REPORT OF THE
STATE CORPORATION COMMISSION'S
BUREAU OF INSURANCE ON

The Possible Establishment and Implementation of an Appeals Process for Insureds Denied Coverage for Experimental Technologies

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

HOUSE DOCUMENT NO. 2

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STATE CORPORATION COMMISSION

BUREAU OF INSURANCE

November 1, 1991

TO: The Honorable L. Douglas Wilder
Governor of Virginia
and
The General Assembly of Virginia

I am pleased to transmit this Report of the State Corporation Commission's Bureau of Insurance on The Possible Establishment and Implementation of an Appeals Process for Insureds Denied Coverage for Experimental Technologies.

The study was initiated and the report prepared pursuant to House Joint Resolution No. 432 of the 1991 Session of the General Assembly of Virginia.

Respectfully submitted,

Steven T. Foster
Commissioner of Insurance

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EXECUTIVE SUMMARY

Purpose

The State Corporation Commission's Bureau of Insurance was requested by the 1991 Session of the General Assembly to study the possible establishment and implementation of an appeals process for insureds denied coverage for "experimental" medical technologies. As stated in House Joint Resolution No. 432, this study was requested because (i) the Commission on Health Care for All Virginians had previously examined this issue; (ii) recent studies have revealed inconsistencies in third-party reimbursement policies for medical procedures considered experimental; (iii) some experimental therapies provide potentially life-saving treatment and may actually be more cost effective than more traditional treatments for which coverage is provided; and (iv) an appeals process is necessary to provide Virginia citizens a "fair and objective" means of obtaining adequate insurance.

Methodology

The Bureau of Insurance began studying this issue by analyzing the data collected by the Commission on Health Care for All Virginians. The Bureau surveyed the other state insurance departments to determine whether any states had established an appeals process for insureds denied coverage for experimental medical treatments and whether any states required coverage to be provided for experimental medical treatments. The Bureau also surveyed the top twenty-five accident and sickness insurers, health services plans, and health maintenance organizations operating in Virginia to determine (i) whether coverage for experimental treatments was being provided; (ii) how insurers determined which treatments were experimental; (iii) who within the company made this determination; (iv) whether a list of these treatments was maintained by the company; and (v) whether any statistics were available to indicate the number of claims that had been paid and/or denied for treatments considered experimental. In addition, a public meeting was held to give the citizens of Virginia an opportunity to provide testimony on problems they may have had in being reimbursed for treatments deemed experimental by their insurer.

Findings

The Bureau's findings can be summarized as follows:

1. The Commission on Health Care for All Virginians concluded in its report that, with so many assessment mechanisms already in place, a state panel appointed to assess new technologies would simply replicate the current assessment processes used by various organizations. It also concluded that mandating and/or paying for experimental procedures would encourage the expenditure of resources and money for tertiary care services and high technology research which, in turn, would greatly increase health care costs.

2. There are certain advantages of setting up an appeals panel such as impartiality, consistency in claims handling, reduction in litigation expenses, quick resolution, and equity for the citizens of Virginia. An appeals panel could also help address some of the concerns that have been noted in recently published medical literature such as the concern that (i) cost containment has become the overriding factor in determining the type of medical treatment a patient will receive, (ii) that decisions regarding new technologies do not take into consideration the speed with

which biomedical research is advancing, and (iii) that reimbursement procedures may actually negatively impact the development of new technologies.

3. Comments provided on the company surveys indicated certain disadvantages associated with setting up an appeals panel. These included duplication of remedies already available to insureds, existence of adequate assessment methodologies currently in place, cost and the lack of predictability in determining adequate rates, possible conflict with ERISA laws for self-insured single employer plans, lack of impartiality by specialists making decisions in their field of expertise, and lack of authority to override specific contract exclusions.

4. Thirty-five (35) state insurance departments responded to the Bureau's survey. According to the responses received, none of the states require coverage to be provided for experimental or investigative treatments. None of the states have an appeals process for insureds who are denied coverage for experimental or investigative treatments. However, three states provided additional information for the study. The Georgia Insurance Department said they had taken the position that experimental or investigative treatments could not be defined more restrictively than any treatment, procedure, facility, equipment, drug usage, device or supply not recognized as accepted medical practice by the American medical community. The New York Insurance Department indicated that they could request an opinion from their health department as to whether a treatment was experimental but that such an opinion had only been requested once. The Connecticut Insurance Department said that under questionable circumstances, the department could require the company to justify or support its conclusion that a treatment was experimental. This type of documentation can be and has been requested in Virginia as well.

5. Twenty-two (22) usable company survey responses were received. Seventeen (17) companies indicated that coverage for experimental treatment was neither provided in their policy nor offered in a rider. Seventeen (17) companies reported that they did not maintain a list of treatments considered experimental. When asked if the company had ever paid a claim for a treatment considered experimental, eighteen (18) companies answered "yes", but most of the companies (17) said they did not track claims data for these types of claims so they were unable to report the number of claims that had either been paid or denied. Finally, five (5) companies indicated they would not be opposed to establishing an appeals process in Virginia. It should also be noted that a number of different responses were provided when the companies were asked how they determined what was experimental, who within the company made this determination, and what types of medical authorities were consulted in making this determination.

6. Twenty-one (21) people testified at the public meeting held in Richmond on July 10th and thirty-four (34) individuals and organizations submitted written comments. Excerpts from the testimony given at the meeting and from the written comments received are contained in the report. Also, selected representative samples of written comments are included in the Appendix. The following summarizes some of the comments given: (i) insurers are given unlimited discretion in determining what is experimental and, as a result, are restricting the delivery of health care in Virginia; (ii) insurers do not use the same criteria to determine what is experimental or investigative and vary considerably in their reimbursement policies for these types of treatments; (iii) the court system is already over-burdened and another system that allows quick resolution is needed; (iv) when an insured proves his or her case in court it does not set a precedent for future decisions made by insurers; (v) an arbitration forum should be available to the

average person where no lawyer needs to be present and no great legal expenses are incurred; (vi) most insureds do not know or do not have a choice in deciding what will be covered under their group insurance policies; and (vii) insurers have been cited for making their own independent evaluation of published scientific literature and disregarding the consensus of opinion of members of the medical community.

Conclusion

While the Bureau of Insurance is of the opinion that an appeals process could be established, such a process may not be the best solution to the problem that currently exists. This type of proposal would have certain drawbacks such as (i) increased administrative responsibilities for the agency in charge of overseeing the activities of an appeals panel; (ii) additional costs associated with the added administrative responsibilities; (iii) increased staffing needs; and (iv) difficulty in locating panel members who would be impartial and who would be willing to serve on the panel. In addition, no other state has established an appeals process for insureds who have been denied coverage for experimental medical technologies. Therefore, the Bureau of Insurance is unable to recommend that an appeals process be established in Virginia.

The Bureau of Insurance concludes that if the public demands this type of coverage, insurers should be encouraged to offer coverage for experimental treatments. This coverage should be made available to those who are willing to purchase it.

GENERAL ASSEMBLY OF VIRGINIA--1991 SESSION

HOUSE JOINT RESOLUTION NO. 432

Requesting the Bureau of Insurance to study the possible establishment a implementation of an appeals process for insureds denied coverage for "experimenta medical technologies.

Agreed to by the House of Delegates, February 22, 1991
Agreed to by the Senate, February 21, 1991

WHEREAS, pursuant to House Joint Resolution No. 213 (1990), the Commission on Health Care for All Virginians studied the development of "fair, objective and efficient means of determining whether particular new medical technologies and procedures are 'experimental' and 'investigative' and therefore not covered under medical insurance policies"; and

WHEREAS, recent studies have revealed "significant inconsistencies" in the third-party reimbursement policies for certain medical procedures, such as bone marrow transplantation, which are sometimes considered "experimental"; and

WHEREAS, many of these "experimental" therapies that are denied coverage by third-party payors provide potentially life-saving treatment and may actually be more cost effective than more traditional treatments for which coverage is provided; and

WHEREAS, an effective appeals process for the denial of insurance coverage for these valuable and innovative treatments is necessary to provide citizens of the Commonwealth a "fair and objective" means of obtaining adequate insurance and ensuring access to necessary health care; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Bureau of Insurance be requested to study the possible establishment and implementation of an appeals process for insureds denied coverage for "experimental" medical technologies. The Bureau shall include, but not be limited to, in its deliberations the prior findings and recommendations of the Commission in determining the appropriateness of an independent appeals mechanism for any beneficiary of any medical insurance policy when coverage is denied for treatments deemed "experimental" or "investigative."

The Bureau is requested to complete its work prior to November 1, 1991, and to rep its findings and recommendations to the Commission on Health Care for All Virginians an the Governor and the 1992 Session of the General Assembly, in accordance with the procedures of the Division of Legislative Automated Systems for the processing of legislative documents.

INTRODUCTION

Legislative Request

The State Corporation Commission's Bureau of Insurance was requested by the 1991 Session of the General Assembly to study the possible establishment and implementation of an appeals process for insureds denied coverage for "experimental" medical technologies. This study was the result of House Joint Resolution No. 432 and was requested because (i) the Commission on Health Care for All Virginians, during 1990, studied the development of an objective means to determine whether new medical technologies and procedures are experimental or investigative and therefore not covered under health insurance policies; (ii) recent studies have revealed inconsistencies in third-party reimbursement policies for medical procedures considered experimental; (iii) some experimental therapies provide potentially life-saving treatment and may actually be more cost effective than more traditional treatments for which coverage is provided; and (iv) an effective appeals process for the denial of insurance coverage for innovative treatments is necessary to provide citizens of the Commonwealth a "fair and objective" means of obtaining adequate insurance and ensuring access to necessary health care. The study resolution directed the Bureau of Insurance to include in its deliberations the prior findings and recommendations of the Commission on Health Care for All Virginians in determining the appropriateness of an independent appeals mechanism for beneficiaries of medical insurance policies when coverage is denied for treatments deemed experimental or investigative.

Methodology

The Bureau of Insurance began its study by analyzing the data collected by the Commission on Health Care for All Virginians for its 1991 Interim Report to the Governor and the General Assembly of Virginia (Senate Document No. 34).

The Bureau of Insurance also conducted two surveys for the study. One survey was sent to the other state insurance departments to determine (i) whether any states had established an appeals process for insureds denied coverage for treatments deemed experimental or investigative; (ii) whether the appeals process was operating successfully (if such a process had been established); and (iii) whether any states required coverage to be provided for experimental medical treatments.

The second survey was sent to the top companies writing accident and sickness insurance policies in Virginia as well as the top health maintenance organizations and health services plans licensed in Virginia. These companies were selected on the basis of premiums written. A total of 25 companies were surveyed. The purpose of the company survey was to determine the following:

(1) whether any coverages for experimental treatment are currently being offered by insurers in Virginia;

(2) how insurers determine which treatments are considered experimental;

(3) who within the company makes the determination that a treatment is experimental;

(4) what medical authorities are consulted in making this determination;

(5) whether insurers maintain a list of treatments they consider experimental;

(6) whether any statistics are available which indicate the number of claims that have been paid for treatments considered experimental;

(7) whether any statistics are available which indicate the number of claims that have been denied because the treatments were considered experimental; and

(8) how many companies would support the establishment of an appeals process in Virginia.

The Bureau of Insurance also held a public meeting to give the citizens of Virginia an opportunity to provide testimony on problems they may have had in getting reimbursed for treatments their insurer considered experimental or investigative and to allow them to provide comments on the need to establish an appeals process for claims denied under these circumstances. Testimony given at that meeting is summarized in this report.

FINDINGS AND RECOMMENDATIONS OF THE COMMISSION ON HEALTH CARE FOR ALL VIRGINIANS

During the 1990 Session of the General Assembly, House Joint Resolution No. 213 was passed requesting the Commission on Health Care for All Virginians to study an objective means of determining whether new medical technologies and procedures are experimental or investigative and therefore not covered under health insurance policies. Two issues were addressed in the Commission's study: (i) how technologies are determined to be experimental; and (ii) what positions have been taken by insurers in determining whether experimental treatments or procedures should be covered.

Industry Position

As reported in the Commission's study, insurance companies generally do not cover treatments deemed experimental. The reasons cited for this include the following:

1. Sufficient data does not exist to demonstrate the new treatment's efficacy;

2. Risks associated with the treatment outweigh the benefits;

3. The new treatment does not produce significantly improved results over traditional treatments;

4. The recipient of experimental treatments may hold the insurer liable if the treatment produces adverse effects; and

5. The costs associated with experimental treatments are usually prohibitive.

Technology Assessment

The Commission's study also reported that, although a number of different groups have attempted to gain control over the process of determining what will be deemed experimental, no standards exist and no set definition has emerged which will allow for a uniform method of evaluating new technologies. Several organizations serve in an advisory capacity to assist in making this determination. These organizations provide research data that has been collected via scientific review and analysis or via expert opinion polls. Some of these organizations include the American College of Physicians, the American Medical Association, the National Institutes of Health, the Food and Drug Administration, and the Agency for Health Care Policy and Research (formerly the National Center for Health Services Research and Health Care Technology Assessment). The following pages provide a brief explanation of the types of assessment methodologies used by each organization:

1. The American College of Physicians evaluates new technologies by choosing medical experts to review literature that has been written on a particular subject and to make recommendations as to the appropriateness of a new procedure or treatment. These recommendations are reviewed by the Clinical Efficacy Assessment Program (CEAP) Committee and several physicians outside the system. When the final recommendations are approved, a policy statement is sent to the Annals of Internal Medicine which is a journal published by the American College of Physicians.

2. The American Medical Association evaluates the safety and effectiveness of drugs, devices, and procedures through a program called DATTA which stands for Diagnostic and Therapeutic Technology Assessment. Physicians who are considered experts in their field are nominated to serve as panel members. Panel members are surveyed to obtain a consensus opinion regarding the safety and effectiveness of the technology in question. A technology may be rated as:

(a) Established - Accepted as appropriate by the practicing medical community for the given indication in the specified patient population.

(b) Promising - Given current knowledge, the technology is appropriate for the given indication in the specified patient population.

(c) Investigational - Evidence is insufficient to determine the appropriateness of the technology and warrants further study. Use of the technology for a given indication in the specified patient population should be confined largely to research protocols.

(d) Doubtful - Given current knowledge, the technology is inappropriate for the given indication in the specified patient population.

(e) Unacceptable - The technology is regarded by the practicing medical community as inappropriate for the given indication in the specified patient population.

Survey results are analyzed and a final assessment is submitted to the Journal of the American Medical Association for publication.

3. The National Institutes of Health also publishes information regarding new technologies. The NIH holds Consensus Development Conferences and issues consensus statements which summarize the conclusions reached by panels of experts during these conferences. Publications which summarize research studies conducted by the NIH are also available through the Office of Medical Applications of Research.

4. The Food and Drug Administration approves drugs and life sustaining and implant devices. In some cases, the FDA has created new categories of drugs to allow increased access to treatment before the drug is officially approved.

5. The Agency for Health Care Policy and Research has a number of organizations under its jurisdiction including the Office of Health Technology Assessment which evaluates the safety and effectiveness of medical technologies being considered for coverage by Medicare and other federally funded programs. This evaluation is done by conducting an extensive literature search, soliciting comments through notices placed in the Federal Register, consulting with the National Institutes of Health, and obtaining opinions from professional societies. Once a final evaluation is made, it is sent to the Health Care Financing Administration (HCFA) which is the agency that coordinates and determines payment rates for Medicare, or to CHAMPUS which is the federal agency that insures military personnel and their dependents.

Some of the other organizational components within the Agency for Health Care Policy and Research include the Center for Medical Effectiveness Research, the Center for General Health Services Intramural Research, the Center for General

Health Services Extramural Research, the Office of Science and Data Development, and the Center for Research Dissemination and Liaison.

Government insurers and private insurers also have guidelines which they use to determine whether a medical procedure is not covered because it is experimental or investigative:

1. The Health Care Financing Administration (HCFA) excludes from Medicare coverage those medical and health care services that are not demonstrated to be safe and effective by acceptable clinical evidence. HCFA makes this determination on the basis of whether the service has been proven safe and effective based on authoritative evidence, or whether the service is generally accepted in the medical community as safe and effective for the condition for which it is used. HCFA refers issues to the Office of Health Technology Assessment (OHTA) if there is a question as to the safety and effectiveness of a health care technology. After considering the recommendation given by OHTA, HCFA decides whether or not a service should be covered. Several criteria are used in making this determination including the following:

(a) Is the service appropriate, i.e. is the service furnished in a setting commensurate with the patient's medical needs and condition, and furnished by qualified personnel?

(b) Is the service experimental or investigational? If it is used for research purposes in accordance with predetermined rules it is considered experimental or investigational. Except for certain breakthrough medical or surgical procedures, a service that is not used widely because there is inadequate evidence of safety and effectiveness is considered experimental or investigational.

(c) Is the service safe and effective? The standards for safety and effectiveness are less stringent when evaluating breakthrough medical or surgical procedures. The more severe and life threatening the disease process, the more acceptable a relatively less safe technology may be when no safer or more effective technologies are available.

(d) Is the service cost-effective, i.e. do the health outcomes justify the additional expenditures? A technology is considered cost-effective if it demonstrates one of the following results:

(i) It is less costly and at least as effective as an alternative covered technology.

(ii) It is effective and more costly than a covered alternative, but improved health outcomes justify the additional expenditure.

(iii) It is less effective and less costly than an existing alternative but is a viable alternative for some patients.

Drugs approved by the FDA are considered safe and effective by HCFA when used for indications specified in their labeling, or when used for indications not specified in their labeling as long as the FDA has not specified such use as non-approved. Drugs that have not received FDA approval for marketing are considered experimental or investigational and are not covered except for certain cancer drugs distributed by the National Cancer Institute.

2. The Virginia Department of Medical Assistance Services (Medicaid) considers the following criteria when evaluating whether coverage will be provided for a new technology:

(a) cost;

(b) medical efficacy;

(c) whether the procedure is available outside the research arena;

(d) whether the procedure is widely available;

(e) potential harm and side effects;

(f) proven rate of success.

A copy of the regulations and procedures used by the Virginia Department of Medical Assistance Services for client appeals is shown in the Appendix. As noted in the letter from the department's director, the regulations do not apply to experimental services not covered by Medicaid.

3. The Blue Cross and Blue Shield Association publishes the following criteria to be used as a guide by individual plans in determining whether a treatment should be covered. The national association recommends that the technology meet all five criteria in order to be given coverage consideration:

(a) The technology must have final approval from the appropriate government regulatory bodies, i.e. FDA approval of drugs for the specific indications being evaluated. Interim approvals in the FDA regulatory process are not sufficient to meet this criteria.

(b) The scientific evidence must permit conclusions concerning the effects of the technology on health outcomes. The evidence should consist of well-conducted investigations published in peer-reviewed journals and should demonstrate that the technology can measure or alter the physiological changes related to the illness or condition. The scientific quality of the supporting evidence and rationale should also be evaluated.

(c) The technology must improve the net health outcome, i.e. the beneficial effects must outweigh any harmful effects.

(d) The technology must be as beneficial as any established alternatives and should improve the net health outcome as much as or more than established alternatives.

(e) The improvement must be attainable outside the investigational settings. When used under the usual conditions of medical practice, the technology should reasonably be expected to satisfy criteria (c) and (d).

Each Blue Cross and Blue Shield plan makes its own coverage decisions and may consider the technology evaluation results obtained by the national association

(see the Appendix for the Coverage Eligibility Guidelines published by Blue Cross and Blue Shield of Virginia).

Conclusions of HJR 213

The Commission on Health Care for All Virginians concluded in its report that, with so many assessment mechanisms already in place, a state panel appointed to assess new technologies would simply replicate the current assessment processes used by various organizations. The Commission was concerned that the same organizational interests would be represented and any bias and partiality that previously existed would be duplicated. In addition, the report suggested that if all fifty states established their own assessment group, it would further complicate the issue and waste resources. The report stated that mandating and/or paying for experimental procedures would encourage the expenditure of resources and money for tertiary care services and high technology research and that this would greatly increase health care costs which would not necessarily be in the public's best interest.

Recommendations of HJR 213

In its recommendations, the Commission on Health Care for All Virginians stated that it would continue to monitor insurance company policy concerning experimental medical technologies and that no further action should be taken at the present time.

ADVANTAGES AND DISADVANTAGES OF ESTABLISHING AN APPEALS PROCESS

In determining the feasibility of establishing an appeals process in Virginia, both the advantages and disadvantages of such a system should be fully considered. During the course of the study, the insurance industry and the public were given a chance to comment on the possible advantages and disadvantages of this issue. The items shown under each section below summarize the comments given.

Advantages

The following list describes the major advantages of setting up an appeals process in Virginia:

1. An appeals process would allow an unbiased group of individuals to make a determination that the decision to deny coverage was either appropriate or inappropriate. The medical staff employed by insurance companies to make these decisions may find it difficult to remain totally impartial during the decision-making process as there is a potential conflict of interest inherent in this type of situation.

2. An appeals panel made up of physicians would give the final decision-making authority to members of the medical community who are best qualified to determine the appropriate treatment for a given indication.

3. An appeals process conducted outside of the traditional court system should help reduce litigation expenses and be handled more expediently.

4. An appeals process would ensure equity for all citizens of Virginia in the process of determining what is considered experimental or investigative. It would establish a set of standards to which all licensed insurers in Virginia would be held accountable.

5. It would provide more consistency in claims handling and would be a source of information for small companies that do not have in-house medical staff.

6. It would serve as a gauge to insurance companies in terms of how the public perceives their product and their coverage decisions.

7. It may bring to light new medical information, especially in view of the advancements that are taking place in medical technology.

8. It would remove allegations that insurers deny coverage solely due to cost and would acknowledge third-party endorsements of insurers' positions in those cases where insurers' positions were upheld.

Disadvantages

Shown below is a list of the possible disadvantages of setting up an appeals process in Virginia:

1. Companies may amend their policies to specifically exclude certain treatments instead of using a general exclusion for anything experimental. This would enable companies to avoid the appeals process altogether.

2. Current remedies exist for the resolution of insurance policy issues either through the courts or through company appeals procedures. An appeals board would be duplicative and would merely add another step in the process rather than offer a final resolution.

3. An appeals panel could not improve upon the existing methodology used in making scientific evaluations.

4. If each state implemented such a program we would end up with fifty different appeals procedures and methodologies. A national appeals process would be preferable to one established at the state level.

5. The cost of establishing an appeals panel would be prohibitive. In addition, the cost to third-party payors for decisions made by an appeals panel would not necessarily have been contemplated in their rates. The lack of predictability would make it difficult for insurers to adequately price their products.

6. An outside agency might not have the requisite expertise to avoid implementation of therapies that could cause the patient more harm than good.

7. An appeals panel could result in inconsistent handling of claims and involve a lengthy process.

8. A state appeals panel would not have jurisdiction over self-insured single employer plans subject to ERISA laws.

9. Specialists who serve on the appeals panel might be biased in favor of treatment in their area of specialization.

10. The medical industry lacks a clear definition of the terms "experimental" and "investigative".

Other Considerations

Other issues must also be considered in evaluating the necessity of establishing an appeals panel. Many physicians are concerned that cost considerations have become the overriding factor in determining the type and quality of health care treatment a patient will ultimately receive.

> The strong concern of cost containment has driven the health care system to the point where public-policy decisions to use or even develop a particular technology increasingly are made only after the potential benefits are explicitly weighed against the costs. Nonphysician segments of the health care community often are swayed by economic considerations, leading to a simplistic view of health care.[1]

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1. William T. McGivney and William R. Hendee, "Technology Assessment in Medicine...The Role of the American Medical Association," Archives of Pathology and Laboratory Medicine, December, 1988, Volume 112, pp. 1181-1185.

Certain segments of the medical community also have concerns that decisions regarding new technologies do not take into consideration the speed with which biomedical research is advancing. "[The] introduction of new technologies accentuates the need for assessment of existing technologies, comparison of the relative efficacies of competing technologies, and identification of obsolete technologies. Improvements in a technology, or the evolution of successive versions of a parent technology, force continual reassessment of the technology."[1]

Additionally, there is concern that reimbursement procedures may affect the advancement of medical technologies.

> The growing conservatism of coverage and reimbursement decisions for medical technologies has significant negative implications for the rate of development and diffusion of new technologies in medicine. The concept that a technology is investigational today and established tomorrow should be replaced by a recognition that the clinical utility of a technology evolves as evidence of safety and effectiveness are accumulated over time. The need for more effective ways to prevent, diagnose and treat disease is the driving force underlying the search for new technologies in medicine. This search is acutely sensitive to regulatory, coverage and reimbursement policies that influence the progression of technologies from the investigational stage into the clinical arena. These policies should be delicately balanced to assure the safety and effectiveness of the technologies while facilitating their movement into clinical medicine. Although the regulatory process seems to be reasonably balanced at the present time, coverage and reimbursement processes do not. Instead, they are increasingly serving as deterrents to the infusion of new technologies into clinical practice, and to the utilization of these technologies to enhance the care and treatment of patients.[2]

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1. Ibid.

2. William T. McGivney and William R. Hendee, "Regulation, Coverage, and Reimbursement of Medical Technologies," International Journal of Radiation Oncology, Biology, and Physics, March, 1990, Vol. 18, pp. 697-700.

SURVEY OF OTHER STATES

A survey of the other state insurance departments was conducted to determine (i) whether any states had established an appeals process for insureds who are denied coverage for treatments deemed experimental or investigative, and (ii) if so, whether the appeals process was operating successfully. The survey also asked each state insurance department whether they required accident and sickness insurers, health maintenance organizations, and health services plans to provide coverage for treatments deemed to be experimental or investigative.

A total of thirty-five (35) states responded to the Bureau's survey. According to the responses received, none of the states require coverage to be provided for experimental or investigative treatments. When asked if an appeals process was available to insureds who were denied such coverage, three states (Michigan, New York and Florida) mentioned their general grievance procedure for consumer complaints, but indicated that they did not have a special appeals process for cases involving experimental treatments. Only one state (Connecticut) answered "yes" to this question and said that their consumer affairs division handled these complaints and that their department's attorney would become involved and a hearing called if necessary. However, during a telephone interview, the Director of Consumer Affairs of the Connecticut Insurance Department indicated that, to his knowledge, they had never held such a hearing and that the insurance department really did not have the regulatory authority or the expertise to make the determination that a treatment was not experimental. He did indicate, however, that in questionable circumstances, the department would require the company to justify or support its conclusion that a treatment was experimental. This type of documentation can be and has been requested in Virginia as well.

The Georgia Insurance Department made the following statement:

> It is our position that experimental or investigative treatment shall not be defined more restrictively than any treatment, procedure, facility, equipment, drug usage, device or supply not recognized as accepted medical practice by the American medical community, and any of such items requiring federal or other governmental agency approval which was not granted at the time services were rendered.

The New York Insurance Department indicated that their Health Department established guidelines to determine what procedures and treatments were to be considered experimental. The department indicated that if they needed an opinion as to whether a treatment or procedure was in fact considered experimental they could request such an opinion from the state health department. However, it was indicated that this type of opinion had only been requested once. They also noted that the final decision rested with the courts. The New York Health Department was contacted to verify the information provided by the insurance department. The staff of the Bureau of Standards Development indicated that they generally relied on guidelines established by the federal government, i.e. the Food and Drug Administration, but could also give opinions, if requested, regarding the experimental status of a particular treatment. It was indicated that this determination would be based on (i) the medical efficacy of the treatment which would take into consideration survival rates; (ii) attending circumstances; (iii) individual medical conditions; and (iv) overall expected outcome. The New York Health Department said their approval was needed for payments made under the Medicaid program for treatments considered experimental, but they said they could also give opinions on coverage decisions made by private insurers.

SURVEY OF INSURERS, HEALTH MAINTENANCE ORGANIZATIONS, AND HEALTH SERVICES PLANS

Purpose of Survey

The Bureau of Insurance sent a survey to the top companies writing accident and sickness insurance policies in Virginia as well as the top health maintenance organizations and health services plans licensed in Virginia. A total of twenty-five (25) companies were surveyed. The purpose of the survey was to determine the following:

(1) whether any coverages for experimental treatments are currently being offered by insurers in Virginia;

(2) how insurers determine which treatments are considered experimental;

(3) who within the company makes the determination that a treatment is experimental;

(4) what medical authorities are consulted in making this determination;

(5) whether insurers maintain a list of treatments they consider experimental;

(6) whether any statistics are available which indicate the number of claims that have been paid for treatments considered experimental;

(7) whether any statistics are available which indicate the number of claims that have been denied because the treatments were considered experimental; and

(8) how many companies would support the establishment of an appeals process in Virginia.

Twenty-two (22) usable responses were received. A summary of these responses is shown below.

Results of Survey

1. When asked whether coverage for experimental treatment was provided in their policy or offered in a rider, seventeen (17) companies answered "no". One company said this coverage was never offered in a rider and most policies had a specific exclusion for experimental treatments. Two companies said this type of coverage was not provided in their policy but was offered in a rider, one company said coverage for experimental treatments could be provided in their policy and offered in a rider, and one company said that coverage was provided in their policy but not offered in a rider.

2. The companies were asked how they determined that a treatment was experimental. The following comments are representative of the responses given:

- the treatment is determined to be experimental if it is not accepted in the health care practice as being effective or needed, if it is not approved by the FDA or AMA, or there are no clinical studies proving its efficacy;

- determination is based on an exhaustive review of the current literature published in peer-reviewed medical journals, review of technology assessments, solicitation of the opinions of expert outside medical consultants, and review of opinions of in-house medical staff;

- determination is based on a review of therapeutic efficacy, safety and acceptance by the practicing community;

- an in-house program evaluates and monitors advances in medical science;

- the company's home office medical department reviews current practice as is reported in the scientific literature;

- treatment is experimental if it is still under investigation by various physicians and is not accepted as safe and effective by established medical societies (such as the AMA, American College of Surgeons, the state medical association, and appropriate specialty boards) and by the Surgeon General and the Food and Drug Administration.

- determination is based on a review of current medical literature, the protocol document, the informed consent document, compendia, and opinions of technology assessment organizations;

- determination is based on current medical standards, industry literature, and the patient's medical status;

- outside specialists are consulted as needed, the nature of the treatment is reviewed as well as the nature of the illness and the relationship between the treatment and the illness;

- the procedure is considered experimental if it has not been approved by the FDA, experience is limited to non-human means of testing, the treatment has not been sufficiently tested in clinical situations, or the treatment is not generally accepted by the medical community for the condition being treated;

- consultation is made with a panel of independent medical physicians who are experts in the field;

- consultation is made with the company's national technology assessment unit, regional and national medical specialty organizations, the National Institutes of Health, and the FDA.

3. When asked who within the company made the determination that a medical treatment was experimental, the following responses were given: the company's medical consultant, the medical director, the national medical director, the claims department, the technology assessment advisory committee, the corporate medical division, the medical policy committee, the health care finance division in consultation with the corporate medical director and medical advisors, and the medical department in cooperation with the Claim Technical Research and Analysis Unit.

4. When asked what medical authorities were consulted in making this determination the following responses were given: the AMA, the FDA, teaching hospitals, clinical studies, published articles, appropriate medical specialty societies,

reports of the Office of Health Technology Assessment, DATTA reports, statements of the Clinical Efficacy Assessment Project (CEAP), medical technology studies of the Office of Technology Assessment, consensus development conference summaries of the Office of Medical Applications and Research of the National Institutes of Health, guideline reports of the Hospital Technology Series of the AMA, drug clearance notices of the FDA, consultation with private research institutes and universities, consultation with private practice specialists, standard text references, peer reviewed literature, the Hayes Directory, HCFA standards, the National Library of Medicine, the U.S. Surgeon General, the Bureau of Devices and Drugs, U.S. Pharmacopial Drug Information, American Hospital Formulary, the U.S. Dept. of Public Health, and the American Dental Association.

5. Among the twenty-two (22) companies that responded to the survey, seventeen (17) indicated that they did not maintain a list of treatments considered experimental. Five (5) companies said they did maintain such a list, but only two (2) were willing to provide it. The other three (3) companies felt this was proprietary information.

6. When asked if the company had ever paid a claim for a treatment considered experimental, eighteen (18) companies answered "yes" and four companies said "no". Of the eighteen companies that indicated coverage for experimental treatment had been provided, the following explanations were given:

- no other treatment was available
- payment was made inadvertently
- clinical use was widely accepted before FDA approval had been given
- some plans do not exclude coverage for experimental treatments
- some treatments are considered experimental by others but not by our company
- some older contracts do not exclude coverage for experimental treatments
- the company was directed to pay by court order
- contract language in the policy did not support denial
- conventional treatment was not producing desired results
- the insurance contract was amended to provide the treatment
- all emerging evidence was promising, the condition was terminal, no other treatment existed, and the treatment was performed at a nationally known medical center.

A few companies listed the specific treatments that had been covered. These included Interferon for treatment of hepatic cancer, a lung transplant, and bone marrow transplants for breast cancer.

7. The companies were also asked if they maintained any statistics on the number of claims that had been denied over the past three years because the

treatment was considered experimental. Seventeen (17) companies said they did not track this type of data, one company said it had not denied any claims for experimental treatment, one company said it had denied two such claims, one company said it had denied four claims, one company approximated 1000, and one company said it had denied 11,834 such claims over the past three years.

8. Even though the majority of companies indicated that they would be opposed to establishing an appeals process in Virginia, five (5) companies said they would not be opposed to this idea.

PUBLIC MEETING

The Bureau of Insurance held a public meeting on July 10, 1991 in Richmond, Virginia. The purpose of the meeting was to give Virginia citizens an opportunity to provide testimony on problems they may have had in getting reimbursed for treatments their insurer considered experimental or investigative. The meeting was also intended to give the citizens of Virginia an opportunity to provide comments on the need to establish an appeals process for claims denied under these circumstances. Twenty-one (21) people testified at the meeting including Delegate Jane H. Woods, sponsor of the house joint resolution that directed the Bureau of Insurance to study this issue. The Bureau also received written comments from thirty-four (34) individuals and organizations who were either unable to attend the meeting or wished to provide additional comments. Excerpts from testimony given at the meeting and from written comments submitted to the Bureau of Insurance are presented below.

Public Testimony

The meeting began with an explanation of the purpose behind the study and the rationale for having the public meeting. Also mentioned during the introductory remarks was the fact that (i) the State Corporation Commission lacked the regulatory authority and the medical expertise to determine what was considered an experimental medical treatment, and (ii) that the meeting was intended to focus on the need of setting up an appeals panel and not on the merits of reimbursing for any one particular type of treatment. The following remarks are representative of the testimony given during the meeting and from written comments.

Delegate Jane H. Woods: My legislative request comes before you now. All I'm looking for is a system, a panel-type process, something that will make it easier for folks so that they can get their insurance resolved quickly, timely, indeed, because many times going to court puts the whole realm of the procedure out of the possible. I ask for a procedure or the consideration of a paneling, a procedure of some kind so that resolutions can occur.

Dr. Richard Binder: It is obvious to me as a physician who has been in academic medicine and then in private practice for a period of greater than 20 years that there are dramatic changes occurring in the delivery of medical care.... The technology of medicine is rapidly evolving. Techniques and technologies are expanding at an impressive rate: new and powerful drugs; CAT scans; MRI scans; heart transplants; liver transplants; lung transplants; bone marrow transplants. These catch the public eye but even more germane is the increasing restriction of medical care delivery that is being mandated not by the public and/or officials, but by insurance carriers. They are doing this by calling advances, which most experts call leading edge delivery of medical care, experimental and they refuse to pay for the use of these drugs and techniques.

Dr. Roy Beveridge: Within Virginia there are 30 cases that I know of in Northern Virginia that have had to go to trial...for transplants for breast cancer. That's 30 in the last 15 months. I think that's a lot. I don't think 30 families and extended families had to go through this. There was a big test case in Maryland where a judge sat for three months and listened to testimony from a wide range of oncologists and everyone that Blue Cross Blue Shield could come up with testified on their behalf. I would like to read to you what the judge said because these are people that spent a long time listening to the debate. This was a three-month decision so this patient was sitting around waiting for three months for her

decision. "Disregarding the specific plan language, Blue Cross decided to deny plaintiff coverage based on its own independent evaluation of published scientific research results completely ignoring the consensus of opinions of the members of the Maryland oncologic community as discussed at length below."

Frank Smusz: Included in this statement is a list of 42 insurance companies who will or have covered ABMT for breast cancer, some on a case-by-case basis.... As you will notice, most Blue Cross Blue Shield plans surrounding Virginia will pay for the ABMT treatment relative to breast cancer, but Blue Cross Blue Shield of Virginia will not. It becomes evident and clear that the largest health insurance company in Virginia, Blue Cross Blue Shield of Virginia, which appears to almost have a monopoly of the subscribers in this state, is restricting the access of medical care Virginians may be able to receive.

Lorraine Smusz: Rather than go to court and put my life in a judge's hand, I decided to go public with this and the people of Virginia felt so much for this cause that we raised $130,000 for my treatment....when you have a terminal disease and you are told maybe you only have a year to live, I don't see how safe could come into it. I mean, you're going to die anyway. So, I feel that we do need some kind of committee that we can appeal to other than the insurance company to give us a second chance.

Dr. Frederick Westervelt: I would support the development of an appeals process designed to adjudicate those issues which we are hearing about this afternoon. Such a process clearly must be comprised of knowledgeable and interested people from the walks of life of the law, the legislature, by all means the patients and public and their advocates and health care providers. To leave decisions of this magnitude solely up to the insurance industry and its closely allied individuals, I believe is to have too narrow a scope of influence to be acceptable.

Frank Cowan: This whole hearing may be a hoax...from the standpoint of Blue Cross Blue Shield of Virginia. They have now specifically excluded lung transplants and autologous bone marrow transplants for breast cancer patients. They're not relying on the general experimental exclusion... starting last November, every time a policy renews itself, they specifically exclude this treatment.... So, I say to you that we clearly need a method outside of the legal arena to quickly resolve these disputes. And certainly we're not talking about paying for every treatment in the world that comes along, but when you have outstanding doctors and the peer review literature is lagging behind, I mean the treatment and the efficacy of the treatment is faster than the literature, we can't deny this treatment to people that need it.

Allan Sonner: The insurance companies should not be allowed, unilaterally, to determine either by category or on a case-by-case basis, which of a host of medical treatments recommended by physicians will or will not be approved for payment. The present system of requiring individual policyholders to sue in an already burdened court system is an unsatisfactory state of affairs.

Mary Jo Kahn: Many breast cancer patients throughout Virginia are being denied treatment which are considered standard care throughout most large medical centers. At present, the life and death issue depends solely on which insurance company [the patient's] employer has chosen. The public is generally poorly informed about this problem and usually does not know this is an issue when choosing an insurance company. Most consumers buy their insurance expecting it to cover them when they need it, when their life depends on it. Coverage should

be based on medical standards of care.... Decisions regarding insurance coverage made by an appeals board would prevent certain treatments from being denied solely on the basis of economic concerns.

Gail Jaspen: We at the Attorney General's Office were struck for the first time by the broad discretion that insurers reserved for themselves to determine what is and what is not experimental. Our immediate concerns were whether health insurance consumers were adequately informed that their policies might not cover life-saving procedures recommended by their physicians, and second, whether insurers should be given that sole discretion to make these determinations.... We're interested in helping the Bureau of Insurance in any way possible to assess the alternatives that may be available for dealing with this dilemma. Today's hearing is an important step because it undoubtedly will raise quite a few of these alternatives. They include mandating mediation arbitration, creating an independent government appeals panel to hear disputes, or perhaps eliminating the experimental treatment exclusion entirely.... We think that a solution does apply in creating a fair, efficient, and impartial means to determine whether a medical procedure is properly reimbursable by a health insurance policy.

Marybeth Downes-Hibey: I'm a cancer patient.... Right now, I am not quite eligible for the bone marrow transplant, but when I am sometime next year [Blue Cross Blue Shield] won't cover that either. I'm just here to--feel I have to save my own life. I need that bone marrow transplant.

Joe Hibey: I just want to amplify a few of my wife's comments.... If things continue the way they are, and Blue Cross Blue Shield maintains the stance in that they won't pay for the markers or the bone marrow transplant...I have no recourse but to sue.... Blue Cross Blue Shield eventually will be paying for these bone marrow transplants, but time is of the essence right now, time for my wife and some other people here today and we don't have time.

Patti Goodall: I don't smoke. I don't drink alcoholic beverages. I'm a vegetarian, exercise, I go for regular checkups. I still got cancer. And now, should my cancer reoccur when I need my insurance company the most, as someone said earlier, they literally will be able to hand me a death sentence. I find that outrageous and immoral. I find it even more frustrating that they can make this decision in the face of so much contrary evidence--in the face of dozens and dozens of very well-respected oncologists and researchers in this country who are saying otherwise--who are saying this is state of the art treatment.... I would personally welcome the establishment of an independent appeals board to decide these matters. I believe that the insurance companies have set themselves up as experts in the field of cancer treatment. I find their expertise sorely lacking as well as their morality.

Dennis Strawderman: Our fears are not that we will be murdered in the street by someone who's wearing a ski mask that will sneak up behind us with a gun or knife, but rather that people will die because of the policies made by executives wearing suits behind closed doors. These policies attempt to negate what the American Medical Association and doctors of oncology across the nation are telling us--that bone marrow transplants are no longer experimental treatment, but rather are now considered state of the art treatment. Our state needs an appeals process for insured persons who were denied coverage by their health insurance company, and we need it now.

Nancy Dopp: The advent of a marrow transplant could be and most likely will become a reality to me in the future. We who have breast cancer need every hope for survival. Therefore, I implore the entire insurance industry to support this new found hope in medicine. We want to live.

Dr. Madid Kuperminc: We physicians call the hassle factor what you're hearing about here--all that we have to go through to get the patient treated. Medical oncologists in Virginia have...to call the insurance company, Blue Cross, to get what they call a preadmission approval for the patients when they come to the hospital. We not only have to tell them why we need them, but what medications we are going to give them. Sometimes we have to spell the name of the medications to the person that takes the information. That's the degree of learned aptitude that Blue Cross has in this...technology operation program. There is absolutely no scientist of merit sitting in that program. All the members of that committee are employed by the National Blue Cross Association. Virginia is privileged to have not even that. They have a medical director and they have a nurse. Neither one of them is qualified...to make those decisions.... But what we are asking for them is for a chance to treat appropriately our patients without intervention from people that are not qualified. Every patient that succeeds does not create a precedent.... Once they have proved their case...the next patients will be denied like it never took place. It is a very, very tiresome process.

Lynn Carroll: My oncologist told me that statistics show that I [had] little chance of survival using traditional methods and my best chance for survival was an autologous bone marrow transplant. He does not consider this treatment to be experimental. Although he told me that it was an issue with some insurance companies, it was not an issue with my insurance company, the Government Employees Hospitalization Association. They paid fully and promptly for all of my treatment.... No insurance company should deny coverage for this treatment when it was recommended by a licensed oncologist just as my insurance company did not deny me treatment.... If a licensed physician is not considered adequate to define treatment, then a review panel that can hear testimony and provide quick resolution will at least help insure that people are not unfairly denied treatment by the insurance company.

Patricia Horrell: My purpose for speaking to you today is to demonstrate to you that the autologous bone marrow transplant for breast cancer and other cancers are effective.... It has given me at 36 years old a new chance for life. Prior to the bone marrow transplant, which my insurance did cover, I had been battling with Stage IV breast cancer for the past five years with multiple regimes of chemotherapy. Since my transplant, which was exactly one year ago, July 3rd was my transplant day, I have been healthy, and have not required any form of chemotherapy. This is the longest time interval since my cancer diagnosis that I've not needed any form of chemotherapy.

Frances Motley: I would like to suggest that preadmission review be substituted with an administrative review panel based on the peer review organization under Medicare, Medicaid--to function when an insurance company has reason to believe that a particular physician is abusing the medical benefits for a particular patient. If the review results in a finding for the insurance company, the physician, not the patient, would be subject to a review panel determined refund to the insurance company for that treatment. The per diem fees for the panel will be borne by the insurance company and assessed against the culpable party determined by the panel. The second suggestion I have, most patients who have health insurance benefits are provided those policies through their employee benefits programs.

These policies serve primarily a tax purpose for the companies who provide them and the covered benefits are rarely selected by the employees. Generally it's on the biggest bang for the buck. When the disputes occur, the employees are generally left on their own. Their employers will not assist them in discussions with the insurance carrier. I would suggest that to provide a more equitable position for the insured that when a patient has a dispute with health insurance company, that an informal low filing cost forum, quick meeting forum be established to form an arbitration situation. A forum similar to but far less formal than that of the medical malpractice review panel currently in the Virginia Code. This would provide an arbitration forum available to the average person. No lawyer would necessarily be needed though they could be consulted and no great legal expenses would be incurred. Again, the per diem fee for the panel would be borne by the insurance company to increase their good faith... for the fulfillment of policy procedure prior to the need for a panel request.

William Metzger: I just want to say a few words because I feel our family is one of the true success stories of the autologous bone marrow transplant procedure.... In 1988, my wife was 34 at the time and mother of two children, ages four and two, was diagnosed with Stage IV metastatic breast cancer and was given a prognosis that was very, very doubtful. As a matter of fact, we were told to expect approximately six to eight months left of life. At that time we looked at various options, one of which we found was the possibility of entering the program down at Duke University. There was never any question on the part of our carrier whether or not this was a recognized and viable procedure. New York Life immediately accepted us and allowed us to go down there. The question became one in my own mind, what is value of human life? I can tell you [it's] $55,000 up front because that's what it cost for Duke to see us. Our insurance company paid it immediately. It was very tragic though when we got down there to see other people that were turned away from the door because their insurance companies or carriers would not come through with the procedure, help them with it.

Rod Mathews: I am a senior officer of Blue Cross and Blue Shield of Virginia. Blue Cross and Blue Shield of Virginia is a non-stock, non-profit Virginia corporation which builds reserves against a well-known health insurance underwriting cycle which we are now at the peak of. We have no stockholders, we pay no dividends. We manage benefits according to the benefit designs that employers pay us to manage. Most of the insurance existing in Virginia, health care insurance existing in Virginia is through employee groups who are insured or self-insured. In the event they are self-insured, then we administer the coverage that they buy. I suggest if the audience and others disagree with the coverage that their employer provides them, they should deal with their employer on that issue. I can assure you that the coverage of experimental procedure is very expensive and will have a direct cost impact on the employee group. I'm here to speak in opposition to the proposal that there be an appeals process for insureds and self-insureds for experimental medical technology. I do it for three reasons. There's a better way to deal with the issue in place and effective. Such an appeals panel would have no effect on explicit contract exclusions. And such a process would add nothing to the existing methodology to determine the safety and efficacy of investigational procedures. Blue Cross and Blue Shield of Virginia does not cover medical services which are not proved to be safe and effective. Our contracts state expressly which investigational procedures are covered and which are not. Contracts no longer have the broad undefined discretion that Mr. Cowan referenced. They're now very specific and I urge each of you to look at your coverage and talk with your employer. The fact of the matter is that principles of constitutional law prohibit the abridgment of lawful private contracts. So the point I want to make is

that the decision of such an appeals panel as is proposed here...would not have effect as a matter of law. Indeed there is a better way to accomplish the purpose of the people here today. It would take nothing short of a statutory mandated coverage law to require coverage of high dose chemotherapy for autologous bone marrow transplant. There's a procedure in place and has been in place for two years. It's called in the vernacular the Mandates Review Commission.... Virginia Medicare does not cover high dose chemotherapy. The federal employees program does not. The Commonwealth of Virginia Employees Health Benefit Plan does not cover high dose chemotherapy with ABMT. CHAMPUS does not and there are 267 health insurance companies authorized to do business in Virginia and very few of those cover ABMT.... We are not unreasonable in concluding that this is experimental investigation, but again, if the employees want to pay for it, we'll manage it. ... A year ago, last fall, we mentioned that while it was yet to be seen whether any kind of meaningful coverage could be offered at some sort of sensible price, we were then and continue to explore the possibility of an endorsement which any person could add to their coverage, either through the group itself or an individual basis, to provide for this coverage. Of course the risk is that there's that principle that all of you bear called adverse selection. If we got into a situation where only those persons purchase it who only needed it, it would be a disaster for all the people. Our responsibility to people we insure is to maintain a solvent viable financial institution. So we have to be careful about taking on risks that will be disastrous for all our insureds. We are pursuing that. I think through the endorsements investigation we will develop the information you ask for.[1]

Gilbert Grossman: We had the privilege of attending the hearing for the establishment and implementation of an appeals process for insureds denied coverage for "experimental" medical technologies.... [Mr. Mathews'] documentation was poor at best. On one side he was willing to provide coverage if paid for by the employers--on the other side when not paid for it became experimental.... As an employer who carries Blue Cross, which I fully fund, I have never been offered the opportunity for this coverage for my employees yet I find that 42 other insurance companies do including 13 other Blue Cross Agencies.

Other Comments Received

Although all of the written comments received by the Bureau could not be included in this report, a representative sample of the letters submitted for the report has been included in the Appendix.

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1. Mr. Mathews has, since the date of the hearing, informed the Bureau of Insurance that Blue Cross and Blue Shield of Virginia plans to offer an experimental treatment rider and a screening/preventive care rider which will be available sometime between April 1, 1992 and July 1, 1992.

CONCLUSION

While the Bureau of Insurance is of the opinion that an appeals process could be established, such a process may not be the best solution to the problem that currently exists. This type of proposal would have certain drawbacks such as (i) increased administrative responsibilities for the agency in charge of overseeing the activities of an appeals panel; (ii) additional costs associated with the added administrative responsibilities; (iii) increased staffing needs; and (iv) difficulty in locating panel members who would be impartial and who would be willing to serve on the panel. In addition, no other state has established an appeals process for insureds who have been denied coverage for experimental medical technologies. Therefore, the Bureau of Insurance is unable to recommend that an appeals process be established in Virginia.

The Bureau of Insurance concludes that if the public demands this type of coverage, insurers should be encouraged to offer coverage for experimental treatments. This coverage should be made available to those who are willing to purchase it.

APPENDIX

BLUE CROSS AND BLUE SHIELD OF VIRGINIA

COVERAGE ELIGIBILITY GUIDELINES

1. Drugs and devices must be FDA approved to market for the particular indication or application in question.

2. There must be sufficient information in the peer reviewed medical and scientific literature to enable Blue Cross and Blue Shield of Virginia to make conclusions about safety and efficacy.

3. The available scientific evidence must demonstrate a net beneficial effect on health outcomes.

4. Drugs, devices and procedures must be as safe and efficacious as existing diagnostic or therapeutic alternatives.

5. Drugs, devices and procedures should reasonable be expected to satisfy criteria 3 and 4 when applied outside the research setting.

JLC/mea(Guidelines)

BLUE CROSS AND BLUE SHIELD ASSOCIATION TECHNOLOGY EVALUATION CRITERIA

The first step in determining eligibility of a medical procedure for coverage is evaluating its health effects, a process known as technology assessment or technology evaluation. The Blue Cross and Blue Shield Association conducts such evaluations of selected technologies. The Association's role is informational. Each Blue Cross and Blue Shield Plan makes its own coverage decisions. In their coverage decisions, plans may consider technology evaluation results and any additional factors they may deem appropriate.

The Blue Cross and Blue Shield Association uses the criteria below to determine whether a technology improves health outcomes such as length of life, ability to function or quality of life. Technologies that meet all five of the following criteria are recommended for coverage consideration.

1. The technology must have final approval from the appropriate government regulatory bodies.
   - A device, drug or biological product must have Food and Drug Administration approval to market for those specific indications and methods of use that the Blue Cross and Blue Shield Association is evaluating.
   - Approval to market refers to permission for commercial distribution. Any other approval that is granted as an interim step in the FDA regulatory process, e.g., an Investigational Device Exemption, is not sufficient.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
   - The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence.
   - The evidence should demonstrate that the technology can measure or alter the physiological changes related to a disease, injury, illness or condition. In addition, there should be evidence, or a convincing argument based on established medical facts, that such measurement or alteration affects the health outcomes.
   - Opinions and evaluations by national medical associations, consensus panels or other technology evaluation bodies are evaluated according to the scientific quality of the supporting evidence and rationale.

3. The technology must improve the net health outcome.
   - The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.

4. The technology must be as beneficial as any established alternatives.
   - The technology should improve the net health outcome as much as or more than established alternatives.

5. The improvement must be attainable outside the investigational settings.
   - When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy criteria 3 and 4.

TEC
Technology Evaluation & Coverage Program

Blue Cross and Blue Shield Association

Technology Evaluation Criteria

COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

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August 9, 1991

Ms. JoAnne Scott, CPCU, AIE, ARP
Principal Insurance Analyst
State Corporation Commission
Bureau of Insurance
P.O. Box 1157
Richmond, Virginia 23209

Dear Ms. Scott:

In response to your inquiry about the Department of Medical Assistance Services' (DMAS), criteria for evaluating coverage for new technology, the Department does consider the criteria you mentioned in your letter.

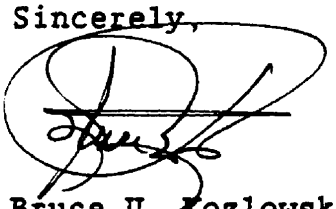
Generally, DMAS' process for evaluating coverage of a new technology begins with a review of recommendations made to HCFA by the Office of Health Technology Assessment (OHTA), a component of the Federal Agency for Health Care Policy Research (AHCPR). OHTA evaluates the safety and effectiveness of new or unestablished medical technologies that are being considered for coverage under Medicare. The assessment process performed by OHTA includes a comprehensive review of the medical literature and emphasizes broad and open participation from within and outside the Federal Government. A range of expert advise is obtained through publication of an announcement in the Federal Register and solicitation of input from Federal agencies, medical specialty societies, insurers and manufacturers. After the information is received from experts and from the scientific literature, the results are analyzed and synthesized into an assessment report. Each report presents a detailed analysis of the safety, clinical effectiveness, and uses of new or unestablished medical technologies. These reports are reviewed and used by DMAS in evaluating coverage for Medicaid recipients in Virginia.

The evaluation process continues with additional research and synthesis by DMAS personnel on any outstanding literature not reviewed by OHTA, and a review of HCFA guidelines, if available. All the information is then compiled and a recommendation is made considering the six criteria mentioned in your letter.

You also requested copies of regulations and procedures used by the Department pertaining to the appeals process. Attached are copies State regulations pertaining to client appeals and Federal regulations pertaining to the appeals process for Medicaid (42 CFR § 431 Subpart E) and Medicare (42 CFR Part 498). Please note that these regulations do not apply to experimental services not covered by Medicaid. Although coverage of non-covered services may be appealed by a recipient, we do not see any grounds upon which such appeal could be approved as no federal matching funds are available for services provided outside the scope of those specified within federal guidelines.

Please feel free to contact me if you have questions or require additional information.

Sincerely,



Bruce U. Kozlowski

Enclosures
BUK/cj

COMMONWEALTH of VIRGINIA

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REGULATORY REVIEW SUMMARY

I. IDENTIFICATION INFORMATION

Title of Final Regulation:	Client Appeals
Director Adoption of Final Regulation:	November 28, 1990
Public Comment Period:	Sept. 25-Nov. 23, 1990 @ 4:30pm
Effective Date:	January 16, 1991
Agency Contact:	Marsha Vandervall, Director Div. of Client Appeals Dept. of Med. Asst. Serv. 600 E. Broad St., Suite 1300 Richmond, Virginia 23219 (804) 371-8488

II. SYNOPSIS

Basis and Authority: The Code of Virginia (1950) as amended, §32.1-324, grants to the Director of the Department of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance in lieu of Board action pursuant to the Board's requirements. The Code also provides, in the Administrative Process Act (APA) §9-6.14:9, for this agency's promulgation of proposed regulations subject to the Department of Planning and Budget's and Governor's reviews. Subsequent to the emergency adoption action and filing with the Registrar of Regulations, the Code requires this agency to initiate the public notice and comment process as contained in Article 2 of the APA.

Discussion: The Code of Federal Regulations §431 Subpart E contains the federal requirements for fair hearings for applicants and recipients. This subpart, in implementing the Social Security Act §1902(a)(3), requires that the State Plan for Medical Assistance provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly. Hearings are also available for individuals if Medicaid takes action to suspend, terminate, or reduce services. The State Plan conforms to this requirement on page 33.

The Virginia General Assembly amended the Administrative Process Act effective July 1, 1989, to allow limited judicial review of public assistance case decisions. In an effort to ensure continued due process fairness in client appeals and in anticipation of the newly established availability of judicial review, the Department has revised its administrative procedures for client appeals.

The volunteer Medicaid Appeals Board, which was used in the past to decide client appeals, has been replaced with a Medical Assistance Appeals Panel which consists of three Administrative Law Judges employed by the Department. The revised Client Appeals system now provides for two levels of review of Medicaid client appeals. The first level is a Hearing Officer decision and the second is a decision by the panel of Administrative Law Judges (ALJ). Since an emergency regulation became effective on January 15, 1990, none of the ALJ decisions has been appealed to the Circuit Court.

The emergency regulations are effective through January 15, 1991 and will be replaced by these final regulations. These final regulations include a clarifying format change to the structure of the previously filed emergency regulations, but the operating premise of the Client Appeals system described in the emergency regulation is unchanged.

Public Comments Received:

DMAS filed proposed regulations with the Registrar of Regulations, in conformance to the Article 2 requirements of the Administrative Process Act, for a comment period from September 25, 1990 through November 23, 1990. The Department received comments from the Department of Planning and Budget (DPB).

All of DPB's comments and recommendations have either been addressed in these final regulations or resolved with the agency.

Three inquiries were received during the public comment period from:

Floyd Steele
Cerebral Palsy Center of Richmond

Martha Adams
Department of Rehabilitation Services

Susan Branner
Fairfax Community Services Board

These individuals requested copies of the regulations but submitted no comments.

Impact: The necessary staff for implementing the new system have been hired, and the operating costs were included in the previously approved budget for FY '91.

Forms: No new forms are required to implement this final regulation.

Evaluation: A system of internal review of Hearing Officer decisions is implemented by these regulations. Additionally, certain decisions rendered by the Administrative Law Judges are subject to review by the Agency Director.

III. FINAL AGENCY ACTION

I hereby approve the foregoing Regulatory Review Summary and attached State regulations and adopt the action stated herein. I hereby certify that these regulations have been promulgated in conformance to the public notice and comment requirements of the Administrative Process Act, Code of Virginia §9-6.14:7.1., Article 2.

11/28/90
Date

Bruce U. Kozlowski, Director
Dept. of Medical Assistance Services

information.

DEPARTMENT OF M ICAL ASSISTANCE SERVICES (BOARD OF)

Title of Regulation: **VR 460-04-8.7. Client Appeals Regulations.**

Statutory Authority: § 32.1-325 of the Code of Virginia.

Effective Date: January 16, 1991.

Summary:

The Code of Federal Regulations § 431 Subpart E contains the federal requirements for fair hearings for applicants and recipients. This subpart, in implementing the Social Security Act § 1902 (a)(3), requires that the State Plan for Medical Assistance provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly. Hearings are also available for individuals if Medicaid takes action to suspend, terminate, or reduce services. The State Plan conforms to this requirement on page 33.

The Virginia General Assembly amended the Administrative Process Act effective July 1, 1989, to allow limited judicial review of public assistance case decisions. In an effort to ensure continued due process fairness in client appeals and, in anticipation of the newly established availability of judicial review, the department has revised its administrative procedures for client appeals.

The volunteer Medicaid Appeals Board, formerly used to decide client appeals, has been replaced with a Medical Assistance Appeals Panel which consists of three Administrative Law Judges employed by the department. The revised Client Appeals system now provides for two levels of review of Medicaid client appeals. The first level is a hearing officer decision and the second is a decision by the panel of Administrative Law Judges. These new procedures should minimize the number of decisions appealed in court.

The department administers this revised system under emergency regulations that are effective until January 15, 1991. While these proposed regulations include a change to the structure of the previously filed emergency regulations by formatting them in the sequence by which the process actually occurs, but the operating premise of the Client Appeals system, described in the emergency regulation remains unchanged.

VR 460-04-8.7. Client Appeals Regulations.

PART I.
GENERAL.

Article 1.
Definitions.

§ 1.1. Definitions.

The following words and terms, when used in these regulations, shall have the following meanings unless the context clearly indicates otherwise:

"Agency" means:

1. An agency which, on the department's behalf, makes determinations regarding applications for benefits provided by the department; and,

2. The department itself when it makes initial determinations regarding client benefits.

"Appellant" means an applicant for or recipient of medical assistance benefits from the department who seeks to challenge an adverse action regarding his benefits or his eligibility for benefits.

"Department" means the Department of Medical Assistance Services.

"Division" means the department's Division of Client Appeals.

"Final decision" means a written determination by a hearing officer which is binding on the department, unless modified on appeal or review.

"Panel" means the Medical Assistance Appeals Panel.

"Representative" means an attorney or agent who has been authorized to represent an appellant pursuant to these regulations.

Article 2.
The Appeal System.

§ 1.2. Division of Client Appeals.

The division shall maintain a two-step appeals system for clients to challenge adverse actions regarding services and benefits provided by the department:

1. Hearing officer review. The first level of appeal is a hearing before a hearing officer. See Part II of these regulations.

2. Medical Assistance Appeals Panel Review. An appellant who believes the hearing officer's decision is incorrect may appeal to the Medical Assistance Appeals Panel for review. See Part III of these regulations.

§ 1.3. Time limitation for appeals.

Hearing officer appeals shall be scheduled and

conducted to comply with the 90-day time limitation imposed by federal regulations, unless waived in writing by the appellant or the appellant's representative.

§ 1.4. Judicial review.

An appellant who believes the decision of the Medical Assistance Appeals Panel is incorrect may seek judicial review pursuant to § 9-6.14:1 et seq. of the Virginia Code and Part 2A, Rules of the Virginia Supreme Court. An appellant must receive a final decision from the panel before seeking judicial review.

Article 3.
Representation.

§ 1.5. Right to representation.

An appellant shall have the full right to representation by an attorney or agent at all stages of appeal.

§ 1.6. Designation of representative.

A. Agents.

An agent must be designated in a written statement which is signed by the appellant. If the appellant is physically or mentally unable to sign a written statement, the division may allow a family member or other person acting on appellant's behalf to represent the appellant.

B. Attorneys.

If the agent is an attorney, a signed statement by an attorney that he is authorized to represent the appellant prepared on the attorney's letterhead, shall be accepted as a designation of representation.

C. Substitution.

A member of the same law firm as a designated representative shall have the same rights as the designated representative.

D. Revocation.

An appellant may revoke representation by another person at any time. The revocation is effective when the department receives written notice from the appellant.

Article 4.
Notice and Appeal Rights.

§ 1.7. Notification of adverse agency action.

The agency which makes an initial adverse determination shall inform the applicant or recipient in a written notice:

1. What action the agency intends to take;

2. The reasons for the intended action;

3. The specific regulations that support or the change in law that requires the action;

4. The right to request an evidentiary hearing, and the methods and time limits for doing so;

5. The circumstances under which benefits are continued if a hearing is requested (see § 1.10); and

6. The right to representation.

§ 1.8. Advance notice.

When the agency plans to terminate, suspend or reduce an individual's eligibility or covered services, the agency must mail the notice described in § 1.7 at least 10 days before the date of action, except as otherwise permitted by federal law.

§ 1.9. Right to appeal

An individual has the right to file an appeal when:

1. His application for benefits administered by the department is denied. However, if an application for State Local Hospitalization coverage is denied because of a lack of funds which is confirmed by the hearing officer, and no factual dispute exists, there is no right to appeal.

2. The agency takes action or proposes to take action which will adversely affect, reduce, or terminate his receipt of benefits;

3. His request for a particular medical service is denied, in whole or in part;

4. The agency does not act with reasonable promptness on his application for benefits or request for a particular medical service; or

5. Federal regulations require that a fair hearing be granted.

§ 1.10. ~~If an appellant files a timely Request of Appeal, his services shall not be terminated or reduced until the appeal has been finally decided unless the appeal is invalidated by the hearing officer.~~ Maintaining services.

A. If the agency mails the 10-day notice described in § 1.8 and the appellant files his Request for Appeal before the date of action, his services shall not be terminated or reduced until all appeals have been finally decided, unless it is determined at the hearing that the sole issue is one of federal or state law or policy and the appellant is promptly informed in writing that services are to be terminated or reduced pending the hearing decision.

B. If the agency's action is sustained on appeal, the

agency may institute any available recovery procedures against the appellant to recoup the cost of any services furnished to the appellant, to the extent they were furnished solely by reason of § 1.10 A of these regulations.

Article 5.
Miscellaneous Provisions.

§ 1.11. Division records.

A. Removal of records.

No person shall take from the division's custody any original record, paper, document, or exhibit which has been certified to the division except as the Director of Client Appeals authorizes, or as may be necessary to furnish or transmit copies for other official purposes.

B. Confidentiality of records.

Information in the appellant's record can be released only to a properly designated representative or other person(s) named in a release of information authorization signed by an appellant, his guardian or power of attorney.

C. Fees.

The fees to be charged and collected for any copies will be in accordance with Virginia's Freedom of Information Act or other controlling law.

D. Waiver of fees.

When copies are requested from records in the division's custody, the required fee shall be waived if the copies are requested in connection with an individual's own review or appeal.

§ 1.12. Computation of time limits.

A. Acceptance of postmark date.

Documents postmarked on or before a time limit's expiration shall be accepted as timely.

B. Computation of time limit.

In computing any time period under these regulations, the day of the act or event from which the designated period of time begins to run shall be excluded and the last day included. If a time limit would expire on a Saturday, Sunday, or state or federal holiday, it shall be extended until the next regular business day.

PART II.
HEARING OFFICER REVIEW.

Article 1.
Commencement of Appeals.

§ 2.1. Evidentiary hearings.

A hearing officer shall review all agency determinations which are properly appealed; conduct informal, fact-gathering hearings; evaluate evidence presented; and issue a written decision sustaining, reversing, or remanding each case to the agency for further proceedings.

§ 2.2. Request for appeal.

Any written communication from an appellant or his representative which clearly expresses that he wants to present his case to a reviewing authority shall constitute an appeal request. This communication should explain the basis for the appeal.

§ 2.3. Place of filing a Request for Appeal.

A Request for Appeal shall be delivered or mailed to the Division of Client Appeals.

§ 2.4. Filing date.

The date of filing shall be the date the request is postmarked, if mailed, or the date the request is received by the department, if delivered other than by mail.

§ 2.5. Time limit for filing.

A Request for Appeal shall be filed within 30 days of the appellant's receipt of the notice of an adverse action described in § 1.8 of these regulations. It is presumed that appellants will receive the notice three days after the agency mails the notice. A Request for Appeal on the grounds that an agency has not acted with reasonable promptness may be filed at any time until the agency has acted.

§ 2.6. Extension of time for filing.

An extension of the 30-day period for filing a Request for Appeal may be granted for good cause shown. Examples of good cause include, but are not limited to, the following situations:

1. Appellant was seriously ill and was prevented from contacting the division;

2. Appellant did not receive notice of the agency's decision;

3. Appellant sent the Request for Appeal to another government agency in good faith within the time limit;

4. Unusual or unavoidable circumstances prevented a timely filing.

§ 2.7. Provision of information.

Upon receipt of a Request for Appeal, the division shall notify the appellant and his representative of general appeals procedures and shall provide further detailed information upon request.

Article 5.
Prehearing Review.

§ 2.8. Review.

A hearing officer shall initially review an assigned case for compliance with prehearing requirements and may communicate with the appellant or his representative and the agency to confirm the agency action and schedule the hearing.

§ 2.9. Medical Assessment.

A. A hearing officer may order an independent medical assessment when:

1. The hearing involves medical issues such as a diagnosis, an examining physician's report, or a medical review team's decision; and

2. The hearing officer determines it necessary to have an assessment by someone other than the person or team who made the original decision, for example, to obtain more detailed medical findings about the impairments, to obtain technical or specialized medical information, or to resolve conflicts or differences in medical findings or assessments in the existing evidence.

B. A medical assessment ordered pursuant to this regulation shall be at the department's expense and shall become part of the record.

§ 2.10. Prehearing action.

A. Invalidation.

A Request for Appeal may be invalidated if it was not filed within the time limit imposed by § 2.5 or extended pursuant to § 2.6.

1. If the hearing officer determines that the appellant has failed to file a timely appeal, the hearing officer shall notify the appellant and the appellant's representative of the opportunity to show good cause for the late appeal.

2. If a factual dispute exists about the timeliness of the Request for Appeal, the hearing officer shall receive evidence or testimony on those matters before taking final action.

3. If a Request for Appeal is invalidated, the hearing officer shall issue a decision pursuant to § 2.22.

B. Administrative dismissal.

A Request for Appeal may be administratively dismissed without a hearing if the appellant has no right to appeal under § 1.9 of these regulations.

1. If the hearing officer determines that the appellant does not have the right to an appeal, the hearing officer shall notify the appellant and appellant's representative of the opportunity to contest the hearing officer's proposed administrative dismissal of the request.

2. If the appellant or the appellant's representative objects to the proposed administrative dismissal, the hearing officer shall conduct a hearing on the matter before taking final action.

3. If a Request for Appeal is administratively dismissed, the hearing officer shall issue a decision pursuant to § 2.22.

C. Judgment on the record

If the hearing officer determines from the record that the agency's determination was clearly in error and that the case should be resolved in the appellant's favor, he shall issue a decision pursuant to § 2.22.

D. Remand to agency.

If the hearing officer determines from the record that the case might be resolved in the appellant's favor if the agency obtains and develops additional information, documentation, or verification, he may remand the case to the agency for action consistent with the hearing officer's written instructions. The remand order shall be sent to the appellant and any representative.

E. Removal to the Medical Assistance Appeals Panel

In cases where the sole issue is one of state or federal law or policy, the case may, with the appellant's approval, be removed to the Medical Assistance Appeals Panel. Such cases will proceed according to the provisions of Part III of these regulations.

1. Before such removal, the hearing officer will send the appellant a statement of undisputed facts and identify the legal questions involved.

2. If the appellant accepts the hearing officer's statement of facts and legal questions involved, he may agree to removal to the panel.

3. If appellant disputes any facts, wants to present additional evidence, or desires a face-to-face hearing, removal is inappropriate, and a hearing must be held.

Article 7.
Hearing.

§ 2.11. Scheduling.

To the extent possible, hearings will be scheduled at the appellant's convenience, with consideration of the travel distance required.

§ 2.12. Notification.

When a hearing is scheduled, the appellant and his representative shall be notified in writing of its time and place.

§ 2.13. Postponement.

A hearing may be postponed for good cause shown. No postponement will be granted beyond 30 days after the date of the Request for Appeal was filed unless the appellant or his representative waives in writing the 90-day deadline for the final decision.

§ 2.14. Location.

The hearing location shall be determined by the division. If for medical reasons the appellant is unable to travel, the hearing may be conducted at his residence.

§ 2.15. Client access to records.

Upon the request of the appellant or his representative, at a reasonable time before the date of the hearing, as well as during the hearing, the appellant and his representative may examine the content of appellant's case file and all documents and records the agency will rely on at the hearing.

§ 2.16. Subpoenas.

Appellants who require the attendance of witnesses or the production of records, memoranda, papers, and other documents at the hearing may request issuance of a subpoena in writing. The request must be received by the division at least five business days before the hearing is scheduled. Such request must include the witness' name, home and work address, county or city of work and residence, and identify the sheriff's office which will serve the subpoena.

§ 2.17. Role of the hearing officer.

The hearing officer shall conduct the hearing, decide on questions of evidence and procedure, question witnesses, and assure that the hearing remains relevant to the issue(s) being appealed. The hearing officer shall control the conduct of the hearing and decide who may participate in or observe the hearing.

§ 2.18. Informality of hearings.

Hearings shall be conducted in an informal, nonadversarial manner. The appellant or his representative has the right to bring witnesses, establish all pertinent facts and circumstances; present an argument without undue interference, and question or refute the testimony or evidence, including the opportunity to confront and cross-examine adverse witnesses.

§ 2.19. Evidence.

The rules of evidence shall not strictly apply. All relevant, nonrepetitive evidence may be admitted, but the probative weight of the evidence will be evaluated by the hearing officer.

§ 2.20. Record of hearing.

All hearings shall be recorded [either by court reporter, tape recorders, or whatever other means the agency deems appropriate] . All exhibits accepted or rejected shall become part of the hearing record.

§ 2.21. Oath or affirmation.

All witnesses shall testify under oath [which shall be administered by the court reporter or the hearing officer, as delegated by the department's director] .

§ 2.22. Dismissal of Request for Appeal.

Request for Appeal may be dismissed if:

1. The appellant or his representative withdraws the request in writing; or

2. The appellant or his representative fails to appear at the scheduled hearing without good cause, and does not reply within 10 days after the hearing officer mails an inquiry as to whether the appellant wishes further action on the appeal.

§ 2.23. Post-hearing supplementation of the record.

A. Medical assessment.

Following a hearing, a hearing officer may order an independent medical assessment as described in § 2.9.

B. Additional evidence.

The hearing officer may leave the hearing record opened for a specified period of time in order to receive additional evidence or argument from the appellant. If the record indicates that evidence exists which was not presented by either party, with the appellant's permission, the hearing officer may attempt to secure such evidence.

C. Appellant's right to reconvene hearing or comment

If the hearing officer receives additional evidence from a person other than the appellant or his representative, the hearing officer shall send a copy of such evidence to the appellant and his representative and give the appellant the opportunity to comment on such evidence in writing or to reconvene the hearing to respond to such evidence.

D. Any additional evidence received will become a part of the hearing record, but the hearing officer must determine whether or not it will be used in making the decision.

§ 2.24. Final decision.

After conducting the hearing and reviewing the record, the hearing officer shall issue a written final decision which either sustains or reverses the agency action or remands the case to the agency for further action consistent with his written instructions. The hearing officer's final decision shall be considered as the agency's final administrative action pursuant to 42 CFR, 431.244(f). The final decision shall include:

1. A description of the procedural development of the case;

2. Findings of fact which identify supporting evidence;

3. Citations to supporting regulations and law;

4. Conclusions and reasoning;

5. The specific action to be taken by the agency to implement the decision; and

6. Notice of further appeal rights to the Medical Assistance Appeals Panel. This notice shall include information about the right to representation, time limits for requesting review, the right to submit written argument, the right to present oral argument, and the right to receive benefits pending review.

§ 2.25. Transmission of the hearing record.

The hearing record shall be forwarded to the appellant and his representative with the hearing decision.

PART III.
MEDICAL ASSISTANCE APPEALS PANEL.

Article 1.
General.

§ 3.1. Composition of the Medical Assistance Appeals Panel.

The panel shall consist of a Senior Administrative Law Judge and two Administrative Law Judges who are appointed by the director of the department and shall serve at his pleasure.

§ 3.2. Function of the panel.

Taking into consideration the record made below, the panel shall review and decide all appeals from hearing officers' decisions by evaluating the evidence in the record and any written and oral argument submitted, consistent with relevant federal and state law, regulations, and policy

Article 2.
Commencement of Panel Review.

§ 3.3. Commencing panel review.

An appeal is commenced when the appellant or his representative files a Request for Review, or another written statement indicating the appellant's belief that the hearing officer's decision is incorrect.

§ 3.4. Place of filing Request for Review.

The Request for Review shall be filed with the Medical Assistance Appeals Panel, Department of Medical Assistance Services, 600 E. Broad St. Richmond, VA 23219.

§ 3.5. Time limit for filing.

A Request for Review shall be filed within 12 days from the date the hearing officer's decision is mailed.

§ 3.6. Extension of time for filing.

An extension of the 12-day period for filing a Request for Review may be granted for good cause shown. A request for an extension shall be in writing and filed with the panel. The request shall include a complete explanation of the reasons that an extension is needed. Good cause includes unusual or unavoidable circumstances which prevented a timely appeal (See § 2.6).

§ 3.7. Dismissal.

A. A Request for Review shall be dismissed if it was not filed within the time limit imposed by § 3.5 or extended pursuant to § 3.6. If a factual dispute exists about the timeliness of the Request for Review, the panel shall receive evidence or testimony on those matters before taking final action.

B. A dismissal shall constitute the panel's final disposition of the appeal.

C. Judgment on the record.

If the panel determines from the evidence in the record that the hearing officer's decision was clearly in error and that the case should be resolved in the appellant's favor, the panel may issue a final decision without receiving written or oral argument from appellant.

Article 5.
Written Argument.

§ 3.8. Right to present written argument.

An appellant may file written argument to present reasons why the hearing officer's decision is incorrect.

§ 3.9. Time limitation.

Written argument by the appellant, if any, shall be filed with the panel within 10 days after the Request for Review is filed.

§ 3.10. Extension.

An extension of the time limit for filing written argument may be granted for good cause shown.

§ 3.11. Evidence.

No additional evidence shall be accepted with the written argument unless it is relevant, nonrepetitive and not reasonably available at the hearing level through the exercise of due diligence.

Article 6.
Oral Argument.

§ 3.12. Requesting oral argument.

An appellant or his representative may ask for a hearing to present oral argument with the Request for Review.

§ 3.13. Place of hearing.

Hearings shall be held at the Department of Medical Assistance Services' central office in Richmond, 600 E. Broad Street, Suite 1300, Richmond, Virginia 23219.

§ 3.14. Notice of hearing.

A. Scheduling the hearing.

Unless judgment on the record is issued pursuant to § 3.7 C, a hearing will be set, and, to the extent possible, scheduled at the appellant's convenience.

B. Notification.

As soon as a hearing is scheduled, the person requesting it will be notified, at least seven days in advance.

C. Postponement.

A hearing may be postponed by the appellant or his representative for good cause shown.

§ 3.15. Function of the Senior Administrative Law Judge.

The Senior Administrative Law Judge shall be the presiding member of the panel. If the Senior Administrative Law Judge is absent, one of the Administrative Law Judges shall preside on a rotating basis.

§ 3.16. Recorded hearing.

The hearing shall be tape recorded.

§ 3.17. Evidence.

No additional evidence will be accepted at the oral argument unless it meets the requirements of § 3.11 and is presented to the panel in advance of the hearing date.

Article 7.
Disposition.

§ 3.18. Disposition.

A. Vote.

The panel decision is made by majority vote, and t decision may be to sustain, reverse or remand the heari officer's decision.

B. Summary affirmance.

By majority vote the panel may summarily affirm t hearing officer's decision by adopting the hearing office decision as its own.

C. Content of decisions.

Decisions shall be accompanied by a written opinio stating facts with supporting evidence, reasons a conclusions, citations to supporting law and regulatio and an order describing the specific action to be taken implement the decision. Information about further appe rights will also be provided.

D. Remand to hearing officer.

A remand order shall clearly state the pane instructions for further development of the evidence or t legal or policy interpretation to be applied to the record.

E. The panel decision shall be sent to appellant and hi representative and the agency. This shall constitute t panel's final disposition of the appeal.

Article 8.
Reconsideration.

§ 3.19. When reconsideration is accorded.

A decision unfavorable to the appellant may reconsidered by the panel on its own motion or up motion by the appellant or his representative allegi error of fact or application of law or policy.

§ 3.20. Filing and content.

Appellant's motion for reconsideration must be fil within 12 days after entry of the panel's decision. Tl motion shall set forth clearly and specifically the alleg error(s) in the panel's decision.

§ 3.21. Review.

The Administrative Law Judge who wrote the majori opinion shall review the sufficiency of the allegations s forth in the motion and may request additional writt argument from the appellant.

§ 3.22. Disposition.

The ruling on the motion for reconsideration shall be in writing and entered as the final order in the case. If the motion is granted, a new decision will be issued in accordance with § 3.18.

BOARD OF NURSING

REGISTRAR'S NOTICE: The repeal of § 5.3 of this regulation, as stricken, is excluded from Article 2 of the Administrative Process Act in accordance with § 9-6.14:4.1 C 4(c) of the Code of Virginia, which excludes regulations that are necessary to meet the requirements of federal law or regulations, provided such regulations do not differ materially from those required by federal law or regulation. The Board of Nursing will receive, consider and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Title of Regulation: **VR 495-01-01. Board of Nursing Regulations.**

Statutory Authority: §§ 54.1-2400 and 54.1-3005 of the Code of Virginia.

Effective Date: January 16, 1991.

Summary:

The Virginia General Assembly, at its 1990 session, amended §§ 54.1-3000 and 54.1-3005 of the Code of Virginia. The first change amended the definition of practical nursing to permit the teaching of those who are or will be nurse aides, subject to such regulations as the Board of Nursing may promulgate. The second change authorizes the Board of Nursing to promulgate regulations, which include standards for the authority of licensed practical nurses to teach nurse aides.

The final regulations amend or relocate some existing regulations and add some new regulations to establish the qualifications for licensed practical nurses who teach in nurse aide education programs and to describe their responsibilities.

Changes resulting from the review of comments will be found in § 5.3 C 3 b. The proposed regulations were changed to permit other instructional personnel to provide classroom instruction in addition to providing skills laboratory and clinical instruction.

These regulations delete the regulation which permitted registration of clinical nurse specialists by exception. Also deleted is § 5.3 which required nurses aides to pay fees related to the nurse aide registry.

All revelant documents are available for inspection at the Board of Nursing, 1601 Rolling Hills Drive, Richmond, Virginia 23229, telephone (804) 662-9909.

VR 495-01-1. Board of Nursing Regulations.

Preamble:

These regulations state the requirements for approval of nursing and nurse aide education programs, the licensing of registered nurses and practical nurses, the registration of clinical nurse specialists and the certification of nurse aides in the Commonwealth of Virginia. The regulations have been adopted by the Virginia State Board of Nursing under the authority of Chapter 24 (§ 54.1-2400) and Chapter 30 (§ 54.1-3000 et seq.) of Title 54.1 of the Code of Virginia.

The board believes that each practitioner of nursing is accountable to the Commonwealth and to the public to maintain high professional standards of practice in keeping with the ethics of the profession of nursing.

The registered nurse shall be responsible and accountable for making decisions that are based upon educational preparation and experience in nursing. The registered nurse shall be held accountable for the quality and quantity of nursing care given to patients by himself or others who are under his supervision. The registered nurse who is a clinical nurse specialist is authorized to provide advanced nursing services consistent with the requirements of law and regulations.

The licensed practical nurse shall be held accountable for the quality and quantity of nursing care given to patients by himself based upon educational preparation and experience.

The certified nurse aide is required to meet standards consistent with federal and state law and regulations in employment settings receiving Medicare and Medicaid reimbursement for care rendered.

PART I.
GENERAL PROVISIONS.

§ 1.1. Definitions.

The following words and terms, when used in these regulations, shall have the following meanings, unless the context clearly indicates otherwise:

"Approval" means the process by which the board or a governmental agency in another state or foreign country evaluates and grants official recognition to nursing education programs that meet established standards not inconsistent with Virginia law.

"Associate degree nursing program" means a nursing education program preparing for registered nurse licensure, offered by a Virginia college or other institution and designed to lead to an associate degree in nursing, provided that the institution is authorized to confer such degree by the State Board of Education, State Council of

Blue Cross
and
Blue Shield
of the National Capital Area

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202/479-8000 Telex 140965 Cable BLUE
Chartered by the Congress of the United States

August 20, 1991

JoAnne Scott, CPCU, AIE
Principal Research Analyst
Bureau of Insurance
P. O. Box 1157
Richmond, Virginia 23209

Dear Ms. Scott:

I regret that Blue Cross and Blue Shield of the National Capital Area (BCBSNCA) was unaware of the July 10, 1991 public hearing held to receive comments on the proposal suggested in HJR 432 (1991) that an appeals process for insureds denied coverage for experimental medical technologies be established. I respectfully request that these comments be submitted as part of the record of the public hearing.

BCBSNCA believes that an appeals process required by the Commonwealth would duplicate the appeals procedures required under the Employee Retirement Income Security Act of 1974 (ERISA). As you may know, ERISA regulated business includes all group accounts except plans sponsored by a government entity or a church. ERISA requires that subscribers be afforded an opportunity to appeal a decision made by an insurer.

The appeals process required under ERISA is included in all BCBSNCA contracts through the following contractual text:

Claims Appeal Procedures

(1) Any denial of a claim may be appealed in writing to the Corporation.

(2) Such appeal should be filed within 90 days of the denial.

(3) The claim will be reviewed in accordance with guidelines established by the Corporation, and a final decision will be made within 60 days from the receipt of the appeal.

(4) If more extensive review is required, the Employee will be notified and a final decision will be made within 120 days.

This federally required appeals process is available to subscribers for any and all claims or services denied including procedures or services denied as experimental.

As you may recall, HJR 213 (1990) called for the study of a "fair and objective and efficient means of determining whether particular new medical technologies and procedures are 'experimental' and 'investigative' and therefore not covered under medical insurance policies". The result of this study, as reported to the Commission on Health Care for All Virginians, found that the existing procedures used by insurers to evaluate new technology and procedures were valid and a new process, developed at the state level, would not improve the process currently used by most insurers.

BCBSNCA does not believe it has been adequately demonstrated that Virginia residents do not have access to an "effective appeals process for the denial of insurance coverage for valuable and innovative treatments" or that Virginia residents lack a "fair and objective means of obtaining adequate insurance and ... access to necessary health care". ERISA requires insurers to advise subscribers and enrollees of their appeal rights in any case where an adverse decision is made. Further, as the report resulting from HJR 213 (1990) indicated, insurers have developed valid and objective technology assessment programs to evaluate the experimental nature of new technologies, procedures, and services.

While HJR 432 addresses experimental procedures in general, discussions often focus the concern on the determination by insurers that autologous bone marrow transplants (ABMT) for breast cancer patients are experimental. BCBSNCA understands the many concerns raised about such a determination. However, BCBSNCA believes that a primary concern of proponents for the establishment of an appeals process for procedures determined by insurers to be experimental, is the belief that because ABMT for breast cancer is a "last hope" effort for some patients, benefits "should" be provided. The problem is not in how the procedure is determined to be experimental or what type of appeal process is afforded the patient. Rather, the concern is that some people believe benefits for the procedure "should" be available because there is no other treatment available to these patients. It appears then, that the proponents really are seeking a mandated benefit for the procedure. The appropriate channel for such action is review by the Special Advisory Commission on Mandated Health Insurance Benefits.

On a related note, you may be interested to know that although benefits for ABMT for breast cancer patients is not available under BCBSNCA's existing contracts, it is anticipated that BCBSNCA will be able to provide an alternative for subscribers who are accepted candidates through a demonstration project being sponsored in cooperation with the National Cancer Institute (NCI). The purpose of the demonstration project on breast cancer treatment is to support a "clinical trials" process to determine the efficacy of high-dose chemotherapy with ABMT compared to standard chemotherapy in the treatment of breast cancer. Many clinical experts, researchers, and professional staff at NCI believe the controversy surrounding the use of high-dose chemotherapy and ABMT for breast cancer can only be resolved through a randomized clinical trial.

The clinical trials will be conducted at several hospitals nationwide. The demonstration project will be limited to a treatment period consisting of two years, with a two year follow-up period. Medical treatment protocols to be used in the clinical trials will be approved by NCI. Up to 1,200 patients are expected to participate in the trial. BCBSNCA subscribers may be eligible to participate in the clinical trials under certain circumstances such as meeting the medical protocols of the clinical trial.

Participation in this type of demonstration project represents a new activity for BCBSNCA and the other Blue Cross and Blue Shield plans which elect to take part in the project, and should not be confused with our role as a nonprofit health services plan. As such, BCBSNCA provides benefits for covered services according to established contractual terms. In this regard, standard chemotherapy treatment received by control group patients in the trials will be handled routinely as a covered service according to the subscriber's eligibility for benefits. In contrast, because high-dose chemotherapy and ABMT for breast cancer is not a contractual benefit, any benefits which are provided by BCBSNCA will be accommodated extracontractually through agreement with the group through which the patient is enrolled, or by separate agreement with the patient where coverage is through a small "community rated" group or non-group coverage.

BCBSNCA appreciates this opportunity to provide comments related to HJR 432. If you have any questions, please call me at (202) 479-8389.

Sincerely,

Gail M. Thompson

Gail M. Thompson
Legislative Affairs Coordinator

HIAA

Health Insurance Association of America

July 25, 1991

JoAnne Goodman Scott, CPCU, AIE
Principal Insurance Analyst
State Corporation Commission
Bureau of Insurance
Box 1157
Richmond, VA 23209

RE: EXPERIMENTAL MEDICAL TECHNOLOGY
HOUSE JOINT RESOLUTION NO. 432

Dear Mrs. Scott:

On behalf of the Health Insurance Association of America (HIAA), I would like to offer the following comments for consideration by the Bureau as you complete your study of the feasibility of establishing an appeal process for insureds denied coverage under their health insurance policies for treatments defined as "experimental" or "investigative".

As you are aware, this is an extremely emotional issue. On the one hand, we are faced with the reality that consumers in need of medical care want to receive the care prescribed in many cases irrespective of the cost, the safety of a given procedure, or the likelihood of a favorable outcome and there is an expectation that insurance will cover the prescribed treatment. On the other hand, insurance companies generally decline to cover experimental treatments when evidence does not exist that such treatments are safe, effective or medically accepted procedures.

We would oppose the establishment of an appeals process for insureds denied coverage for "experimental" medical technologies for the following reasons:

a. the medical industry lacks a clear definition of "experimental" or "investigative". In fact, a conference has been scheduled by the Agency for Health Care Policy and Research (Department of Health & Human Services) on Experimental vs. State-of-the-Art Technologies for November. HIAA

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will participate in that conference. I have enclosed information for you on the conference;

b. current administrative remedies exist for the resolution of insurance policy issues; and

c. these concerns are ultimately an issue for consideration by the courts and a special appeals board would merely add another step in the process rather than offer a final resolution of the matter.

Thank you for the opportunity to comment.

Sincerely,

Reginia G. Palmer

Reginia G. Palmer
Assistant General Counsel

Enclosures

VIRGINIA COMMONWEALTH UNIVERSITY
Massey Cancer Center

July 9, 1991

JoAnne Scott
Principal Insurance Analyst
Bureau of Insurance
P. O. Box 1157
Richmond, Virginia 23209

Dear Ms. Scott:

I will not be able to attend the State Corporation Commission's public meeting July 10th on an appeals process for insureds who are denied coverage for procedures deemed experimental or investigative. However, I have a strong and abiding interest in this matter as a physician who tries my best to take optimal care of patients. Several examples spring to light.

First, a 37 year old man covered by Blue Cross/ Blue SHield was diagnosed with hairy cell leukemia. His wife called the National Cancer Institute because he did not trust his primary hematologist/oncologist's opinion regarding therapy. The first doctor had recommended removal of the spleen followed by chemotherapy or Interferon treatment. However, a new treatment deemed "investigational" was available which has put 150 of 150 patients into complete remissions with no sign of disease recurrence. The patient, through me, obtained that therapy at M.D. Anderson Cancer Center in Houston, Texas. The patient's hospital bill was denied coverage by Blue Cross/Blue Shield because it was "investigational". Had the patient chosen standard ineffective treatment with no chance of cure (and what many state-of-the-art practitioners would deem as less than optimal practice) Blue Cross/Blue Shield would have paid for it without blinking an eye.

Second, a 37 year old woman was diagnosed with recurrent breast cancer. I referred her to Duke University for the most promising treatment available to such patients, high dose chemotherapy using autologous bone marrow transplantation to support her through a period of bone marrow hypoplasia. Blue Cross/Blue Shield promptly turned down her request stating that such therapy was investigational even though nearly all practitioners agreed that it is a viable option and often the preferred treatment for patients in her condition. Blue Cross/Blue Shield made this determination without consulting any experts in the field or without consulting any experts in Virginia who deal directly with bone marrow transplantation. They told me that the decision about her therapy was based only on efficacy and toxicity, not cost. The patient and I were clearly convinced that efficacy was better and

the patient was clearly willing to risk toxicity for a chance at long-term, disease-free survival. Conventional therapy offered her no hope of long-term survival with a median survival of only 18 months. By refusing to pay for therapy which both the patient and the doctor and the physician desired and deemed best, they clearly took medical decision-making out of the hands of the traditional decision makers.

Third, the idea at Blue Cross/Blue Shield or their insurers does not factor cost into decisions about treatment is laughable. I have treated patients on investigational protocols throughout the years including chemotherapy and immune therapy. In one case where I was the principal investigator, I treated Kaposi's sarcoma - AIDS patients with Tagamet, a commonly available anti-ulcer drug. The majority of those patients that I treated were on Blue Cross/Blue Shield. Not a single one was denied payment, not because of lack of efficacy but because of the low-cost of the treatment. In addition, the treatment I was giving had no "trigger" mechanism such as a high insurance bill that would led Blue Cross/Blue Shield to believe that it was investigational.

Fourth, Blue Cross/Blue Shield and other insurers have traditionally paid no heed to effectiveness of treatment, but have left that decision to physicians. I can literally make up any combination of medicines and give it to a patient with breast cancer or colon cancer and be guaranteed reimbursement by Blue Cross/Blue Shield. I can give these medicines and be reimbursed despite the fact that second and third-line chemotherapy for breast cancer and first-line chemotherapy for colon cancer has virtually no effectiveness in prolonging patients lives and in those instances studied, has minimal impact on the quality of patients survival. I have never once had a Blue Cross/Blue Shield claims adjuster call me up and state "Dr. Smith, is the treatment your working really effective? Does it prolong survival compared to other treatments? Is the toxicity worse or better than other treatments?" The only time I've ever received questioning has been when Blue Cross/Blue Shield has denied therapy for bone marrow transplantation. Insurance adjusters don't care about quality as long as the cost is within their realm to price a product alongside their competitors. When their cost begin to rise such that they must raise prices, then we begin to hear questions about effectiveness.

I am sorry that I will not be able to attend the hearing, because I am working on the hospital ward trying to teach future physicians. I understand the dilemma that insurance companies find themselves in. I also understand firsthand the dilemma that patients and physicians are in -- having effective therapy that is being denied not on the basis of effectiveness, but on the basis of cost. I wouldn't object to that if the insurance companies were honest in their representation and would come to be bedside with me and explain why they are not paying for therapy.

Sincerely,

Tom Smith

Thomas J. Smith, M.D
Director of Cancer Education
Medical Director, John N. Dalton
Oncology Clinics

Settlement Consultants/Mediate-Tech
"The Equitable Solution"
Post Office Box 375 Charlottesville, VA 22902 (804)977-6343

30 August 1991

Ms. JoAnne Scott
SCC Bureau of Insurance
P.O. Box 1157
Richmond, VA 23209

Re: Written Comment on Appeals Process for insureds denied coverage for "experimental" medical technologies

Dear Ms. Scott:

Our firm was unable to respond in time for your July 1991 deadline on this issue. However, in light of the importance of the establishment of a fair and efficient appeals process, and the need to thoroughly study all possible alternatives, I am submitting the comment on this issue anyway. I hope that you will at least be able to give it some consideration before the report is finalized and delivered before the Governor, General Assembly and the Commission on Health Care for All Virginians.

The solution I have suggested, mediation, could certainly be used to create a practical process by which these disputes could be dealt with early on, even before appeal. All parties involved would understand each other better having used mediation, and will be more likely to accept a decision created by those parties.

Please feel free to call or write with any questions. And thank you for the opportunity to respond to this vital issue.

Sincerely,

Diana L. M. Simmons, JD
Case Manager

enclosure

WRITTEN COMMENT FOR PUBLIC MEETING ON DENIED HEALTH INSURANCE COVERAGE FOR EXPERIMENTAL TREATMENTS

In Joint House Resolution No. 432, it is acknowledged that some procedures labelled "experimental", thus denying coverage, may actually be more potentially beneficial to the patients (as well as cost effective) than the "traditional treatments" covered by insurance. In a world of constant change where technological advances in medicine occur frequently and new and different medical problems plague society, the need to deal more fairly and effectively with insureds denied coverage becomes clear. Thus far, the insurance industry has been unable to keep abreast of these constant changes in technology and its policies on "experimental" versus "traditional" procedures exemplifies this problem. The following proposal would help alleviate this situation, and would allow involved parties to present input on the important issues that affect so many people's lives.

Our recommendation is that an appeals process utilizing mediation as an informal intermeasure would be a most effective tool for handling these disputes over coverage. Classical mediation, the use of a third party neutral to empower disputants to reach agreement, has a reputation for high success rates (80% plus in some studies). It could be used as an integral part of the appeals process once denial of treatment has occurred, byt before more formal procedures are implemented. Fopr example, an insured who has been denied coverage fir ab experimental procedure could fiel a statement of intent to appeal, or the like. The case would be required to be submitted within a

certain number of days to a mediation firm for processing. The mediation firm would have a certain number of days (10) to confirm a date, time and place where the parties have agreed to meet to discuss the coverage denial. Al parties necessary to resolve the disagreement would be included. The insured and his representatives (Doctor, Lawyer) would be able to deal directly with the insurance company's representatives. Each party would have an opportunity to present their positions as to why the procedure should or should not be considered "experimental" for that insured, and thus whehter vocerage should be extended for that particular treatment. The various factores involved could be adequately brough forth, examinded, and discussed, such as what previous traditional treatments the insured has been submitted ot, the severity of the medial problem and so on. Once the parties reach agreement, they cna sign an agreement on resolution of the matter that would be binding on all parties as far as coverage or non-coverage issues on that specific treatment.

Resolving the coverage disputes early on will save a great deal of time, funds and effort that would be needed to use a more formal appeals process immediately upon denial. Use of mediation as an intermeasure before the formal appeal allows those parties the possibility of an immediate, personalized outcome of their request for a redetermination. Parties would have more opportunities for true understanding and human interaction. Mediation could provide a peaceful resolution in the majority of cases appealed and would prevent further appeals

being required. Finally, it preserves the integrity and dignity of the parties by taking into account the humanistic aspects of medical procedures, involving patients and their families, doctors and hospitals, and people dedicated to providing monetary assistance for medical needs of insured persons.

July 7, 1991

Ms. Joann Scott
Principal Insurance Analysis
Bureau of Insurance
P.O. Box 1157
Richmond, VA 23209

Dear Ms. Scott:

I am unable to attend the public meeting on July 10, 1991 at 1:00 P.M. concerning House Resolution #432 and want my support for a change in current policy known. I strongly support a change in the current insurance coverage for women who have advanced or metastatic breast cancer. Virginia Blue Cross/Blue Shield should cover bone marrow transplant treatments for these patients.

Also, I do not think a person who is undergoing treatment during a very stressful time of her (or his) life should have to endure the stress of a battle for insurance payments. Whatever course of action is decided upon, I hope it will be humane as well as medically fair.

I recognize our country is experiencing a health care crisis. However, denying coverage for this procedure is not the way to resolve the dilemma. Please add my concerns to those you receive in the mail and those of the people who attend the meeting. Thank you.

Sincerely,

Ronne T Jacobs

Ronne T. Jacobs

RONNE JACOBS ASSOCIATES
Organization and Management Development
401 September Drive / Richmond, VA 23229 / Telephone (804) 741-3388

Joann Scott
Financial Insurance Analysis
Bureau of Insurance
P. O. Box 1157
Richmond, Va. 23209

Dear Ms. Scott:

I am writing to express my strong support for House Resolution #342 to establish an appeals process for insured persons with cancer and other diseases who are denied coverage for "experimental" or "investigative" procedures and treatment.

Many of the kinds of treatment that are being excluded by insurance companies in Virginia are very effective. Some are covered by insurance companies in many other states. Victims and their families are suffering enough without the additional burden of having to battle insurance companies. The arbitrary nature of these exclusions are unfairly cruel.

Thank you for your consideration.

Sincerely,

Phoebe F. Antrim

Phoebe F. Antrim

July 11, 1991
8029 Post Oak Road
Richmond, Virginia 23235
(804) 323-3893

Ms. Jo Anne Scott
Bureau of Insurance
State Corporation Commission
P.O. Box 1157
Richmond, Virginia 23209

Dear Ms. Scott:

It was a great pleasure to meet you yesterday at the General Assembly. You and your colleagues did a wonderful job handling what must've been for you an emotionally draining issue.

My family has been touched by this terrible visitor and thankfully, I was able to provide my wife with the bone marrow harvest which may save her life. I am very concerned however about all the patients who are being denied this treatment by their insurance carriers.

I'm surprisingly happy that Blue Cross of Virginia sent their representative to speak to you - as it actually did underscore the point we were all trying to make to you. Should people such as these be the ones making critical decisions regarding high-technology medicine? I think not. I sincerely hope that you will agree that Virginians need a better way to arbitrate these matters.

My personal thanks to you and your staff for taking the time to consider this problem. If I may be of service in any way please feel free to contact me.

Sincerely yours,

Rick Odato

2175 Wildwood Road
Salem, VA 24153
July 5, 1991

Ms. Joanne Scott, Principal
Insurance Analyst
State Corporation Commission
Bureau of Insurance
P. O. Box 1157
Richmond, VA 23209

Dear Ms. Scott:

I have been notified that sometime the week of July 8 a request initiated by Lorraine Smusz will be heard by the Commission asking that insurance companies be required to pay for bone marrow transplants.

I would like for you to be aware that I wholeheartedly support this request. Insurance premiums are paid for health coverage; and when people get to the point they no longer have a chance to live and are still willing to undergo this very distressing treatment to save their life, insurance companies should be obligated to pay for this health care.

On May 30 of this year, a very close friend of mine passed away after losing a battle with breast cancer. In the beginning when the lump was found, her doctors told her she had nothing to worry about because she had chosen the strongest treatment available. After a fight that lasted approximately two years, the cancer finally spread throughout her entire body.

As if she didn't have enough to worry about, her insurance company kept postponing paying her bills back to September of 1990 stating that they needed to reevaluate her charges. From September 1990 until the day she passed away, Jackie had been in and out of the hospital numerous times and close to death on many of those occasions. By receiving statement after statement from the doctors, hospital, etc., she not only had the worry from her disease, but also the burden from the insurance company in not paying her bills.

Please approve this request and force all insurance companies to pay for those expenses that they, by right, should be obligated to pay. After all, isn't this what they have been representing to policyholders for years.

Thank you very much for taking your time to review my opinion.

Sincerely,

K. Alisa Carroll

K. Alisa Carroll

/kac