisiana also passed clinical trials legislation in 1999. A clinical trials mandate was recently proposed in Arizona but was not enacted.

REVIEW CRITERIA

SOCIAL IMPACT

a. *The extent to which the treatment or service is generally utilized by a significant portion of the population.*

Approximately 27,000 Virginians were diagnosed with cancer in 1995 and another 27,000 were diagnosed in 1996. Proponents related that about 5% of adults with cancer are included in clinical trials.

b. *The extent to which insurance coverage for the treatment or service is already generally available.*

The Bureau of Insurance resurveyed the 50 largest accident and sickness insurers in Virginia regarding this bill. Fifteen insurers completed the survey. Nine companies indicated they would cover participation in cancer trials after the July 1, 1999 effective date of House Bill 871. Three companies responded that they did not provide the coverage prior to the bill, and three companies responded that they did provide the coverage.

The AAHP reached an agreement with the NIH to work together to develop a process that will increase participation in NIH-sponsored clinical trails. The agreement was reached in 1999.

c. *If coverage is not generally available, the extent to which the lack of coverage results in persons being unable to obtain necessary health care treatments.*

Proponents believe that more patients would pursue clinical trials, if there were confidence that their insurance was available to cover participation. One physician estimated there would be an increase of patients from 5% to 10%.

d. *If the coverage is not generally available, the extent to which the lack of coverage results in unreasonable financial hardship on those persons needing treatment.*

Proponents of the bill acknowledged that the insured prospective clinical trials participants receive coverage for normal patient care. However, the lack of coverage for clinical trials is viewed as increasing the reluctance of patients to enter the trials and limits the progress in cancer treatment advances.

e. *The level of public demand for the treatment or service.*

Currently, approximately 5% of adult cancer patients are included in cancer trials. Proponents believe that at least another 5% would be candidates for trials.

f. *The level of public demand and the level of demand from providers for individual or group insurance coverage of the treatment or service.*

Representatives of the Massey Cancer Center at MCV and the University of Virginia Cancer Center spoke in support of a mandate for clinical trials coverage. They believe coverage is necessary to protect patients from the loss of, or fear of loss of, benefits if they participate in clinical trials. One cancer patient testified about the impact clinical trial participation had on her life. She testified that the quality of her life was greatly improved and that she was diagnosed with cancer over ten years ago. She expected to suffer distressful side effects from her treatment but the side effects for her were minimal because she participated in a clinical trial. She was able to continue working and enjoying her life because of the trial's use of a new drug.

g. *The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts.*

The level of interest of collective bargaining organizations in negotiating privately for the inclusion of this coverage in group contracts is not known.

h. *Any relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.*

No information or findings of the state health planning agency or the appropriate health system agency regarding the social impact of clinical trials for cancer were presented.

FINANCIAL IMPACT

a. *The extent to which the proposed insurance coverage would increase or decrease the cost of treatment or service over the next five years.*

The cost of the treatments provided in clinical trials is not expected to increase because of insurance coverage.

b. *The extent to which the proposed insurance coverage might increase the appropriate or inappropriate use of the treatment or service.*

The appropriate use of and participation level of clinical trials is expected to experience some increase. Proponents believe that more patients will enroll in trials if they do not have the additional financial concerns caused by a lack of, or potential lack of, insurance coverage.

c. *The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.*

Proponents made the argument that there is little difference in the cost for participation in clinical trials and the cost of standard treatments. They cited the results of the Mayo Clinic study of patients treated from 1988 to 1994. The study's results appeared in the May 19, 1999 issue of the Journal of the National Cancer Institute. The study found an average cost per patient in trials of $46,424 and an average cost of $44,133 for patients receiving standard treatment.

d. *The extent to which the insurance coverage may affect the number and types of providers of the mandated treatment or service over the next five years.*

The number and types of providers is not expected to be affected by coverage for participation in clinical trials for cancer.

e. *The extent to which insurance coverage might be expected to increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.*

In response to the Bureau of Insurance's survey, eight companies provided estimates on the cost increase for individual policies. The estimates ranged from $.04 to $2 per month, with one company estimating .5%. Ten companies provided estimates on the cost increase for group coverage. The estimates ranged from $.04 to $8.34 per month, with one insurer estimating less than 2%.

f. *The impact of coverage on the total cost of health care.*

The total cost of health care is not expected to be significant.

MEDICAL EFFICACY

a. *The contribution of the benefit to the quality of patient care and the health status of the population, including the results of any research demonstrating the medical efficacy of the treatment or service compared to alternatives or not providing the treatment or service.*

Proponents of the bill believe that optimal care is provided to patients that are subjects in well-designed clinical trials, approved by appropriate scientific agencies. Participants in this type of trial would receive either the most recent available standard treatment or an alternative that has shown potential for some improvement.

b. *If the legislation seeks to mandate coverage of an additional class of practitioners:*

1) The results of any professionally acceptable research demonstrating the medical results achieved by the additional class of practitioners relative to those already covered.

Not applicable.

2) *The methods of the appropriate professional organization that assure clinical proficiency.*

Not applicable.

EFFECTS OF BALANCING THE SOCIAL, FINANCIAL AND MEDICAL EFFICACY CONSIDERATIONS

a. *The extent to which the benefit addresses a medical or a broader social need and whether it is consistent with the role of health insurance.*

Proponents make the argument that the benefit addresses a medical need and is consistent with the role of health insurance. They believe that clinical trial participation is essential to medical research that leads to improvement in treatments and higher survival rates for cancer.

b. *The extent to which the need for coverage outweighs the costs of mandating the benefit for all policyholders.*

Eight companies estimated costs of from $.04 to $2 per month to provide the required coverage in individual policies. One company estimated .5%. Ten companies estimated costs of from $.04 to $8.34 per month to provide the coverage in group contracts. One insurer estimated less than 2%.

c. *The extent to which the need for coverage may be solved by mandating the availability of the coverage as an option for policyholders.*

The cost of a mandated offer of coverage is anticipated to be higher because the cost would rest only on those who select the coverage. In the case of group insurance, the decision of whether to select the optional coverage would lie with the master contract holder and not the individual.

RECOMMENDATION

The Advisory Commission voted on the provisions of House Bill 871 regarding coverage for clinical trial participation for cancer treatments

on July 28, 1999. The Advisory Commission voted unanimously (Yes-10, No-0) to recommend that coverage for participation in clinical trials for cancer be enacted.

The Advisory Commission did express concern about the potential impact of the bill on insurance premiums.

CONCLUSION

The Advisory Commission believes, based on the information it has reviewed, that the mandate of coverage for participation in clinical trials for cancer required by House Bill 871 is beneficial to Virginians. The bill is the result of discussion and work by the various interested parties.

1999 SESSION

994699753

HOUSE BILL NO. 2404

Offered January 21, 1999

A BILL to amend and reenact § 38.2-4319 of the Code of Virginia, and to amend the Code of Virginia by adding a section numbered 38.2-3418.8, relating to accident and sickness insurance; coverage for clinical trials for life-threatening diseases.

Patrons—Keating, Almand, Armstrong, Barlow, Baskerville, Brink, Christian, Cranwell, Crittenden, Darner, Day, Deeds, Hull, Jackson, Joannou, Moss, Phillips, Plum, Puller, Tate, Van Landingham, Van Yahres and Watts; Senators: Gartlan, Howell, Marsh, Miller, Y.B., Puckett, Reynolds, Ticer, Walker and Whipple

Referred to Committee on Corporations, Insurance and Banking

Be it enacted by the General Assembly of Virginia:

1. That § 38.2-4319 of the Code of Virginia is amended and reenacted, and that the Code of Virginia is amended by adding a section numbered 38.2-3418.8, as follows:

§ 38.2-3418.8. Coverage for clinical trials for life-threatening diseases.

A. Notwithstanding the provisions of § 38.2-3419, each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; each corporation providing individual or group accident and sickness subscription contracts; and each health maintenance organization providing a health care plan for health care services shall provide coverage for clinical trials for life-threatening diseases under any such policy, contract or plan delivered, issued for delivery, or renewed in this Commonwealth on and after July 1, 1999.

B. The reimbursement for the participation in clinical trials for life-threatening diseases shall be determined according to the same formula by which charges are developed for other medical and surgical procedures. Such coverage shall have durational limits, dollar limits, deductibles and coinsurance factors that are no less favorable than for physical illness generally.

C. For purposes of this section:

"Cooperative group" means a formal network of facilities that collaborate on research projects and have an established NIH-approved peer review program operating within the group. "Cooperative group" includes (i) the National Cancer Institute Clinical Cooperative group, (ii) the National Cancer Institute Community Clinical Oncology Program, (iii) the AIDS Clinical Trials Group, and (iv) the Community Programs for Clinical Research in AIDS.

"FDA" means the Federal Food and Drug Administration.

"Member" means a policyholder, subscriber, insured, or certificate holder or a covered dependent of a policyholder, subscriber, insured or certificate holder.

"Multiple project assurance contract" means a contract between an institution and the federal Department of Health and Human Services that defines the relationship of the institution to the federal Department of Health and Human Services and sets out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects.

"NIH" means the National Institutes of Health.

"Patient cost" means the cost of a medically necessary health care service that is incurred as a result of the treatment being provided to the member for purposes of a clinical trial. "Patient cost" does not include (i) the cost of nonhealth care services that a patient may be required to receive as a result of the treatment being provided for purposes of a clinical trial, (ii) costs associated with managing the research associated with the clinical trial, or (iii) costs that would not be covered under the patient's policy, plan, or contract for noninvestigational treatments.

D. Coverage for clinical trials for life-threatening diseases shall be provided for participation in a clinical trial as a result of (i) a life-threatening condition or (ii) prevention, early detection, and treatment studies on cancer. Such coverage shall be required if:

1. The treatment is being conducted in a Phase I, Phase II, Phase III, or Phase IV clinical trial for cancer; or

2. The treatment is being conducted in a Phase II, Phase III, or Phase IV clinical trial for any

other life-threatening condition. Such treatment may, however, be provided on a case-by-case basis if the treatment is being provided in a Phase I clinical trial for any life-threatening condition other than cancer.

E. The treatment described in subsection D shall be provided by a clinical trial approved by:

1. One of the National Institutes of Health;

2. An NIH cooperative group or an NIH center;

3. The FDA in the form of an investigational new drug application;

4. The Federal Department of Veterans Affairs; or

5. An institutional review board of an institution in the Commonwealth that has a multiple project assurance contract approved by the Office of Protection from Research Risks of the NIH.

F. The facility and personnel providing the treatment shall be capable of doing so by virtue of their experience, training, and expertise.

G. Coverage under this section shall apply only if:

1. There is no clearly superior, noninvestigational treatment alternative; and

2. The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the noninvestigatonal alternative.

H. The provisions of this section shall not apply to short-term travel, accident-only, limited or specified disease policies or contracts designed for issuance to persons eligible for coverage under Title XVIII of the Social Security Act, known as Medicare, or any other similar coverage under state or governmental plans or to short-term nonrenewable policies of not more than six months' duration.

§ 38.2-4319. Statutory construction and relationship to other laws.

A. No provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-200, 38.2-203, 38.2-210 through 38.2-213, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-305, 38.2-316, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.) of this title, 38.2-1057, 38.2-1306.2 through 38.2-1309, Articles 4 (§ 38.2-1317 et seq.) and 5 (§ 38.2-1322 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.) and 2 (§ 38.2-1412 et seq.) of Chapter 14, §§ 38.2-1800 through 38.2-1836, 38.2-3401, 38.2-3405, 38.2-3405.1, 38.2-3407.2 through 38.2-3407.6, 38.2-3407.9, 38.2-3407.10, 38.2-3407.11, 38.2-3407.12, 38.2-3411.2, 38.2-3414.1, 38.2-3418.1 through ~~38.2-3418.7~~ *38.2-3418.8*, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3542, 38.2-3543.2, Chapter 53 (§ 38.2-5300 et seq.) and Chapter 58 (§ 38.2-5800 et seq.) of this title shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§ 38.2-4200 et seq.) of this title except with respect to the activities of its health maintenance organization.

B. Solicitation of enrollees by a licensed health maintenance organization or by its representatives shall not be construed to violate any provisions of law relating to solicitation or advertising by health professionals.

C. A licensed health maintenance organization shall not be deemed to be engaged in the unlawful practice of medicine. All health care providers associated with a health maintenance organization shall be subject to all provisions of law.

D. Notwithstanding the definition of an eligible employee as set forth in § 38.2-3431, a health maintenance organization providing health care plans pursuant to § 38.2-3431 shall not be required to offer coverage to or accept applications from an employee who does not reside within the health maintenance organization's service area.

VIRGINIA ACTS OF ASSEMBLY -- 1999 SESSION

CHAPTER 649

An Act to amend and reenact §§ 2.1-20.1, 32.1-137.6, 32.1-137.15, 38.2-3407.10, 38.2-4209, 38.2-4214, 38.2-4312, 38.2-4319, 38.2-4509 and 38.2-5804 of the Code of Virginia and to amend the Code of Virginia by adding sections numbered 38.2-3407.9:01 and 38.2-3407.11:1; by adding in Article 1 of Chapter 34 of Title 38.2 sections numbered 38.2-3407.13, 38.2-3407.14 and 38.2-3407.15; by adding sections numbered 38.2-3418.8 and 38.2-3418.9; and by adding in Title 38.2 a chapter numbered 59, consisting of sections numbered 38.2-5900 through 38.2-5905, relating to the state employees' health insurance plan and to managed care health insurance plans generally.

[H 871]

Approved March 28, 1999

Be it enacted by the General Assembly of Virginia:

1. That §§ 2.1-20.1, 32.1-137.6, 32.1-137.15, 38.2-3407.10, 38.2-4209, 38.2-4214, 38.2-4312, 38.2-4319, 38.2-4509 and 38.2-5804 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding sections numbered 38.2-3407.9:01 and 38.2-3407.11:1; by adding in Article 1 of Chapter 34 of Title 38.2 sections numbered 38.2-3407.13, 38.2-3407.14 and 38.2-3407.15; by adding sections numbered 38.2-3418.8 and 38.2-3418.9; and by adding in Title 38.2 a chapter numbered 59, consisting of sections numbered 38.2-5900 through 38.2-5905, as follows:

§ 2.1-20.1. Health and related insurance for state employees.

A. 1. The Governor shall establish a plan for providing health insurance coverage, including chiropractic treatment, hospitalization, medical, surgical and major medical coverage, for state employees and retired state employees with the Commonwealth paying the cost thereof to the extent of the coverage included in such plan. The Department of Personnel and Training shall administer this section. The plan chosen shall provide means whereby coverage for the families or dependents of state employees may be purchased. The Commonwealth may pay all or a portion of the cost thereof, and for such portion as the Commonwealth does not pay, the employee may purchase the coverage by paying the additional cost over the cost of coverage for an employee.

2. Such contribution shall be financed through appropriations provided by law.

B. The plan shall:

1. a. Include coverage for low-dose screening mammograms for determining the presence of occult breast cancer. Such coverage shall make available one screening mammogram to persons age thirty-five through thirty-nine, one such mammogram biennially to persons age forty through forty-nine, and one such mammogram annually to persons age fifty and over and may be limited to a benefit of fifty dollars per mammogram subject to such dollar limits, deductibles, and coinsurance factors as are no less favorable than for physical illness generally. The term "mammogram" shall mean an X-ray examination of the breast using equipment dedicated specifically for mammography, including but not limited to the X-ray tube, filter, compression device, screens, film, and cassettes, with an average radiation exposure of less than one rad mid-breast, two views of each breast.

b. In order to be considered a screening mammogram for which coverage shall be made available under this section:

(1) The mammogram must be (i) ordered by a health care practitioner acting within the scope of his licensure and, in the case of an enrollee of a health maintenance organization, by the health maintenance organization physician, (ii) performed by a registered technologist, (iii) interpreted by a qualified radiologist, and (iv) performed under the direction of a person licensed to practice medicine and surgery and certified by the American Board of Radiology or an equivalent examining body. A copy of the mammogram report must be sent or delivered to the health care practitioner who ordered it;

(2) The equipment used to perform the mammogram shall meet the standards set forth by the Virginia Department of Health in its radiation protection regulations; and

(3) The mammography film shall be retained by the radiologic facility performing the examination

in accordance with the American College of Radiology guidelines or state law.

2. Include coverage for the treatment of breast cancer by dose-intensive chemotherapy with autologous bone marrow transplants or stem cell support when performed at a clinical program authorized to provide such therapies as a part of clinical trials sponsored by the National Cancer Institute. For persons previously covered under the plan, there shall be no denial of coverage due to the existence of a preexisting condition.

3. Include coverage for postpartum services providing inpatient care and a home visit or visits which shall be in accordance with the medical criteria, outlined in the most current version of or an official update to the "Guidelines for Perinatal Care" prepared by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists or the "Standards for Obstetric-Gynecologic Services" prepared by the American College of Obstetricians and Gynecologists. Such coverage shall be provided incorporating any changes in such Guidelines or Standards within six months of the publication of such Guidelines or Standards or any official amendment thereto.

4. *a.* Include an appeals process for resolution of written complaints concerning denials or partial denials of claims that shall provide reasonable procedures for resolution of such written complaints and shall be published and disseminated to all covered state employees. Such appeals process shall include a separate expedited emergency appeals procedure which shall provide resolution within one business day of receipt of a complaint concerning situations requiring immediate medical care. *For appeals involving adverse decisions as defined in § 32.1-137.7, the Department shall contract with one or more impartial health entities to review such decisions. Impartial health entities may include medical peer review organizations and independent utilization review companies. The Department shall adopt regulations to assure that the impartial health entity conducting the reviews has adequate standards, credentials and experience for such review. The impartial health entity shall examine the final denial of claims to determine whether the decision is objective, clinically valid, and compatible with established principles of health care. The decision of the impartial health entity shall (i) be in writing, (ii) contain findings of fact as to the material issues in the case and the basis for those findings, and (iii) be final and binding if consistent with law and policy.*

b. Prior to assigning an appeal to an impartial health entity, the Department shall verify that the impartial health entity conducting the review of a denial of claims has no relationship or association with (i) the covered employee, (ii) the treating health care provider, or any of its employees or affiliates, (iii) the medical care facility at which the covered service would be provided, or any of its employees or affiliates, or (iv) the development or manufacture of the drug, device, procedure or other therapy which is the subject of the final denial of a claim. The impartial health entity shall not be a subsidiary of, nor owned or controlled by, a health plan, a trade association of health plans, or a professional association of health care providers. There shall be no liability on the part of and no cause of action shall arise against any officer or employee of an impartial health entity for any actions taken or not taken or statements made by such officer or employee in good faith in the performance of his powers and duties.

5. Include coverage for early intervention services. For purposes of this section, "early intervention services" means medically necessary speech and language therapy, occupational therapy, physical therapy and assistive technology services and devices for dependents from birth to age three who are certified by the Department of Mental Health, Mental Retardation and Substance Abuse Services as eligible for services under Part H of the Individuals with Disabilities Education Act (20 U.S.C. § 1471 et seq.). Medically necessary early intervention services for the population certified by the Department of Mental Health, Mental Retardation and Substance Abuse Services shall mean those services designed to help an individual attain or retain the capability to function age-appropriately within his environment, and shall include services which enhance functional ability without effecting a cure.

For persons previously covered under the plan, there shall be no denial of coverage due to the existence of a preexisting condition. The cost of early intervention services shall not be applied to any contractual provision limiting the total amount of coverage paid by the insurer to or on behalf of the insured during the insured's lifetime.

6. Include coverage for prescription drugs and devices approved by the United States Food and Drug Administration for use as contraceptives.

7. Not deny coverage for any drug approved by the United States Food and Drug Administration for use in the treatment of cancer on the basis that the drug has not been approved by the United States Food and Drug Administration for the treatment of the specific type of cancer for which the drug has been prescribed, if the drug has been recognized as safe and effective for treatment of that specific type of cancer in one of the standard reference compendia.

8. Not deny coverage for any drug prescribed to treat a covered indication so long as the drug has been approved by the United States Food and Drug Administration for at least one indication and the drug is recognized for treatment of the covered indication in one of the standard reference compendia or in substantially accepted peer-reviewed medical literature.

9. Include coverage for equipment, supplies and outpatient self-management training and education, including medical nutrition therapy, for the treatment of insulin-dependent diabetes, insulin-using diabetes, gestational diabetes and noninsulin-using diabetes if prescribed by a healthcare professional legally authorized to prescribe such items under law. To qualify for coverage under this subdivision, diabetes outpatient self-management training and education shall be provided by a certified, registered or licensed health care professional.

10. Include coverage for reconstructive breast surgery. For purposes of this section, "reconstructive breast surgery" means surgery performed on and after July 1, 1998, (i) coincident with a mastectomy performed for breast cancer or (ii) following a mastectomy performed for breast cancer to reestablish symmetry between the two breasts. For persons previously covered under the plan, there may be no denial of coverage due to preexisting conditions.

11. Include coverage for annual pap smears.

12. Include coverage providing a minimum stay in the hospital of not less than forty-eight hours for a patient following a radical or modified radical mastectomy and twenty-four hours of inpatient care following a total mastectomy or a partial mastectomy with lymph node dissection for treatment breast cancer. Nothing in this subdivision shall be construed as requiring the provision of inpatient verage where the attending physician in consultation with the patient determines that a shorter period of hospital stay is appropriate.

13. Include coverage (i) to persons age fifty and over and (ii) to persons age forty and over who are at high risk for prostate cancer, according to the most recent published guidelines of the American Cancer Society, for one PSA test in a twelve-month period and digital rectal examinations, all in accordance with American Cancer Society guidelines. For the purpose of this subdivision, "PSA testing" means the analysis of a blood sample to determine the level of prostate specific antigen.

14. Permit any individual covered under the plan direct access to the health care services of a participating specialist (i) authorized to provide services under the plan and (ii) selected by the covered individual. The plan shall have a procedure by which an individual who has an ongoing special condition may, after consultation with the primary care physician, receive a referral to a specialist for such condition who shall be responsible for and capable of providing and coordinating the individual's primary and specialty care related to the initial specialty care referral. If such an individual's care would most appropriately be coordinated by such a specialist, the plan shall refer the individual to a specialist. For the purposes of this subdivision, "special condition" means a condition or disease that (i) is life-threatening, degenerative, or disabling and (ii) requires specialized medical care over a prolonged period of time. Within the treatment period authorized by the referral, such specialist shall be permitted to treat the individual without a further referral from the individual's primary care provider and may authorize such referrals, procedures, tests, and other medical services related to the initial referral as the individual's primary care provider would otherwise be permitted to provide or authorize. The plan shall have a procedure by which an individual who has an ongoing special condition that requires ongoing care from a specialist may receive a standing referral to such specialist for the treatment of the special condition. If the primary care provider, in consultation with the plan and the specialist, if any, determines that such a standing referral is appropriate, the plan or issuer shall make such a referral to a specialist. Nothing contained herein shall prohibit the plan from requiring a participating specialist to provide written notification to the covered individual's primary care physician of any visit to such specialist. Such notification may include a description of the health care services rendered at the time of the visit.

15. a. Include provisions allowing employees to continue receiving health care services for a

period of up to ninety days from the date of the primary care physician's notice of termination from any of the plan's provider panels.

b. The plan shall notify any provider at least ninety days prior to the date of termination of the provider, except when the provider is terminated for cause.

c. For a period of at least ninety days from the date of the notice of a provider's termination from any of the plan's provider panels, except when a provider is terminated for cause, a provider shall be permitted by the plan to render health care services to any of the covered employees who (i) were in an active course of treatment from the provider prior to the notice of termination and (ii) request to continue receiving health care services from the provider.

d. Notwithstanding the provisions of clause a, any provider shall be permitted by the plan to continue rendering health services to any covered employee who has entered the second trimester of pregnancy at the time of the provider's termination of participation, except when a provider is terminated for cause. Such treatment shall, at the covered employee's option, continue through the provision of postpartum care directly related to the delivery.

e. Notwithstanding the provisions of clause a, any provider shall be permitted by the plan to continue rendering health services to any covered employee who is determined to be terminally ill (as defined under § 1861 (dd) (3) (A) of the Social Security Act) at the time of a provider's termination of participation, except when a provider is terminated for cause. Such treatment shall, at the covered employee's option, continue for the remainder of the employee's life for care directly related to the treatment of the terminal illness.

f. A provider who continues to render health care services pursuant to this subdivision shall be reimbursed in accordance with the carrier's agreement with such provider existing immediately before the provider's termination of participation.

16. a. Include coverage for patient costs incurred during participation in clinical trials for treatment studies on cancer, including ovarian cancer trials.

b. The reimbursement for patient costs incurred during participation in clinical trials for treatment studies on cancer shall be determined in the same manner as reimbursement is determined for other medical and surgical procedures. Such coverage shall have durational limits, dollar limits, deductibles, copayments and coinsurance factors that are no less favorable than for physical illness generally.

c. For purposes of this subdivision:

"Cooperative group" means a formal network of facilities that collaborate on research projects and have an established NIH-approved peer review program operating within the group. "Cooperative group" includes (i) the National Cancer Institute Clinical Cooperative Group and (ii) the National Cancer Institute Community Clinical Oncology Program.

"FDA" means the Federal Food and Drug Administration.

"Multiple project assurance contract" means a contract between an institution and the Federal Department of Health and Human Services that defines the relationship of the institution to the Federal Department of Health and Human Services and sets out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects.

"NCI" means the National Cancer Institute.

"NIH" means the National Institutes of Health.

"Patient" means a person covered under the plan established pursuant to this section.

"Patient cost" means the cost of a medically necessary health care service that is incurred as a result of the treatment being provided to a patient for purposes of a clinical trial. "Patient cost" does not include (i) the cost of nonhealth care services that a patient may be required to receive as a result of the treatment being provided for purposes of a clinical trial, (ii) costs associated with managing the research associated with the clinical trial, or (iii) the cost of the investigational drug or device.

d. Coverage for patient costs incurred during clinical trials for treatment studies on cancer shall be provided if the treatment is being conducted in a Phase II, Phase III, or Phase IV clinical trial. Such treatment may, however, be provided on a case-by-case basis if the treatment is being provided in a Phase I clinical trial.

e. The treatment described in clause d shall be provided by a clinical trial approved by:

(1) The National Cancer Institute;

(2) An NCI cooperative group or an NCI center;

(3) The FDA in the form of an investigational new drug application;

(4) The Federal Department of Veterans Affairs; or

(5) An institutional review board of an institution in the Commonwealth that has a multiple project assurance contract approved by the Office of Protection from Research Risks of the NCI.

f. The facility and personnel providing the treatment shall be capable of doing so by virtue of their experience, training, and expertise.

g. Coverage under this section shall apply only if:

(1) There is no clearly superior, noninvestigational treatment alternative;

(2) The available clinical or preclinical data provides a reasonable expectation that the treatment will be at least as effective as the noninvestigatonal alternative; and

(3) The patient and the physician or health care provider who provides services to the patient under the plan conclude that the patient's participation in the clinical trial would be appropriate, pursuant to procedures established by the plan.

17. Include coverage providing a minimum stay in the hospital of not less than twenty-three hours following a laparoscopy-assisted vaginal hysterectomy and forty-eight hours following a vaginal hysterectomy, as outlined in Milliman and Robertson's nationally recognized guidelines. Nothing in this subdivision shall be construed as requiring the provision of the total hours referenced when the attending physician, in consultation with the patient, determines that a shorter hospital stay is appropriate.

C. Claims incurred during a fiscal year but not reported during that fiscal year shall be paid from such funds as shall be appropriated by law. Appropriations, premiums and other payments shall be deposited in the employee health insurance fund, from which payments for claims, premiums, cost containment programs and administrative expenses shall be withdrawn from time to time. The funds of the health insurance fund shall be deemed separate and independent trust funds, shall be segregated from all other funds of the Commonwealth, and shall be invested and administered solely in the interests of the employees and beneficiaries thereof. Neither the General Assembly nor any public officer, employee, or agency shall use or authorize the use of such trust funds for any purpose other than as provided in law for benefits, refunds, and administrative expenses, including but not limited to legislative oversight of the health insurance fund.

D. For the purposes of this section:

"Peer-reviewed medical literature" means a scientific study published only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased independent experts in a journal that has been determined by the International Committee of Medical Journal Editors to have met the Uniform Requirements for Manuscripts submitted to biomedical journals. Peer-reviewed medical literature does not include publications or supplements to publications that are sponsored to a significant extent by a pharmaceutical manufacturing company or health carrier.

"Standard reference compendia" means the American Medical Association Drug Evaluations, the American Hospital Formulary Service Drug Information, or the United States Pharmacopoeia Dispensing Information.

"State employee" means state employee as defined in § 51.1-124.3, employee as defined in § 51.1-201, the Governor, Lieutenant Governor and Attorney General, judge as defined in § 51.1-301 and judges, clerks and deputy clerks of regional juvenile and domestic relations, county juvenile and domestic relations, and district courts of the Commonwealth, interns and residents employed by the School of Medicine and Hospital of the University of Virginia, and interns, residents, and employees of the Medical College of Virginia Hospitals Authority as provided in § 23-50.16:24.

E. Provisions shall be made for retired employees to obtain coverage under the above plan. The Commonwealth may, but shall not be obligated to, pay all or any portion of the cost thereof.

F. Any self-insured group health insurance plan established by the Department of Personnel and Training which utilizes a network of preferred providers shall not exclude any physician solely on the basis of a reprimand or censure from the Board of Medicine, so long as the physician otherwise meets the plan criteria established by the Department.

G. The plan established by the Department shall include, in each planning district, at least two

health coverage options, each sponsored by unrelated entities. In each planning district that does not have an available health coverage alternative, the Department shall voluntarily enter into negotiations at any time with any health coverage provider who seeks to provide coverage under the plan. This section shall not apply to any state agency authorized by the Department to establish and administer its own health insurance coverage plan separate from the plan established by the Department.

H. 1. Any self-insured group health insurance plan established by the Department of Personnel that includes coverage for prescription drugs on an outpatient basis may apply a formulary to the prescription drug benefits provided by the plan if the formulary is developed, reviewed at least annually, and updated as necessary in consultation with and with the approval of a pharmacy and therapeutics committee, a majority of whose members are actively practicing licensed (i) pharmacists, (ii) physicians, and (iii) other health care providers.

2. If the plan maintains one or more closed drug formularies, the plan shall establish a process to allow a person to obtain, without additional cost-sharing beyond that provided for formulary prescription drugs in the plan, a specific, medically necessary nonformulary prescription drug if the formulary drug is determined by the plan, after reasonable investigation and consultation with the prescribing physician, to be an inappropriate therapy for the medical condition of the person. The plan shall act on such requests within one business day of receipt of the request.

I. Any plan established by the Department of Personnel and Training requiring preauthorization prior to rendering medical treatment shall have personnel available to provide authorization at all times when such preauthorization is required.

J. Any plan established by the Department of Personnel and Training shall provide to all covered employees written notice of any benefit reductions during the contract period at least thirty days before such reductions become effective.

K. No contract between a provider and any plan established by the Department of Personnel and Training shall include provisions which require a health care provider or health care provider group to deny covered services that such provider or group knows to be medically necessary and appropriate that are provided with respect to covered employees with similar medical conditions.

L. 1. The Department of Personnel and Training shall appoint an Ombudsman to promote and protect the interests of covered employees under any state employee's health plan.

2. The Ombudsman shall:

a. Assist covered employees in understanding their rights and the processes available to them according to their state health plan.

b. Answer inquiries from covered employees by telephone and electronic mail.

c. Provide to covered employees information concerning the state health plans.

d. Develop information on the types of health plans available, including benefits and complaint procedures and appeals.

e. Make available, either separately or through an existing Internet website utilized by the Department of Personnel and Training, information as set forth in clause d and such additional information as he deems appropriate.

f. Maintain data on inquiries received, the types of assistance requested, any actions taken and the disposition of each such matter.

g. Upon request, assist covered employees in using the procedures and processes available to them from their health plan, including all appeal procedures. Such assistance may require the review of health care records of a covered employee, which shall be done only with that employee's express written consent. The confidentiality of any such medical records shall be maintained in accordance with the confidentiality and disclosure laws of the Commonwealth.

h. Ensure that covered employees have access to the services provided by the Ombudsman and that the covered employees receive timely responses from the Ombudsman or his representatives to the inquiries.

i. Report annually on his activities to the standing committees of the General Assembly having jurisdiction over insurance and over health and the Joint Commission on Health Care by December 1 of each year.

M. 1. The plan established by the Department of Personnel and Training shall not refuse to accept or make reimbursement pursuant to an assignment of benefits made to a dentist or oral surgeon by a

covered employee.

2. For purposes of this subsection, "assignment of benefits" means the transfer of dental care coverage reimbursement benefits or other rights under the plan. The assignment of benefits shall not be effective until the covered employee notifies the plan in writing of the assignment.

§ 32.1-137.6. Complaint system.

A. Each managed care health insurance plan licensee subject to § 32.1-137.2 shall establish and maintain for each of its managed care health insurance plans a complaint system approved by the Commissioner and the Bureau of Insurance to provide reasonable procedures for the resolution of written complaints in accordance with the requirements established under this article and Title 38.2, and shall include the following:

1. A record of the complaints shall be maintained for the period set forth in § 32.1-137.16 for review by the Commissioner.

2. Each managed care health insurance plan licensee shall provide complaint forms and/or written procedures to be given to covered persons who wish to register written complaints. Such forms or procedures shall include the address and telephone number *of the managed care licensee* to which complaints shall be directed *and the mailing address, telephone number, and the electronic mail address of the Managed Care Ombudsman established pursuant to § 38.2-5904* and shall also specify any required limits imposed by or on behalf of the managed care health insurance plan. *Such forms and written procedures shall include a clear and understandable description of the covered person's right to appeal adverse decisions pursuant to § 32.1-137.15.*

B. The Commissioner, in cooperation with the Bureau of Insurance, shall examine the complaint system. The effectiveness of the complaint system of the managed care health insurance plan licensee in allowing covered persons, or their duly authorized representatives, to have issues regarding quality f care appropriately resolved under this article shall be assessed by the State Health Commissioner nder this article. Compliance by the health carrier and its managed care health insurance plans with the terms and procedures of the complaint system, as well as the provisions of Title 38.2, shall be assessed by the Bureau of Insurance.

C. As part of the renewal of a certificate, each managed care health insurance plan licensee shall submit to the Commissioner *and to the Managed Care Ombudsman* an annual complaint report in a form agreed and prescribed by the Board and the Bureau of Insurance. The complaint report shall include, but shall not be limited to (i) a description of the procedures of the complaint system, (ii) the total number of complaints handled through the complaint system, (iii) the disposition of the complaints, (iv) a compilation of the nature and causes underlying the complaints filed, (v) the time it took to process and resolve each complaint, and (vi) the number, amount, and disposition of malpractice claims adjudicated during the year with respect to any of the managed care health insurance plan's health care providers.

The Department of Personnel and Training and the Department of Medical Assistance Services shall file similar periodic reports with the Commissioner, in a form prescribed by the Board, providing appropriate information on all complaints received concerning quality of care and utilization review under their respective health benefits program and managed care health insurance plan licensee contractors.

D. The Commissioner shall examine the complaint system under subsection B for compliance of the complaint system with respect to quality of care and shall require corrections or modifications as deemed necessary.

E. The Commissioner shall have no jurisdiction to adjudicate individual controversies arising under this article.

F. The Commissioner of Health or the nonprofit organization pursuant to § 32.1-276.4 may prepare a summary of the information submitted pursuant to this provision and § 32.1-122.10:01 to be ncluded in the patient level data base.

§ 32.1-137.15. Final adverse decision; appeal.

A. Each entity shall establish an appeals process, including a process for expedited appeals, to consider any final adverse decision that is appealed by a covered person, his representative, or his provider. Except as provided in subsection E, notification of the results of the appeal process shall be provided to the appellant no later than sixty working days after receiving the required documentation.

The decision shall be in writing and shall state the criteria used and the clinical reason for the decision. *If the appeal is denied, such notification shall include a clear and understandable description of the covered person's right to appeal final adverse decisions to the Bureau of Insurance in accordance with Chapter 59 (§ 38.2-5900 et seq.) of Title 38.2, the procedures for making such an appeal, and the binding nature and effect of such an appeal, including all forms prescribed by the Bureau of Insurance pursuant to § 38.2-5901. Such notification shall also include the mailing address, telephone number, and electronic mail address of the Managed Care Ombudsman. Further, such notification shall advise any such covered person that, except in the instance of fraud, any such appeal herein may preclude such person's exercise of any other right or remedy relating to such adverse decision.*

B. Any case under appeal shall be reviewed by a peer of the treating health care provider who proposes the care under review or who was primarily responsible for the care under review. With the exception of expedited appeals, a physician advisor who reviews cases under appeal shall be a peer of the treating health care provider, shall be board certified or board eligible, and shall be specialized in a discipline pertinent to the issue under review.

A physician advisor or peer of the treating health care provider who renders a decision on appeal shall: (i) not have participated in the adverse decision or any prior reconsideration thereof; (ii) not be employed by or a director of the utilization review entity; and (iii) be licensed to practice in Virginia, or under a comparable licensing law of a state of the United States, as a peer of the treating health care provider.

C. The utilization review entity shall provide an opportunity for the appellant to present additional evidence for consideration on appeal. Before rendering an adverse appeal decision, the utilization review entity shall review the pertinent medical records of the covered person's provider and the pertinent records of any facility in which health care is provided to the covered person which have been furnished to the entity.

D. In the appeals process, due consideration shall be given to the availability or nonavailability of alternative health care services proposed by the entity. No provision herein shall prevent an entity from considering any hardship imposed by the alternative health care on the patient and his immediate family.

E. When an adverse decision or adverse reconsideration is made and the treating health care provider believes that the decision warrants an immediate appeal, the treating health care provider shall have the opportunity to appeal the adverse decision or adverse reconsideration by telephone on an expedited basis.

The decision on an expedited appeal shall be made by a physician advisor, peer of the treating health care provider, or a panel of other appropriate health care providers with at least one physician advisor on the panel.

The utilization review entity shall decide the expedited appeal no later than one business day after receipt by the entity of all necessary information.

An expedited appeal may be requested only when the regular reconsideration and appeals process will delay the rendering of health care in a manner that would be detrimental to the health of the patient. Both providers and utilization review entities shall attempt to share the maximum information by telephone, facsimile machine, or otherwise to resolve the expedited appeal in a satisfactory manner.

An expedited appeal decision may be further appealed through the standard appeal process established by the entity unless all material information and documentation were reasonably available to the provider and to the entity at the time of the expedited appeal, and the physician advisor reviewing the case under expedited appeal was a peer of the treating health care provider, was board certified or board eligible, and specialized in a discipline pertinent to the issue under review.

F. The appeals process required by this section does not apply to any adverse decision, reconsideration, or final adverse decision rendered solely on the basis that a health benefit plan does not provide benefits for the health care rendered or requested to be rendered.

G. No entity performing utilization review pursuant to this article or ~~Chapter 53 (§ 38.2-5300 et seq.) of Title 38.2~~ *Article 2.1 (§ 32.1-138.6 et seq.) of Chapter 5*, shall terminate the employment or other contractual relationship or otherwise penalize a health care provider for advocating the interest of his patient or patients in the appeals process or invoking the appeals process, unless the provider

engages in a pattern of filing appeals that are without merit.

§ 38.2-3407.9:01. Prescription drug formularies.

A. Each (i) insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense-incurred basis, (ii) corporation providing individual or group accident and sickness subscription contracts, and (iii) health maintenance organization providing a health care plan for health care services, whose policy, contract or plan, including any certificate or evidence of coverage issued in connection with such policy, contract or plan, includes coverage for prescription drugs on an outpatient basis may apply a formulary to the prescription drug benefits provided by the insurer, corporation, or health maintenance organization if the formulary is developed, reviewed at least annually, and updated as necessary in consultation with and with the approval of a pharmacy and therapeutics committee, a majority of whose members are actively practicing licensed pharmacists, physicians and other licensed health care providers.

B. If an insurer, corporation, or health maintenance organization maintains one or more closed drug formularies, each insurer, corporation or health maintenance organization shall:

1. Make available to participating providers and pharmacists and to any nonpreferred or nonparticipating pharmacists as described in §§ 38.2-3407.7 and 38.2-4312.1, the complete, current drug formulary or formularies, or any updates thereto, maintained by the insurer, corporation, or health maintenance organization, including a list of the prescription drugs on the formulary by major therapeutic category that specifies whether a particular prescription drug is preferred over other drugs; and

2. Establish a process to allow an enrollee to obtain, without additional cost-sharing beyond that provided for formulary prescription drugs in the enrollee's covered benefits, a specific, medically necessary nonformulary prescription drug if the formulary drug is determined by the insurer, corporation, or health maintenance organization, after reasonable investigation and consultation with the prescribing physician, to be an inappropriate therapy for the medical condition of the enrollee. The insurer, corporation or health maintenance organization shall act on such requests within one business day of receipt of the request.

§ 38.2-3407.10. Health care provider panels.

A. As used in this section:

"Carrier" means:

1. Any insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense incurred basis;

2. Any corporation providing individual or group accident and sickness subscription contracts;

3. Any health maintenance organization providing health care plans for health care services;

4. Any corporation offering prepaid dental or optometric services plans; or

5. Any other person or organization that provides health benefit plans subject to state regulation, and includes an entity that arranges a provider panel for compensation.

"Enrollee" means any person entitled to health care services from a carrier.

"Provider" means a hospital, physician or any type of provider licensed, certified or authorized by statute to provide a covered service under the health benefit plan.

"Provider panel" means those providers with which a carrier contracts to provide health care services to the carrier's enrollees under the carrier's health benefit plan. However, such term does not include an arrangement between a carrier and providers in which any provider may participate solely on the basis of the provider's contracting with the carrier to provide services at a discounted fee-for-service rate.

B. Any such carrier which offers a provider panel shall establish and use it in accordance with the following requirements:

1. Notice of the development of a provider panel in the Commonwealth or local service area shall be filed with the Department of Health Professions.

2. Carriers shall provide a provider application and the relevant terms and conditions to a provider upon request.

C. A carrier that uses a provider panel shall establish procedures for:

1. Notifying an enrollee of:

a. The termination from the carrier's provider panel of the enrollee's primary care provider who was furnishing health care services to the enrollee; and

b. The right of an enrollee upon request to continue to receive health care services for a period of up to ~~sixty~~ *ninety* days from the date of the primary care provider's notice of termination from a carrier's provider panel, except when a provider is terminated for cause.

2. Notifying a provider at least ~~sixty~~ *ninety* days prior to the date of the termination of the provider, except when a provider is terminated for cause.

3. Providing reasonable notice to primary care providers in the carrier's provider panel of the termination of a specialty referral services provider.

4. Notifying the purchaser of the health benefit plan, whether such purchaser is an individual or an employer providing a health benefit plan, in whole or in part, to its employees and enrollees of the health benefit plan of:

a. A description of all types of payment arrangements that the carrier uses to compensate providers for health care services rendered to enrollees, including, but not limited to, withholds, bonus payments, capitation and fee-for-service discounts; and

b. The terms of the plan in clear and understandable language which reasonably informs the purchaser of the practical application of such terms in the operation of the plan.

D. Whenever a provider voluntarily terminates his contract with a carrier to provide health care services to the carrier's enrollees under a health benefit plan, he shall furnish reasonable notice of such termination to his patients who are enrollees under such plan.

E. A carrier may not deny an application for participation or terminate participation on its provider panel on the basis of gender, race, age, religion or national origin.

F. 1. For a period of at least ~~sixty~~ *ninety* days from the date of the notice of a provider's termination from the carrier's provider panel, except when a provider is terminated for cause, the provider shall be permitted by the carrier to render health care services to any of the carrier's enrollees who:

a. Were in an active course of treatment from the provider prior to the notice of termination; and

b. Request to continue receiving health care services from the provider.

2. Notwithstanding the provisions of subdivision 1, any provider shall be permitted by the carrier to continue rendering health services to any enrollee who has entered the second trimester of pregnancy at the time of a provider's termination of participation, except when a provider is terminated for cause. Such treatment shall, at the enrollee's option, continue through the provision of postpartum care directly related to the delivery.

3. Notwithstanding the provisions of subdivision 1, any provider shall be permitted by the carrier to continue rendering health services to any enrollee who is determined to be terminally ill (as defined under § 1861 (dd) (3) (A) of the Social Security Act) at the time of a provider's termination of participation, except when a provider is terminated for cause. Such treatment shall, at the enrollee's option, continue for the remainder of the enrollee's life for care directly related to the treatment of the terminal illness.

~~2.~~ *4.* A carrier shall reimburse a provider under this subsection in accordance with the carrier's agreement with ~~the providers~~ *such provider existing immediately before the provider's termination of participation.*

G. 1. A carrier shall provide to a purchaser prior to enrollment and to existing enrollees at least once a year a list of members in its provider panel, which list shall also indicate those providers who are not currently accepting new patients.

2. The information provided under subdivision 1 shall be updated at least once a year.

H. No contract between a carrier and a provider may require that the provider indemnify the carrier for the carrier's negligence, willful misconduct, or breach of contract, if any.

I. No contract between a carrier and a provider shall require a provider, as a condition of participation on the panel, to waive any right to seek legal redress against the carrier.

J. No contract between a carrier and a provider shall prohibit, impede or interfere in the discussion of medical treatment options between a patient and a provider.

K. A contract between a carrier and a provider shall permit and require the provider to discuss medical treatment options with the patient.

L. Any carrier requiring preauthorization prior to rendering medical treatment shall have personnel available to provide such authorization at all times when such preauthorization is required.

M. Carriers shall provide to their group policyholders written notice of any benefit reductions during the contract period at least sixty days before such benefit reductions become effective. Group policyholders shall, in turn, provide to their enrollees written notice of any benefit reductions during the contract period at least thirty days before such benefit reductions become effective.

N. No contract between a provider and a carrier shall include provisions which require a health care provider or health care provider group to deny covered services that such provider or group knows to be medically necessary and appropriate that are provided with respect to a specific enrollee or group of enrollees with similar medical conditions.

~~L.~~ *O.* The Commission shall have no jurisdiction to adjudicate controversies arising out of this section.

~~M.~~ *P.* The requirements of this section shall apply to all insurance policies, contracts, and plans delivered, issued for delivery, reissued, or extended on or after July 1, 1996~~, or at any time after the effective date hereof when any term of any such policy, contract, or plan is changed or any premium adjustment is made. In addition, the requirements of this section shall apply to contracts between carriers and providers that are entered into or renewed on or after July 1, 1996~~. *However, the ninety-day period referred to in subdivisions C 1 b and C 2 of this section and the requirements set forth in subdivisions F 2 and F 3 and the requirements set forth in subsections L, M, and N shall apply to contracts between carriers and providers that are entered into or renewed on or after July 1, 1999.*

§ 38.2-3407.11:1. Access to specialists; standing referrals.

A. Each (i) insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense-incurred basis, (ii) corporation providing individual or group accident and sickness subscription contracts, and (iii) health maintenance organization providing a health care plan for health care services shall permit any individual covered thereunder direct access, as provided in subsection B, to the health care services of a participating specialist (i) authorized to provide services under such policy, contract or plan and (ii) selected by such individual.

B. An insurer, corporation, or health maintenance organization, in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has an ongoing special condition may, after consultation with the primary care physician, receive a referral to a specialist for such condition who shall be responsible for and capable of providing and coordinating the individual's primary and specialty care related to the initial specialty care referral. If such an individual's care would most appropriately be coordinated by such a specialist, such plan or issuer shall refer the individual to a specialist. For the purposes of this section, "special condition" means a condition or disease that is (i) life-threatening, degenerative, or disabling and (ii) requires specialized medical care over a prolonged period of time.

C. Within the treatment period authorized by the referral, such specialist shall be permitted to treat the individual without a further referral from the individual's primary care provider and may authorize such referrals, procedures, tests, and other medical services related to the initial referral as the individual's primary care provider would otherwise be permitted to provide or authorize.

D. An insurer, corporation, or health maintenance organization, in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has an ongoing special condition that requires ongoing care from a specialist may receive a standing referral to such specialist for the treatment of the special condition. If the plan or issuer, or if the primary care provider in consultation with the plan or issuer and the specialist, if any, determines that such a standing referral is appropriate, the plan or issuer shall make such a referral to a specialist.

E. Nothing contained herein shall prohibit an insurer, corporation, or health maintenance organization from requiring a participating specialist to provide written notification to the covered individual's primary care physician of any visit to such specialist. Such notification may include a description of the health care services rendered at the time of the visit.

F. Each insurer, corporation or health maintenance organization subject to the provisions of this

section shall inform subscribers of the provisions of this section. Such notice shall be provided in writing, and included in the policy or evidence of coverage.

G. The requirements of this section shall apply to all insurance policies, contracts, and plans delivered, issued for delivery, reissued, renewed, or extended or at any time when any term of any such policy, contract, or plan is changed or any premium adjustment is made. The provisions of this section shall not apply to short-term travel or accident-only policies, to short-term nonrenewable policies of not more than six months' duration, or policies or contracts issued to persons eligible under Title XVIII of the Social Security Act, known as Medicare, or any other similar coverage under state or federal governmental plans.

§ 38.2-3407.13. Refusal to accept assignments prohibited; dentists and oral surgeons.-

A. No insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense-incurred basis, no corporation providing individual or group accident and sickness subscription contracts, and no dental services plan offering or administering prepaid dental services shall refuse to accept or make reimbursement pursuant to an assignment of benefits made to a dentist or oral surgeon by an insured, subscriber or plan enrollee.

B. For the purpose of this section "assignment of benefits" means the transfer of dental care coverage reimbursement benefits or other rights under an insurance policy, subscription contract or dental services plan by an insured, subscriber or plan enrollee to a dentist or oral surgeon. The assignment of benefits shall not be effective until the insured, subscriber or enrollee notifies the insurer, corporation or plan in writing of the assignment.

§ 38.2-3407.14. Notice of premium increases.

A. Each (i) insurer issuing individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense-incurred basis, (ii) corporation providing individual or group accident and sickness subscription contracts, and (iii) health maintenance organization providing a health care plan for health care services, shall provide in conjunction with the proposed renewal of coverage under any such policies, contracts or plans, prior written notice of intent to increase by more than thirty-five percent the annual premium charged for coverage thereunder.

B. Notice required by this section shall be provided in writing at least sixty days prior to the proposed renewal of coverage under any such policy, contract, or plan to the policyholder, contract holder or subscriber, as appropriate.

§ 38.2-3407.15. Refusal to accept assignments prohibited.

A. No insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense-incurred basis, no corporation providing individual or group accident and sickness subscription contracts and no health maintenance organization providing a health care plan for health care services shall refuse to accept or make reimbursement pursuant to an assignment of benefits made to a health care provider or hospital by an insured, subscriber or plan enrollee, provided that if the health care provider or hospital obtains such assignment of benefits, then the health care provider or hospital shall accept the reimbursement under such assignment as payment in full for the services covered by such assignment and shall not charge or bill the insured, subscriber or plan enrollee any further amount except for the amount of any applicable deductible, copayment or coinsurance.

B. For the purpose of this section, "assignment of benefits" means the transfer of health care coverage reimbursement benefits or other rights under an insurance policy, subscription contract or health care plan by an insured, subscriber or plan enrollee to a health care provider or hospital.

C. This section shall not apply to an assignment of benefits made to a dentist or oral surgeon.

§ 38.2-3418.8. Coverage for clinical trials for treatment studies on cancer.

A. Notwithstanding the provisions of § 38.2-3419, each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; each corporation providing individual or group accident and sickness subscription contracts; and each health maintenance organization providing a health care plan for health care services shall provide coverage for patient costs incurred during participation in clinical trials for treatment studies on cancer, including ovarian cancer trials, under

any such policy, contract or plan delivered, issued for delivery, or renewed in this Commonwealth on and after July 1, 1999.

B. The reimbursement for patient costs incurred during participation in clinical trials for treatment studies on cancer shall be determined in the same manner as reimbursement is determined for other medical and surgical procedures. Such coverage shall have durational limits, dollar limits, deductibles, copayments and coinsurance factors that are no less favorable than for physical illness generally.

C. For purposes of this section:

"Cooperative group" means a formal network of facilities that collaborate on research projects and have an established NIH-approved peer review program operating within the group. "Cooperative group" includes (i) the National Cancer Institute Clinical Cooperative Group and (ii) the National Cancer Institute Community Clinical Oncology Program.

"FDA" means the Federal Food and Drug Administration.

"Member" means a policyholder, subscriber, insured, or certificate holder or a covered dependent of a policyholder, subscriber, insured or certificate holder.

"Multiple project assurance contract" means a contract between an institution and the Federal Department of Health and Human Services that defines the relationship of the institution to the Federal Department of Health and Human Services and sets out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects.

"NCI" means the National Cancer Institute.

"NIH" means the National Institutes of Health.

"Patient cost" means the cost of a medically necessary health care service that is incurred as a result of the treatment being provided to the member for purposes of a clinical trial. "Patient cost" does not include (i) the cost of nonhealth care services that a patient may be required to receive as a result of the treatment being provided for purposes of a clinical trial, (ii) costs associated with managing the research associated with the clinical trial, or (iii) the cost of the investigational drug or device.

D. Coverage for patient costs incurred during clinical trials for treatment studies on cancer shall be provided if the treatment is being conducted in a Phase II, Phase III, or Phase IV clinical trial. Such treatment may, however, be provided on a case-by-case basis if the treatment is being provided in a Phase I clinical trial.

E. The treatment described in subsection D shall be provided by a clinical trial approved by:

1. The National Cancer Institute;

2. An NCI cooperative group or an NCI center;

3. The FDA in the form of an investigational new drug application;

4. The Federal Department of Veterans Affairs; or

5. An institutional review board of an institution in the Commonwealth that has a multiple project assurance contract approved by the Office of Protection from Research Risks of the NCI.

F. The facility and personnel providing the treatment shall be capable of doing so by virtue of their experience, training, and expertise.

G. Coverage under this section shall apply only if:

1. There is no clearly superior, noninvestigational treatment alternative;

2. The available clinical or preclinical data provides a reasonable expectation that the treatment will be at least as effective as the noninvestigatonal alternative; and

3. The member and the physician or health care provider who provides services to the member under the insurance policy, subscription contract or health care plan conclude that the member's participation in the clinical trial would be appropriate, pursuant to procedures established by the insurer, corporation or health maintenance organization and as disclosed in the policy and evidence of coverage.

H. The provisions of this section shall not apply to short-term travel, accident-only or contracts designed for issuance to persons eligible for coverage under Title XVIII of the Social Security Act, known as Medicare, or any other similar coverage under state or governmental plans or to short-term nonrenewable policies of not more than six months' duration.

§ 38.2-3418.9. Minimum hospital stay for hysterectomy.

A. Notwithstanding the provisions of § 38.2-3419, each insurer proposing to issue an individual or group hospital policy or major medical policy in this Commonwealth; each corporation proposing to issue an individual or group hospital, medical or major medical subscription contract; and each health maintenance organization providing a health care plan for health care shall provide coverage for laparoscopy-assisted vaginal hysterectomy and vaginal hysterectomy as provided in this section.

B. Such coverage shall include benefits for a minimum stay in the hospital of not less than twenty-three hours for a laparoscopy-assisted vaginal hysterectomy and forty-eight hours for a vaginal hysterectomy as outlined in Milliman & Robertson's nationally recognized guidelines. Nothing in this section shall be construed as requiring the provision of the total hours referenced when the attending physician, in consultation with the patient, determines that a shorter period of hospital stay is appropriate.

C. The requirements of this section shall apply to all insurance policies, contracts and plans delivered, issued for delivery, reissued or extended on and after July 1, 1999, or at any time thereafter when any term of the policy, contract or plan is changed or any premium adjustment is made.

D. This section shall not apply to short-term travel, accident-only or to contracts designed for issuance to persons eligible for coverage under Title XVIII of the Social Security Act, known as Medicare, or any other similar coverage under state or federal governmental plans.

§ 38.2-4209. Preferred provider subscription contracts.

A. As used in this section, a "preferred provider subscription contract" is a contract that specifies how services are to be covered when rendered by providers participating in a plan, by nonparticipating providers, and by preferred providers.

B. Notwithstanding the provisions of §§ 38.2-4218 and 38.2-4221, any nonstock corporation may, as a feature of its plan, offer preferred provider subscription contracts pursuant to the requirements of this section that limit the numbers and types of providers of health care services eligible for payment as preferred providers.

C. Any such nonstock corporation shall establish terms and conditions that shall be met by a hospital, physician or other type of provider listed in § 38.2-4221 in order to qualify for payment as a preferred provider under the subscription contracts. These terms and conditions shall not discriminate unreasonably against or among health care providers. No hospital, physician or type of provider listed in § 38.2-4221 willing to meet the terms and conditions offered to it or him shall be excluded. Differences in prices among hospitals or other institutional providers produced by a process of individual negotiations with the providers or based on market conditions, or price differences among providers in different geographical areas shall not be deemed unreasonable discrimination. The Commission shall have no jurisdiction to adjudicate controversies growing out of this subsection.

D. Mandated types of providers listed in § 38.2-4221 and types of providers whose services are required to be made available and which have been specifically contracted for by the holder of any subscription contract shall, to the extent required by § 38.2-4221, have the same opportunity as do doctors of medicine to qualify for payment as preferred providers.

E. Preferred provider subscription contracts shall provide for payment for services rendered by nonpreferred providers, but the payments need not be the same as for preferred providers.

F. No contract between a nonstock corporation and a provider shall include provisions which require a health care provider or health care provider group to deny covered services that such provider or group knows to be medically necessary and appropriate that are provided with respect to a specific enrollee or group of enrollees with similar medical conditions.

§ 38.2-4214. Application of certain provisions of law.

No provision of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-200, 38.2-203, 38.2-210 through 38.2-213, 38.2-218 through 38.2-225, 38.2-230, 38.2-232, 38.2-305, 38.2-316, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, 38.2-700 through 38.2-705, 38.2-900 through 38.2-904, 38.2-1017, 38.2-1018, 38.2-1038, 38.2-1040 through 38.2-1044, Articles 1 (§ 38.2-1300 et seq.) and 2 (§ 38.2-1306.2 et seq.) of Chapter 13, §§ 38.2-1312, 38.2-1314, 38.2-1317 through 38.2-1328, 38.2-1334, 38.2-1340, 38.2-1400 through 38.2-1444, 38.2-1800 through 38.2-1836, 38.2-3400, 38.2-3401, 38.2-3404, 38.2-3405, 38.2-3405.1, 38.2-3407.1 through 38.2-3407.6, 38.2-3407.9,

38.2-3407.9:01, 38.2-3407.10, 38.2-3407.11, *38.2-3407.11:1*, 38.2-3407.12, *38.2-3407.13*, *38.2-3407.14*, *38.2-3407.15*, 38.2-3409, 38.2-3411 through 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3501, 38.2-3502, 38.2-3514.1, 38.2-3514.2, 38.2-3516 through 38.2-3520 as they apply to Medicare supplement policies, §§ 38.2-3522.1 through 38.2-3523.4, ~~§§~~ 38.2-3525, 38.2-3540.1, 38.2-3541, 38.2-3542, 38.2-3543.2, 38.2-3600 through 38.2-3607, Chapter 53 (§ 38.2-5300 et seq.), ~~and~~ Chapter 58 (§ 38.2-5800 et seq.) *and Chapter 59 (§ 38.2-5900 et seq.)* of this title shall apply to the operation of a plan.

§ 38.2-4312. Prohibited practices.

A. No health maintenance organization or its representative may cause or knowingly permit the use of (i) advertising that is untrue or misleading, (ii) solicitation that is untrue or misleading, or (iii) any form of evidence of coverage that is deceptive. For the purposes of this chapter:

1. A statement or item of information shall be deemed to be untrue if it does not conform to fact in any respect that is or may be significant to an enrollee or person considering enrollment in a health care plan;

2. A statement or item of information shall be deemed to be misleading, whether or not it may be literally untrue, if the statement or item of information may be understood by a reasonable person who has no special knowledge of health care coverage as indicating (i) a benefit or advantage if that benefit or advantage does not in fact exist or (ii) the absence of any exclusion, limitation or disadvantage of possible significance to an enrollee or person considering enrollment in a health care plan if the absence of that exclusion, limitation, or disadvantage does not in fact exist; consideration shall be given to the total context in which the statement is made or the item of information is communicated; and

3. An evidence of coverage shall be deemed to be deceptive if it causes a reasonable person who has no special knowledge of health care plans to expect benefits, services, charges, or other advantages that the evidence of coverage does not provide or that the health care plan issuing the evidence of coverage does not regularly make available for enrollees covered under the evidence of coverage; consideration shall be given to the evidence of coverage taken as a whole and to the typography, format, and language.

B. The provisions of Chapter 5 (§ 38.2-500 et seq.) of this title shall apply to health maintenance organizations, health care plans, and evidences of coverage except to the extent that the Commission determines that the nature of health maintenance organizations, health care plans, and evidences of coverage render any of the provisions clearly inappropriate.

C. No health maintenance organization, unless licensed as an insurer, may use in its name, contracts, or literature (i) any of the words "insurance," "casualty," "surety," "mutual," or (ii) any other words descriptive of the insurance, casualty, or surety business or deceptively similar to the name or description of any insurance or fidelity and surety insurer doing business in this Commonwealth.

D. No health maintenance organization shall discriminate on the basis of race, creed, color, sex or religion in the selection of health care providers for participation in the organization.

E. No health maintenance organization shall unreasonably discriminate against physicians as a class or any class of providers listed in § 38.2-4221 or pharmacists when contracting for specialty or referral practitioners or providers, provided the plan covers services which the members of such classes are licensed to render. Nothing contained in this section shall prevent a health maintenance organization from selecting, in the judgment of the health maintenance organization, the numbers of providers necessary to render the services offered by the health maintenance organization.

F. No contract between a health maintenance organization and a provider shall include provisions which require a health care provider or health care provider group to deny covered services that such provider or group knows to be medically necessary and appropriate that are provided with respect to a specific enrollee or group of enrollees with similar medical conditions.

§ 38.2-4319. Statutory construction and relationship to other laws.

A. No provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-200, 38.2-203, 38.2-210 through 38.2-213, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-305, 38.2-316, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.) of this title, §§

38.2-1057, 38.2-1306.2 through 38.2-1309, Articles 4 (§ 38.2-1317 et seq.) and 5 (§ 38.2-1322 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.) and 2 (§ 38.2-1412 et seq.) of Chapter 14, §§ 38.2-1800 through 38.2-1836, 38.2-3401, 38.2-3405, 38.2-3405.1, 38.2-3407.2 through 38.2-3407.6, 38.2-3407.9, *38.2-3407.9:01*, 38.2-3407.10, 38.2-3407.11, *38.2-3407.11:1*, 38.2-3407.12, *38.2-3407.14*, *38.2-3407.15*, 38.2-3411.2, 38.2-3414.1, 38.2-3418.1 through ~~38.2-3418.7~~ *38.2-3418.9*, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3542, 38.2-3543.2, Chapter 53 (§ 38.2-5300 et seq.), ~~and~~ Chapter 58 (§ 38.2-5800 et seq.) *and Chapter 59 (§ 38.2-5900 et seq.)* of this title shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§ 38.2-4200 et seq.) of this title except with respect to the activities of its health maintenance organization.

B. Solicitation of enrollees by a licensed health maintenance organization or by its representatives shall not be construed to violate any provisions of law relating to solicitation or advertising by health professionals.

C. A licensed health maintenance organization shall not be deemed to be engaged in the unlawful practice of medicine. All health care providers associated with a health maintenance organization shall be subject to all provisions of law.

D. Notwithstanding the definition of an eligible employee as set forth in § 38.2-3431, a health maintenance organization providing health care plans pursuant to § 38.2-3431 shall not be required to offer coverage to or accept applications from an employee who does not reside within the health maintenance organization's service area.

§ 38.2-4509. Application of certain laws.

A. No provision of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-200, 38.2-203, 38.2-210 through 38.2-213, 38.2-218 through 38.2-225, 38.2-229, 38.2-316, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, 38.2-900 through 38.2-904, 38.2-1038, 38.2-1040 through 38.2-1044, Articles 1 (§ 38.2-1300 et seq.) and 2 (§ 38.2-1306.2 et seq.) of Chapter 13, *§§* 38.2-1312, 38.2-1314, Article 4 (§ 38.2-1317 et seq.) of Chapter 13, *§§* 38.2-1400 through 38.2-1444, 38.2-1800 through 38.2-1836, 38.2-3401, 38.2-3404, 38.2-3405, 38.2-3407.10, *38.2-3407.13, 38.2-3407.14, 38.2-3407.15*, 38.2-3415, 38.2-3541, 38.2-3600 through 38.2-3603, ~~and~~ Chapter 58 (§ 38.2-5800 et seq.) *and Chapter 59 (§ 38.2-5900 et seq.)* of this title shall apply to the operation of a plan.

B. The provisions of subsection A of § 38.2-322 shall apply to an optometric services plan. The provisions of subsection C of § 38.2-322 shall apply to a dental services plan.

C. The provisions of Article 1.2 (§ 32.1-137.7 et seq.) of Chapter 5 of Title 32.1 shall not apply to either an optometric or dental services plan.

§ 38.2-5804. Complaint system.

A. A health carrier subject to subsection B of § 38.2-5801 shall establish and maintain for each of its MCHIPs a complaint system approved by the Commission and the State Health Commissioner to provide reasonable procedures for the resolution of written complaints in accordance with requirements in or established pursuant to provisions in this title and Title 32.1 and shall include the following:

1. A record of the complaints shall be maintained for no less than five years.

2. Such health carrier shall provide complaint forms and/or written procedures to be given to covered persons who wish to register written complaints. Such forms or procedures shall include the address and telephone number *of the managed care licensee* to which complaints shall be directed *and the mailing address, telephone number, and electronic mail address of the Managed Care Ombudsman*, and shall also specify any required limits imposed by or on behalf of the MCHIP. *Such forms and written procedures shall include a clear and understandable description of the covered person's right to appeal adverse decisions pursuant to § 32.1-137.15.*

B. The Commission, in cooperation with the State Health Commissioner, shall examine the complaint system. The effectiveness of the complaint system of the managed care health insurance plan licensee in allowing covered persons, or their duly authorized representatives, to have issues regarding quality of care appropriately resolved under this chapter shall be assessed by the State

Health Commissioner pursuant to provisions in Title 32.1 and the regulations promulgated thereunder. Compliance by the health carrier and its managed care health insurance plans with the terms and procedures of the complaint system, as well as the provisions of this title, shall be assessed by the Commission.

C. The health carrier for each MCHIP shall submit to the Commission and the State Health Commissioner an annual complaint report in a form prescribed by the Commission and the Board of Health. The complaint report shall include (i) a description of the procedures of the complaint system, (ii) the total number of complaints handled through the grievance or complaint system, (iii) the disposition of the complaints, (iv) a compilation of the nature and causes underlying the complaints filed, (v) the time it took to process and resolve each complaint, and (vi) the number, amount, and disposition of malpractice claims adjudicated during the year with respect to any of the MCHIP's affiliated providers.

D. The provisions of Chapter 5 (§ 38.2-500 et seq.) of this title shall apply to the health carrier, its MCHIPs, and evidence of coverage and representations thereto, except to the extent that the Commission determines that the nature of the health carrier, its MCHIP, and evidences of coverage and representations thereto render any of the provisions clearly inappropriate.

CHAPTER 59.

INDEPENDENT EXTERNAL REVIEW OF ADVERSE UTILIZATION REVIEW DECISIONS.

§ 38.2-5900. Application of chapter; definitions.

This chapter shall apply to all utilization review entities established pursuant to Article 1.2 (§ 32.1-137.7 et seq.) of Chapter 5 of Title 32.1. The definitions in § 32.1-137.7 shall have the same meanings ascribed to them in § 32.1-137.7 when used in this chapter.

§ 38.2-5901. Review by the Bureau of Insurance.

A. A covered person or a treating health care provider, with the consent of the covered person, may in accordance with this section appeal to the Bureau of Insurance for review of any final adverse decision concerning a health service costing more than $500, determined in accordance with regulations adopted by the Commission. The appeal shall be filed within thirty days of the final adverse decision, shall be in writing on forms prescribed by the Bureau of Insurance, shall include a general release executed by the covered person for all medical records pertinent to the appeal, and shall be accompanied by a fifty-dollar nonrefundable filing fee. The fee shall be collected by the Commission and paid directly into the state treasury and credited to the fund for the maintenance of the Bureau of Insurance as provided in subsection B of § 38.2-400. The Commission may, for good cause shown, waive the filing fee upon a finding that payment of the filing fee will cause undue financial hardship for the covered person. The Bureau of Insurance shall provide a copy of the written appeal to the utilization review entity which made the final adverse decision.

B. The Bureau of Insurance or its designee shall conduct a preliminary review of the appeal to determine (i) whether the applicant is a covered person or a treating health care provider with the consent of the covered person, (ii) whether the benefit or service that is the subject of the application reasonably appears to be a covered service costing more than $500, (iii) whether all complaint and appeal procedures available under Article 1.2 (§ 32.1-137.7 et seq.) of Chapter 5 of Title 32.1 have been exhausted, and (iv) whether the application is otherwise complete and filed in compliance with this section. Such preliminary review shall be conducted within five working days of receipt of all information and documentation necessary to conduct a preliminary review. The Bureau of Insurance shall not accept for review any application which fails to meet the criteria set forth in this subsection. Within three working days of completion of the preliminary review, the Bureau of Insurance or its designee shall notify the applicant and the utilization review entity in writing whether the appeal has been accepted for review, and if not accepted, the reasons therefor.

C. The covered person, the treating health care provider, and the utilization review entity shall provide copies of the medical records relevant to the final adverse decision to the Bureau of Insurance within ten working days after the Bureau of Insurance has mailed written notice of its acceptance of the appeal. The confidentiality of such medical records shall be maintained in accordance with the confidentiality and disclosure laws of the Commonwealth. The Bureau of Insurance or its designee may, if deemed necessary, request additional medical records from the covered person, any treating health care provider or the utilization review entity. Failure to comply

with such request within ten working days from the date of such request may result in dismissal of the appeal or reversal of the final adverse decision in the discretion of the Commissioner of Insurance.

D. The Commissioner of Insurance, upon good cause shown, may provide an extension of time for the covered person, the treating health care provider, the utilization review entity and the Commission to meet the established time requirements set forth in this section.

§ 38.2-5902. Appeals; impartial health entity.

A. The Bureau of Insurance shall contract with one or more impartial health entities for the purpose of performing the review of final adverse decisions. The Commission shall adopt regulations to assure that the impartial health entity conducting the review has adequate standards, credentials and experience for such review. The impartial health entity shall examine the final adverse decision to determine whether the decision is objective, clinically valid, compatible with established principles of health care, and appropriate under the terms of the contractual obligations to the covered person. The impartial health entity shall review the written appeal; the response of the utilization review entity; any affidavits which either the covered person, the treating health care provider, or the utilization review entity may file with the Bureau of Insurance; and such medical records as the impartial health entity shall deem appropriate. The impartial health entity shall issue its written recommendation affirming, modifying or reversing the final adverse decision within thirty working days of the acceptance of the appeal by the Bureau of Insurance. The Commissioner of Insurance, based upon such recommendation, shall issue a written ruling affirming, modifying or reversing the final adverse decision. Such written ruling shall not be construed as a final finding, order or judgment of the Commission, and shall be exempt from the application of the Administrative Process Act (§ 9-6.14:1 et seq.). The Commissioner's written ruling shall carry out the recommendations of the impartial health entity unless the impartial health entity exceeded its authority or acted arbitrarily or capriciously. The written ruling of the Commissioner shall bind the covered person and the issuer of the covered person's policy or contract for health benefits to the extent to which each would have been obligated by a judgment entered in an action at law or in equity with respect to the issues which the impartial review entity may examine when reviewing a final adverse decision under this section. The impartial health entity shall not be affiliated or a subsidiary of, nor owned or controlled by a health plan, a trade association of health plans, or a professional association of health care providers.

B. The Bureau of Insurance shall contract with one or more impartial health entities such as medical peer review organizations and independent utilization review. Prior to assigning an appeal to an impartial health entity, the Bureau of Insurance shall verify that the impartial health entity conducting the review of a final adverse decision has no relationship or association with (i) the utilization review entity, or any officer, director or manager of such utilization review entity, (ii) the covered person, (iii) the treating health care provider, or any of its employees or affiliates, (iv) the medical care facility at which the covered service would be provided, or any of its employees or affiliates, or (v) the development or manufacture of the drug, device, procedure or other therapy which is the subject of the final adverse decision. The impartial health entity shall not be a subsidiary of, nor owned or controlled by, a health plan, a trade association of health plans, or a professional association of health care providers.

C. There shall be no liability on the part of and no cause of action shall arise against any officer or employee of an impartial health entity for any actions taken or not taken or statements made by such officer or employee in good faith in the performance of his powers and duties.

D. Any managed care health insurance plan licensee that is required to provide previously denied services as a result of the review by the impartial health entity shall be subject to payment of such fees as the Commission shall deem appropriate to cover the costs of the review.

§ 38.2-5903. Assessment to fund appeals.

A. Each licensed insurer writing insurance as defined in § 38.2-109, each health maintenance organization organized in accordance with the provisions of Chapter 43 (§ 38.2-4300 et seq.), and each nonstock corporation organized in accordance with the provisions of Chapter 42 (§ 38.2-4200 et seq.) or Chapter 45 (§ 38.2-4500 et seq.) shall pay, in addition to any other assessments provided in this title, an assessment in an amount not to exceed 0.015 percent of the direct gross premium income during the preceding calendar year. The assessment shall be apportioned and assessed and paid as

prescribed by § 38.2-403.

B. The assessments made by the Commission under subsection A and paid into the state treasury shall be deposited to a special fund designated "Bureau of Insurance Special Fund—State Corporation Commission," and out of such special fund and the unexpended balance thereof shall be appropriated the sums necessary for the regulation, supervision and examination of all entities subject to regulation under this title.

§ 38.2-5904. Office of the Managed Care Ombudsman established; responsibilities.

A. The Office of the Managed Care Ombudsman is hereby created within the Bureau of Insurance. The Managed Care Ombudsman shall promote and protect the interests of covered persons under managed health insurance plans in the Commonwealth. All state agencies shall assist and cooperate with the Managed Care Ombudsman in the performance of his duties under this chapter.

B. The Managed Care Ombudsman shall:

1. Assist covered persons in understanding their rights and the processes available to them according to their managed health insurance plan.

2. Answer inquiries from covered persons and other citizens by telephone, mail, electronic mail and in person.

3. Provide to covered persons and other citizens information concerning managed care health insurance plans and other utilization review entities upon request.

4. Develop information on the types of managed health insurance plans available in the Commonwealth, including mandated benefits and utilization review procedures and appeals.

5. Make available, either separately or through an existing Internet website utilized by the Bureau of Insurance, information as set forth in subdivision 4 and such additional information as he deems appropriate.

6. In conjunction with complaint and inquiry data maintained by the Bureau of Insurance, maintain data on inquiries received, the types of assistance requested, any actions taken and the disposition of each such matter.

7. Upon request, assist covered persons in using the procedures and processes available to them from their managed health insurance plan, including all utilization review appeals. Such assistance may require the review of insurance and health care records of a covered person, which shall be done only with that person's express written consent. The confidentiality of any such medical records shall be maintained in accordance with the confidentiality and disclosure laws of the Commonwealth.

8. Ensure that covered persons have access to the services provided through the Office and that the covered persons receive timely responses from the representatives of the Office to the inquiries.

9. Provide assessments of proposed and existing managed care health insurance laws and other studies of managed care health insurance plan issues upon request by any of the standing committees of the General Assembly having jurisdiction over insurance or health or the Joint Commission on Health Care.

10. Monitor changes in federal and state laws relating to health insurance.

11. Report annually on his activities to the standing committees of the General Assembly having jurisdiction over insurance and over health and the Joint Commission on Health Care by December 1 of each year, which report shall include a summary of significant new developments in federal and state laws relating to health insurance each year.

12. Carry out activities as the Commission determines to be appropriate.

§ 38.2-5905. Regulations.

The Commission shall promulgate regulations effectuating the purpose of this chapter. Such regulations shall include (i) provisions for expedited consideration of appeals in cases involving emergency health care and (ii) standards, credentials and qualifications for impartial health entities.

2. That the State Corporation Commission shall promulgate the first set of regulations to implement the provisions of Chapter 59 of Title 38.2 of this act to be effective within 280 days after the enactment of this provision.

3. That this act shall take effect on July 1, 1999; however, the appeal processes set forth in Chapter 59 of Title 38.2 of this act shall not take effect until the earlier of (i) ninety days following the promulgation of regulations by the State Corporation Commission as set forth in § 38.2-5905 or (ii) July 1, 2000.

4. That § 38.2-3407.15, the amendment to §§ 38.2-4214, 38.2-4319 and 38.2-4509 citing § 38.2-3407.15 shall not become effective unless reenacted by the 2000 Session of the General Assembly. Prior to the 2000 Session of the General Assembly, the Joint Commission on Health Care and the Bureau of Insurance shall review the financial impact that the enactment of these provisions will have on health care costs, health insurance premiums, and the availability of health care in the Commonwealth.