REPORT OF THE
SPECIAL ADVISORY COMMISSION ON MANDATED HEALTH INSURANCE BENEFITS

Coverage for Therapies for Biologically Based Mental Illnesses

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

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January 9, 2001

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

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

This report documents a study conducted by the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) to assess the social and financial impact and the medical efficacy of Senate Bill 165, regarding a proposed mandate of coverage for therapies for biologically based mental illnesses.

Respectfully submitted,

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TABLE OF CONTENTS

SECTION	PAGE
INTRODUCTION	1
SUMMARY OF PROPOSED LEGISLATION	1
SOCIAL IMPACT	4
FINANCIAL IMPACT	14
MEDICAL EFFICACY	14
CURRENT INDUSTRY PRACTICES	15
INSURANCE REQUIREMENTS IN OTHER STATES	15
REVIEW CRITERIA:	16
SOCIAL IMPACT	16
FINANCIAL IMPACT	18
MEDICAL EFFICACY	19
EFFECTS OF BALANCING THE SOCIAL, FINANCIAL, AND MEDICAL EFFICACY CONSIDERATIONS	20
CONCLUSION	21
RECOMMENDATION	21
APPENDICES:	
A - SENATE BILL 165	A-1
SENATE BILL 165 AMENDED	A-2

INTRODUCTION

Senate Bill 165 was referred to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) by the Senate Committee on Commerce and Labor in the 2000 Session of the General Assembly. Senator John S. Edwards introduced the bill.

The Advisory Commission held a public hearing on November 9, 2000, in Richmond, to receive public comments on Senate Bill 165. Two concerned citizens and a representative of the Speech, Language and Hearing Association of Virginia (SHAV) spoke in support of the bill. The Virginia Association of Health Plans (VAHP) and a physician for Kaiser Permanente spoke in opposition to the bill. Written comments in support of the bill were received from a concerned citizen, the Autism Program of Virginia (TAP-VA), and SHAV. Written comments in opposition to the bill were received from the VAHP, the Health Insurance Association of America (HIAA), a physician for Kaiser Permanente, Trigon Blue Cross Blue Shield (Trigon), and the Virginia Chamber of Commerce.

SUMMARY OF PROPOSED LEGISLATION

The language of the bill amends existing § 2.1-20.1 in the health insurance requirements for state employees. The bill also amends § 38.2-3412.1:01 in Title 38.2 of the Code of Virginia. The section contains requirements for the coverage for biologically based mental illness. Group accident and sickness policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; each corporation providing group accident and sickness subscription contracts and health maintenance organization health care plans must provide coverage for biologically based mental illnesses. The term "biologically based mental illness" is defined as:

> ...any mental or nervous condition caused by a biological disorder of the brain that results in a clinically significant syndrome that substantially limits the person's functioning; specifically, the following diagnoses are defined as biologically based mental illness as they apply to adults and children: schizophrenia, schizoaffective disorder, bipolar disorder, major depressive disorder, panic disorder, obsessive-compulsive disorder, attention deficit hyperactivity disorder, autism, and drug and alcoholism addiction.

The benefits for the biologically based mental illnesses may be different from benefits for other illnesses, conditions, or disorders if the benefits meet the medical criteria necessary to achieve the same outcomes achieved by the benefits for any other covered illness, condition, or disorder.

The coverage is not to be separate from coverage for any other illness, condition, or disorder for determining deductibles, benefit year or lifetime durational limits, benefit year or lifetime dollar limits, lifetime episodes or treatment limits, copayment and coinsurance factors and benefit year maximums for deductibles, copayment, and coinsurance.

The language in the bill requires the coverage to include speech and language therapy, occupational therapy, physical therapy, and related therapies that are relevant to the treatment of these illnesses, whether or not they effect a cure.

The existing section does not apply to (i) short-term travel, accident only, limited or specified disease policies; (ii) short-term nonrenewable policies of not more than six months' duration; (iii) policies, contracts, or plans issued in the individual market or small group market to employers with less than 25 employees; or (iv) policies issued for persons eligible for coverage under Medicare or any other coverage under state or federal government plans.

Section 38.2-3412.1:01 does not preclude the use of usual and customary procedures to determine the appropriateness of, and medical necessity for, treatment of biologically based mental illnesses provided that the determinations are made in the same manner as determinations for the treatment of any other illness, condition, or disorder.

Two other bills, Senate Bill 266 and Senate Bill 605, were introduced in the 2000 Session that would require similar coverage for state employees only. They were continued in the House Committee on Appropriations until 2001.

The original bill language requires coverage for some of the services mandated for young children under § 38.2-3418.5 that mandates coverage for early intervention services. The coverage under that mandate must be limited to $5,000 per year. This appears to create a conflict. The bill did not include an effective date for the new requirements.

The original bill language does not restrict the number of sessions or time periods for the therapies relating to biologically based mental illnesses. If it is intended that insurers are not allowed to restrict the therapies to situations when reasonable improvements can be made or restrictions on the amount of therapy that must be covered, there may also be a concern with the current language in subsection C. That subsection allows insurers to restrict coverage similar to other illnesses in terms of durational limits. It is uncertain how insurers would determine how to treat this benefit the same as any other illness.

Senator Edwards, patron of the bill, informed Advisory Commission staff that it was his intention to request an amendment to the bill. The amended bill revises the current requirements in § 38.2-3418.5 that, as previously mentioned,

requires coverage for "early intervention services" in policies, contracts, and plans. The section requires coverage for medically necessary early intervention services in policies, contracts, and plans. The coverage shall be limited to $5,000 per insured or member per policy or calendar year and, except for the requirement in subsection C, the coverage is not to be subject to dollar limits, deductibles, and coinsurance factors no less favorable than for physical illness generally. The section defines *"early intervention services"* as

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

Subsection C of § 38.2-3418.5 provides that "The cost of early intervention services shall not be applied to any contractual provision limiting the total amount of coverage paid by the insurer, corporation or health maintenance organization to or on behalf of the insured or member during the insured's or member's lifetime."

Subsection D of § 38.2-3418.5 defines "Financial costs" as "...any copayment, coinsurance, or deductible in the policy or plan. Financial costs may be paid through the use of federal Part H program funds, state general funds, or local government funds appropriated to implement Part H services for families who may refuse the use of their insurance to pay for early intervention services due to a financial cost."

The section does not apply to short-term travel, accident only, limited or specified disease policies, policies or contracts designed for issuance to persons eligible for coverage under Medicare, or any other similar coverage under state or governmental plans or to short-term nonrenewable policies of not more than six months' duration.

The amended bill revises the definition of early intervention services to include "children ages three through twelve with diagnosed developmental disabilities" and medically necessary early intervention services is revised to include "medically necessary early intervention services for children ages three to twelve with diagnosed developmental disabilities." The amended bill restricts the

provision in subsection C to "children from birth to age three who are certified by the Department of Mental Health, Mental Retardation and Substance Abuse Services." The amended bill also restricts the definition of "financial costs" for children birth to age three who are certified by the Department of Mental Health, Mental Retardation and Substance Abuse Services.

The language in the amended bill does not define "developmental disabilities."

SOCIAL IMPACT

Section 300.7(a)(1) of 34 CFR Part 300 states, as used in the Individuals with Disabilities Education Act (IDEA) Regulation:

> ...the term child with a disability means a child evaluated in accordance with Secs. 300.530-300.536 as having mental retardation, a hearing impairment including deafness, a speech or language impairment, a visual impairment including blindness, serious emotional disturbance (hereafter referred to as emotional disturbance), an orthopedic impairment, autism, traumatic brain injury, an other health impairment, a specific learning disability, deaf-blindness, or multiple disabilities, and who, by reason thereof, needs special education and related services.

As of December 1, 1998, there were approximately 95,000 children between the ages of three and twelve receiving special education services in Virginia public schools.

Individuals with Disabilities Education Act

The Virginia Department for Rights of Virginians with Disabilities and the Virginia Assistive Technology System provide a summary of the IDEA in "Assistive Technology for Children and Adolescents" from their joint Training Manual on Assistive Technology. The summary as it relates to the proposed mandate appears below:

Individuals with Disabilities Education Act

The *Individuals with Disabilities Education Act (IDEA), P.L. 101-476 (formerly known as the Education of the Handicapped Act [EHA, P.L. 94-142] and its amendments)*, mandates a free appropriate public education for children and youth with disabilities. It also assures that the rights of children and youth with disabilities and their parents or guardians are protected in terms of fairness, appropriateness, and due process in decision-making about the provision of special education and related services.

The *Individuals with Disabilities Education Act (IDEA)* makes it possible for states and localities to receive federal funds to assist in the education of infants, toddlers, preschoolers, children and youth with disabilities. Basically, in order to remain eligible for federal funds under the law, states must assure that:

- all children and youth with disabilities, regardless of the severity of their disability, will receive a free, appropriate public education (FAPE).
- an Individualized Education Program (IEP) or an Individualized Family Services Plan (IFSP) will be drawn up for every child who is eligible for special education and related services, or early intervention services.
- to the maximum extent appropriate, all children and youth with disabilities will be educated in the regular education environment.
- children and youth receiving special education have the right to receive related services necessary to fully benefit from special education instruction.
- parents have the right to participate in every decision related to the identification, evaluation, and placement of their child.
- parents must give consent for any initial evaluation, assessment or placement.
- the right of parents to challenge and appeal any decision related to the identification, evaluation, and placement, or any issue concerning the provision of the FAPE is fully protected and clearly detailed in the due process procedures.
- parents have the right to confidentiality of information.

When the EHA was amended in 1986, the age of eligibility for special education and related services for all children with disabilities was lowered to age three beginning with the 1991-1992 school year. The law also established the *Handicapped Infants and Toddlers Program (Part H)*. Under this program, children from birth to three are eligible for early intervention services. In addition, the infant or toddler's family may receive services they may need to assist them as their child develops.

With the 1990 amendments to the special education law, a number of significant changes were made. The name of the law was changed from the *Education of the Handicapped Act* to the *Individuals with Disabilities Education Act (IDEA)*. In addition, assistive technology and transition services were added under the new amendments and now must be considered when developing a child's IEP.

Developmental Disabilities

The Centers for Disease Control and Prevention (CDC) states, "Developmental disabilities are a diverse group of physical, cognitive, psychological, sensory and speech impairments that begin anytime during development up to 18 years of age." In many or most cases, the cause of the developmental disability is not known.

The CDC estimates that 17% of children in the United States under age 18 have a developmental disability. It estimates that 2% of school-aged children have a serious developmental disability. State and federal education departments spend about $36 billion per year for special education programs for those 3 to 21 years old.

The CDC Division of Birth Defects, Child Development and Disability and Health includes attention deficit hyperactivity disorder, autism, cerebral palsy, hearing impairment, mental retardation, and vision impairment in its monitoring and development studies.

According to the CDC, approximately 10,000 babies in the United States develop cerebral palsy each year. Cerebral palsy is a disorder of movement or coordination caused by an abnormality of the brain. At least 80% of people with cerebral palsy develop it before birth or by the time they are one month old. The cause of cerebral palsy is often unknown.

The CDC estimates that between one to two children in every 1,000 has a moderate to severe hearing impairment in both ears. The cause of the impairment may not be known. The age of diagnosis of the hearing impairment is vital to the development of a child's speech, language, cognitive, and psychosocial abilities.

Another 12 of every 1,000 school children have mental retardation. Mental retardation is described by the CDC as a disorder characterized by a significantly below average score on tests of mental ability and limitations. The tests cover self-direction, school, work and leisure activities, daily living, social and communication skills. The cause of some mental retardation is not known. Some of the known causes are genetic factors, including Down syndrome or fragile X syndrome, and environmental factors, including alcohol consumption during pregnancy.

Approximately 600,000 children ages 6 to 21 received special education services in the United States in the 1995-96 school year because of mental retardation.

Vision impairment is estimated to affect 1 in 1,000 children with low vision or leave them legally blind. Impaired vision affects emotional, neurological, and

physical development because it can limit the experiences and kinds of information a child receives. Children with vision impairment may need special education programs to assist them.

Attention Deficit Hyperactivity Disorder is defined in the 1994 Diagnostic and Statistical Manual of Mental Disorders, Ed. IV (DSM-IV) as "disruptive behavior disorder characterized by the presence of a set of chronic and impairing behavior patterns that display abnormal levels of inattention, hyperactivity, or their combination." There is a symptom checklist that provides the specific criteria for making the diagnosis.

ADHD is estimated by the CDC to affect more than 2 million children and adolescents in the United States.

According to Interstate Research Associates, Inc., autism is a developmental disorder that is usually apparent by the age of three. It is a neurological or brain disorder that produces disabilities in behavior, communication, and social interaction. Autism occurs in children at a rate of from 5 to 15 out of 10,000 births. There are different estimates because of the different definitions of autism. Autism occurs more often in boys than in girls. It is believed to be caused by a number of factors, and the cause in many cases is not known.

The number of individuals in Virginia with autism is estimated to be 20,100 to 26,800. Another 30,100 to 68,370 individuals have Asperger's Syndrome or Pervasive Developmental Disorders (these conditions are defined below). These numbers are based on Virginia's population estimate of 6,700,000, using the prevalence rate from the National Institutes of Health (NIH).

There are approximately 41,607 Virginians under the age of 21 with the disorders, using the same population estimate and NIH prevalence rates.

The California Department of Developmental Services described autism in A Report to the Legislature - Changes in the Population of Persons with Autism and Pervasive Developmental Disorders in California's Developmental Services System: 1987 through 1998.

> Autism is a profound and poorly understood developmental disorder that severely impairs a person's abilities, particularly in the areas of language and social relations. Autistic children typically are normal in appearance and physically well developed. Their disabilities in communication and comprehension range from profound to mild. Historically, about 75 percent of persons with autism are classified as mentally retarded. Their most distinctive feature, however - which helps distinguish them from those solely

mentally retarded - is that they seem isolated from the world around them.

Autism is manifest uniquely and heterogeneously in a given individual as a collection of symptoms, which are rarely the same from one individual to another. Two children with the same diagnosis, intellectual ability and family resources are more likely to be recognized more for their differences than their similarities. Variation in the degree of impact on the individual is well documented and subtypes of the disorder have been identified. The professional community continues to work to clarify the confusion and controversy concerning the nature, causes, methods of diagnosis, and treatment of autism. As research has uncovered subtle differences in the onset and development of symptoms, different types of autism have been described. The current Diagnostic and Statistical Manual Fourth Edition (DSM IV), published in 1994, identifies five different disorders referred to collectively as the pervasive developmental disorders (PDDs).

The Autism Society of America describes autism as "a complex developmental disability that typically appears during the first three years of life. The result of a neurological disorder that affects the functioning of the brain, autism and its associated behaviors have been estimated to occur in as many as 1 in 500 individuals (Centers for Disease Control and Prevention 1997). Autism is four times more prevalent in boys than girls and knows no racial, ethnic, or social boundaries. Family income, lifestyle, and educational levels do not affect the chance of autism's occurrence.

The Diagnostic Statistical Manual Fourth Edition (DSM-IV), published in 1994, describes different disorders referred to as "pervasive developmental disorders" and include the following diagnoses: autistic disorder, pervasive developmental disorder not otherwise specified Asperger's disorder, Rett's disorder, and childhood disintegrational disorder.

I. DSM-IV Diagnostic Criteria for 299.00 Autistic Disorder

A. A total of six (or more) items from (1), (2), and (3), with at least two from (1), and one each from (2) and (3):

1. qualitative impairment in social interaction, as manifested by at least two of the following:

(a) marked impairment in the use of multiple nonverbal behaviors such as eye-to-eye gaze, facial expression, body postures, and gestures to regulate social interaction;

(b) failure to develop peer relationships appropriate to developmental level;

(c) lack of spontaneous seeking to share enjoyment, interests, or achievements with other people (e.g., by a lack of showing, bringing, or pointing out objects of interest); or

(d) lack of social or emotional reciprocity.

2. qualitative impairments in communication as manifested by at least one of the following:

(a) delay in, or total lack of, the development of spoken language (not accompanied by an attempt to compensate through alternative modes of communication such as gesture or mime);

(b) in individuals with adequate speech, marked impairment in the ability to initiate or sustain a conversation with others;

(c) stereotyped and repetitive use of language or idiosyncratic language; or

(d) lack of varied, spontaneous make-believe play or social imitative play appropriate to developmental level.

3. restricted repetitive and stereotyped patterns of behavior, interests, and activities, as manifested by at least one of the following:

(a) encompassing preoccupation with one or more stereotyped and restricted patterns of interest that is abnormal either in intensity or focus;

(b) apparent inflexible adherence to specific, nonfunctional routines or rituals;

(c) stereotyped and repetitive motor mannerisms (e.g., hand or finger flapping or twisting, or complex whole-body movements); or

(d) persistent preoccupation with parts of objects.

B. Delays or abnormal functioning in at least one of the following areas, with onset prior to age 3 years:

1. social interaction;

2. language as used in social communication; or

3. symbolic or imaginative play.

C. The disturbance is not better accounted for by Rett's Disorder or Childhood Disintegrative Disorder.

Description of the Other PDD Disorders:

The following is a brief description of the other four pervasive developmental disorders:

II. **Pervasive Developmental Disorder** (PDD, NOS 299.80) is diagnosed when autistic symptoms are present but the full criteria for autistic disorder are not met. Therefore, persons diagnosed with PDD, NOS present with autistic symptoms, but typically are not as involved with the social and communication deficits as persons who meet the full criteria for autism. Generally, they are higher functioning and more responsive to treatment. PDD and NOS, along with Asperger's disorder, is thought by some researchers to be as common as autism.

III. **Asperger's Disorder** (299.80) was first described by a German doctor, Hans Asperger, in 1944 (one year after Leo Kanner's first paper on autism). In his paper, Dr. Asperger discussed individuals who exhibited many idiosyncratic, odd-like behaviors. Unlike children with autism, children diagnosed with Asperger's disorder develop lucid speech before age four years and their grammar and vocabularies are usually adequate for normal conversation. Their speech is sometimes stilted, and their repetitive voice tends to be flat and emotionless. Their conversations revolve around themselves. Asperger's disorder is characterized by concrete and literal thinking. Persons with Asperger's disorder are usually obsessed with complex topics, weather, music, astronomy, history, etc. Intellectual ability for most is in the normal to above normal range in verbal ability and in the below average range on tasks of visual-perceptual organization. Sometimes it is assumed that the individual who has autism and average mental ability has Asperger's disorder. However, it appears that there may be several forms of high-functioning autism, of which Asperger's disorder is only one form.

IV. **Rett's Disorder** (299.80) is a degenerative disorder which affects only females and usually develops between six months and eighteen months of age. Some of their characteristic behaviors may include the following: loss of speech, repetitive hand wringing, body rocking, and social withdrawal. Those individuals suffering from this disorder may be severely to profoundly mentally retarded. This disorder, along with childhood disintegrative disorder, is extremely rare.

V. **Childhood Disintegrative Disorder** (CDD 299.10) is included among the PDDs because these children apparently develop normally for two or more years before suffering a distinct regression in their abilities. Affected children lose previously acquired functional skills in expressive or receptive language, social skills or adaptive behavior, including bowel or bladder control, play, or motor skills. Individuals with this disorder are rarer than persons with autism or one of the other PDDs; they exhibit the social, communicative, and behavioral deficits observed in autism, including loss of desire for social contact, diminished eye contact, and loss of nonverbal communication.

Speech and Language Therapy

The National Information Center for Children and Youth with Disabilities (NICHCY) describes speech and language disorders as problems in communication and related areas, including oral motor function. NICHCY describes speech-language pathologists assisting children with communication disorders in various ways. They provide individual therapy with children and may also work with their teachers to facilitate the child's communication at school. The speech-language pathologists also work with the family to develop goals and techniques for effective therapy.

According to the National Institute on Deafness and Other Communication Disorders (NIDCD), if a developmental disability is suspected, the child's physician will usually refer the child to a number of specialists, including a speech-language pathologist. The speech-language pathologist will perform a comprehensive evaluation of the child's ability to communicate and will design and administer treatment. No one treatment has been found to assist all individuals with autism, or other speech-language disorder. The best treatment begins early, before school age, and is planned individually. The goal of the therapy should be to improve communication. Verbal communication may be a realistic goal for some children, but others may only achieve gestured communication. Treatment should include periodic in-depth evaluation.

Speech and language therapy for children typically includes assessment, evaluation, and facilitation of purposeful activities to develop or achieve the highest possible level of communication. Speech-language therapy includes:

- the performance and interpretation of evaluations to assess functional communication skills, oral motor functioning, oral sensitivity and hearing, and specifically how each of these relate to activities of daily living;
- planning, administration, and modification of therapeutic interventions that focus on social communicative interactions, social play, nonverbal communication,

planned gestural communication systems (sign), paralinguistic skills, language comprehension, language expression, conversations, voicing, feeding, oral motor functioning and auditory processing;

- the provision of consultative, educational and other advisory services to enhance effectiveness of treatment programs and carry over in all settings;

- adaptation of environments and processes to enhance performance; and

- assessment of the need for and use of augmentative communication devices and training in their use.

Occupational Therapy

Children and their families receive comprehensive evaluation. Individual needs and skills are identified and specific recommendations are established. Therapy may be individual or group. The treatment might include improvement in these areas:

- upper extremity neuromotor and musculoskeletal status
- developmental skills
- activities of daily living skills
- integration of sensory motor processing
- visual perceptual motor skills
- motor skills for school activities
- oral motor skills
- prevocational/vocational skills
- assistance with adaptive equipment/technology
- prevention of deformities through splinting.

Programs to provide education for parents or therapy at home may be recommended.

Occupational therapy services include:

- assessment, treatment, and education of the individual and family;

- interventions directed toward developing or improving daily living skills and play skills;

- ♦ providing for the development of sensorimotor, oral-motor, perceptual, or neuromuscular functioning; range of motion; or emotional, cognitive, motivational, or psychosocial components of performance;
- ♦ assessment of the need for and use of assistive technology, orthotic or prosthetic devices and training in their use; and
- ♦ adaptation of environments and processes to enhance performance.

Physical Therapy

Physical therapy promotes health and the prevention of physical disability through the evaluation and rehabilitation of patients disabled by pain, disease, or injury. Treatment utilizes therapeutic measures. Treatment for children with developmental disabilities can include motor skills training, adaptive physical education, movement education and gymnastic classes.

For developmental disabilities, physical therapy would typically involve identifying, assessing, evaluating, and treating disabling movement disorders. The goal of physical therapy intervention is to minimize the inability to perform functional/developmental activities in a typical manner. Physical therapy may include:

- the performance and interpretation of tests and measurements to assess patho-physiological, patho-mechanical, and developmental deficits of bodily systems to determine treatment and prognosis;
- the planning of therapeutic interventions that focus on posture, locomotion, strength, endurance, coordination, joint mobility, flexibility, and functional movement abilities;
- the provision of consultative, educational and developmental screening advisory services;
- assessment, recommendation, and fabrication of orthoses and adaptive seating/positioning equipment; and
- the use of therapeutic exercises, assistive devices, physical agents, modalities, manual procedures such as joint and soft tissue mobilization, neuromuscular education, bronchopulmonary hygiene and ambulation/gait training.

Financial Impact

In July of 1997, estimates of the annual cost of therapies for children in the Virginia Individuals with Disabilities Education Act (IDEA) early intervention program were presented to the Advisory Commission. The proponents estimated an average annual cost per child of $2,100 for physical therapy, occupational therapy, speech and language therapy, and assistive technology devices. During the previous year of 1996, a total of 4,430 children were served by the IDEA early intervention programs.

The language in amended Senate Bill 165 would limit the amount paid per insured or member per policy or calendar year to $5,000.

Medical Efficacy

The working groups of the National Institutes of Health (NIH) Autism Conference published a number of conclusions and recommendations in *State of the Science in Autism: Report to the National Institutes of Health - Journal of Autism and Development Disorders, Volume 26, No. 2, 1996.*

The working groups believe that although there is no cure for autism, it is treatable through educational interventions of various types. Early intervention is particularly effective, and it is presumed that effectiveness is due to the "plasticity" of the neural systems at that time. The working groups stated that it is clear that "persons of ages and levels of ability can benefit from access to consistently available, proven treatment." The working groups acknowledge that treatment responses are not uniform for all persons. Many children can be brought to the point of near normal functioning, but others are not as responsive to social or behavioral intervention programs.

According to the working groups research has demonstrated the feasibility of significant gains in language, social adjustment, pre-academic and academic achievement, as well as other positive outcomes. The use of medications is considered appropriate only rarely without the addition of other treatment, including educational and behavioral interventions.

Those who oppose Senate Bill 165 point to the possibility of inaccurate diagnosis and resulting inappropriate treatment.

Kaiser Permanente opposed Senate Bill 165, in part, because of its belief that the legislation would exclude pediatricians from being the primary health care professionals managing the needs of children with disabilities. Written comments from Kaiser Permanente questioned the application of the current mandate of coverage for early intervention services. Kaiser contends the bill will

allow diagnosis to be made by allied health providers with limited oversight by a state agency. Kaiser also believes the bill could require therapy for up to nine years, when the child's condition does not respond to therapy because of severe impairment or misdiagnosis.

CURRENT INDUSTRY PRACTICES

The Bureau of Insurance surveyed 60 of the top writers of accident and sickness insurance in Virginia in March and May 2000. Fifty companies responded to the survey by July 18, 2000. Twenty-four companies do not write the type of coverage to which the mandate would apply. Twenty-six companies completed the survey. Seventeen of the responding companies indicated that they provide the coverage required by the original bill. Three of seventeen do limit the coverage, one to 90 days per illness and one to 30 days. The third company provides 30 days inpatient treatment and 52 outpatient visits per year for up to $50 per visit.

Ten companies provided estimates of the cost of adding or providing this coverage in individual standard contracts. The estimates ranged from $.11 to $4.36 per month and from .1% to 3% of the policy premium. Twelve companies provided figures for the cost of the coverage for a group contract. Those figures ranged from $.11 to $25.00 per month. Two companies provided estimates per member per month of $1.34 and $1.41. Two other companies estimated a cost of less than 1% and 3%, respectively, of overall premium.

Public schools in Virginia do provide services that are individually determined for each child. The IEP team determines what services are needed for educational purposes. The need is documented in the IEP.

INSURANCE REQUIREMENTS IN OTHER STATES

There are at least five states that have some type of requirement for coverage for autism, according to information from the National Association of Insurance Commissioners (NAIC). Colorado requires policies to cover autism in the same manner as any other accident or sickness. Connecticut requires groups to cover biologically based mental illness at least equal to coverage for medical or surgical conditions. The Connecticut requirement includes autism. Kentucky requires all health benefit plans to provide coverage for autism for children from 2 to 21. There is a $500 maximum per month. Hawaii requires coverage to determine treatment and utilization guidelines for autism.

Legislation was introduced in Florida in March of 2000 to require coverage for "autism spectrum disorder." The legislation was not enacted.

At least three states, Colorado, Connecticut, and Louisiana, have requirements for therapy. Colorado requires a minimum of 20 therapy benefits per year for physical, occupation, or speech therapy for congenital defects or birth abnormalities. Connecticut requires that rehabilitation services be offered for all group coverage. Louisiana requires the offering of coverage for physical therapy, occupational therapy, and speech and language therapy.

In addition to Virginia's requirement of coverage for early intervention services, Massachusetts, Tennessee, and Washington have requirements for neurodevelopmental therapy. Massachusetts requires coverage for early intervention services, including speech and physical therapy from birth to the third birthday. Tennessee requires the offer of coverage for speech disorders. Washington requires coverage for neurodevelopmental therapy for individuals ages six and under in employer-sponsored group policies.

REVIEW CRITERIA

SOCIAL IMPACT

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

There were 4,430 children in Virginia that received services from IDEA early intervention programs in 1996. Those children were 0 to 3 years in age.

The Department of Education reports that as of December 1, 1998, there were 95,073 children ages 3 to 12 in Virginia receiving special education services in Virginia's schools under Part B of the Individuals with Disabilities Education Act.

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

Twenty-six companies completed the survey of the top 60 writers of accident and sickness insurance in Virginia in March and May of 2000. Seventeen of the twenty-six companies indicated that they provided the coverage required by Senate Bill 165.

Three of the seventeen companies reported that they limit the coverage. One company limits the therapies to 90 days per illness, and one company limits the coverage to 30 days.

Proponents of Senate Bill 165 make the argument that coverage for therapies are typically viewed by insurers as a limited treatment for recovery from

illnesses, such as a stroke. They say that long-term need for therapy needs of disabled children are not generally available.

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

Proponents of the bill say that children with autism and related biologically based mental illnesses do not receive the amount of therapy that is needed to improve their quality of life. They point to insurer decisions that certain therapies were educationally appropriate, as opposed to medically appropriate.

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

The treatment plans for children with developmental disabilities would vary, based on the individual child's condition and needs. One citizen that supports the bill estimated costs of from $12,000 to $15,000 a year to provide the therapy that his son needs.

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

Based on information from state agencies, there are nearly 100,000 children under age 12 in Virginia needing treatment for developmental disabilities as defined in the IDEA regulations.

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

Written and oral comments supporting Senate Bill 165 were received from SHAV. They believe that it is critical that Virginians with developmental disabilities and biologically based mental illnesses are fully covered by mandated coverage.

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

The interest of collective bargaining organizations in negotiating for this coverage is not known.

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

Information on the number of children receiving services from school systems in Virginia was obtained from the Department of Education. There were approximately 95,000 children between the ages of 3 and 12 receiving special education services in Virginia's schools in December 1998.

FINANCIAL IMPACT

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

Some opponents of the bill believe that passage of Senate Bill 165 will contribute to uncontrolled use of allied health services. Those who support the bill believe that services provided will be limited to those that are clearly medically necessary.

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

Mandated coverage would be expected to increase the appropriate use of treatments, if children are going without necessary care in the absence of coverage. Those who oppose the bill believe that some care may be inappropriately provided.

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

Proponents of treatment for developmental disabilities make the argument that early, appropriate treatment can improve the quality of life and functioning for children with developmental disabilities. Many proponents believe that early treatment can reduce the need for some care in later years.

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

The enactment of Senate Bill 165 is not anticipated to significantly affect the number and types of providers of therapies in the next five years.

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

The Bureau of Insurance surveyed 60 of the top writers of accident and sickness insurance in Virginia in March and May 2000, regarding Senate Bill 165. Fifty companies responded to the survey by July 18, 2000. Twenty-four companies do not write the type of coverage to which the mandate would apply.

Twenty-six companies completed the survey. Seventeen of the responding companies indicated that they provide the coverage required by the original bill. Three of the seventeen do limit the coverage, one to 90 days per illness and one to 30 days.

Ten companies provided estimates of the cost of adding or providing this coverage in individual standard contracts. The estimates ranged from $.11 to $4.36 per month and from .1% to 3% of the policy premium. Twelve companies provided figures for the cost of the coverage for a group contract. Those figures ranged from $.11 to $25.00 per month. Two companies provided estimates per member per month of $1.34 and $1.41. Two other companies estimated less than 1% and 3%, respectively.

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

Proponents believe that the bill will result in improvements at younger ages that can reduce costs for care, if children are not treated when it is easier to impact their condition.

Those who oppose the bill believe it will shift costs from school systems to the insured population.

MEDICAL EFFICACY

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

Kaiser Permanente opposed Senate Bill 165, in part, because of its belief that the legislation would exclude pediatricians from being the primary health care professionals managing the needs of children with disabilities. Written comments from Kaiser Permanente questioned the application of the current mandate of coverage for early intervention services. Kaiser contended that the bill will allow diagnosis to be made by allied health providers with limited oversight by a state agency. Comments from Kaiser indicated also that it believes the bill could require therapy for up to nine years, when the child's condition does not respond to therapy because of severe impairment or misdiagnosis.

Proponents of the bill believe that therapies can improve the capabilities of and quality of life for developmentally disabled children.

The working groups of the National Institutes of Health (NIH) Autism Conference published a number of conclusions and recommendations in *State of*

the Science in Autism: Report to the National Institutes of Health - Journal of Autism and Development Disorders, Volume 26, No. 2, 1996.

The working groups believe that although there is no cure for autism, it is treatable through educational interventions of various types. Early intervention is particularly effective, and it is presumed that effectiveness is due to the "plasticity" of the neural systems at that time. The working groups stated that it is clear that "persons of all ages and levels of ability can benefit from access to consistently available, proven treatment." The working groups acknowledge that treatment responses are not uniform for all persons. Many children can be brought to the point of near normal functioning, but others are not as responsive to social or behavioral intervention programs.

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

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

Not applicable.

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

Not applicable.

EFFECTS OF BALANCING THE SOCIAL, FINANCIAL, AND MEDICAL EFFICACY CONSIDERATIONS

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

Proponents of the bill believe that it addresses a medical need and that the mandated coverage is consistent with the role of health insurance. The proponents believe that until there is a clearer distinction between medical and educational appropriateness of care, there is a need for more resources for children with developmental disabilities.

The VAHP, HIAA, Trigon, and the Virginia Chamber of Commerce all commented that the mandated services are already provided by the public school system.

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

Proponents make the argument that additional resources need to be available for children with developmental disabilities.

The HIAA believes that "it is not prudent" to mandate coverage of the mental parity mandate. The HIAA believes that even a small increase in cost can affect the availability of health coverage, particularly for small businesses. The VAHP does not believe it is appropriate to expand the early intervention mandate enacted in 1998 because there is no cost data on the current effect of the mandate. The Virginia Chamber of Commerce, VAHP, and Trigon note that many of the services that would be covered are currently provided in Virginia through the public school system. VAHP believes that the legislation would shift the responsibility for these children from school districts to health insurers.

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

Mandating the offer of coverage for this benefit would make it available to the policyholder. In group coverage, the group policyholder would make the decision to accept the coverage. The majority of health coverage in Virginia is issued to employer-employee groups. The employer would make the decision to accept or reject the coverage in those instances.

CONCLUSION

The Advisory Commission voted unanimously (7-0), on December 14, 2000, to recommend that Senate Bill 165 not be enacted. The Advisory Commission believes coverage for therapies is an important concern for children from the age of three through twelve. However, the Advisory Commission is concerned about the expansion of a mandate with only preliminary information on the cost of the current benefit. Accordingly, the Commission believes that a mandate of coverage as proposed by Senate Bill 165 or the amended bill is not advisable at this time.

RECOMMENDATION

The amended version of Senate Bill 165 would expand the recently enacted mandate of coverage for early intervention services. There were concerns that the cost associated with the existing mandate has not been determined. There were also concerns regarding the lack of a definition of developmental disabilities in the proposal. The Advisory Commission believes that a mandate of coverage as proposed should not be enacted.

000015420

1 **SENATE BILL NO. 165**
2 Offered January 12, 2000
3 *A BILL to amend and reenact §§ 2.1-20.1 and 38.2-3412.1:01 of the Code of Virginia, relating to*
4 *coverage for biologically based mental illness; coverage for speech, occupational, physical and*
5 *related therapies.*
6 ----------
7 Patrons—Edwards and Puller
8 ----------
9 Referred to Committee on Commerce and Labor
10 ----------
11 **Be it enacted by the General Assembly of Virginia:**
12 **1. That §§ 2.1-20.1 and 38.2-3412.1:01 of the Code of Virginia are amended and reenacted as**
13 **follows:**
14 § 2.1-20.1. Health and related insurance for state employees.
15 A. 1. The Governor shall establish a plan for providing health insurance coverage, including
16 chiropractic treatment, hospitalization, medical, surgical and major medical coverage, for state
17 employees and retired state employees with the Commonwealth paying the cost thereof to the extent
18 of the coverage included in such plan. The Department of Personnel and Training shall administer this
19 section. The plan chosen shall provide means whereby coverage for the families or dependents of
20 state employees may be purchased. The Commonwealth may pay all or a portion of the cost thereof,
21 and for such portion as the Commonwealth does not pay, the employee may purchase the coverage by
22 paying the additional cost over the cost of coverage for an employee.
23 2. Such contribution shall be financed through appropriations provided by law.
24 B. The plan shall:
25 1. a. Include coverage for low-dose screening mammograms for determining the presence of occult
26 breast cancer. Such coverage shall make available one screening mammogram to persons age
27 thirty-five through thirty-nine, one such mammogram biennially to persons age forty through
28 forty-nine, and one such mammogram annually to persons age fifty and over and may be limited to a
29 benefit of fifty dollars per mammogram subject to such dollar limits, deductibles, and coinsurance
30 factors as are no less favorable than for physical illness generally. The term "mammogram" shall
31 mean an X-ray examination of the breast using equipment dedicated specifically for mammography,
32 including but not limited to the X-ray tube, filter, compression device, screens, film, and cassettes,
33 with an average radiation exposure of less than one rad mid-breast, two views of each breast.
34 b. In order to be considered a screening mammogram for which coverage shall be made available
35 under this section:
36 (1) The mammogram must be (i) ordered by a health care practitioner acting within the scope of
37 his licensure and, in the case of an enrollee of a health maintenance organization, by the health
38 maintenance organization physician, (ii) performed by a registered technologist, (iii) interpreted by a
39 qualified radiologist, and (iv) performed under the direction of a person licensed to practice medicine
40 and surgery and certified by the American Board of Radiology or an equivalent examining body. A
41 copy of the mammogram report must be sent or delivered to the health care practitioner who ordered
42 it;
43 (2) The equipment used to perform the mammogram shall meet the standards set forth by the
44 Virginia Department of Health in its radiation protection regulations; and
45 (3) The mammography film shall be retained by the radiologic facility performing the examination
46 in accordance with the American College of Radiology guidelines or state law.
47 2. Include coverage for the treatment of breast cancer by dose-intensive chemotherapy with
48 autologous bone marrow transplants or stem cell support when performed at a clinical program
49 authorized to provide such therapies as a part of clinical trials sponsored by the National Cancer
50 Institute. For persons previously covered under the plan, there shall be no denial of coverage due to
51 the existence of a preexisting condition.
52 3. Include coverage for postpartum services providing inpatient care and a home visit or visits
53 which shall be in accordance with the medical criteria outlined in the most current version of or an
54 official update to the "Guidelines for Perinatal Care" prepared by the American Academy of Pediatrics

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1 and the American College of Obstetricians and Gynecologists or the "Standards for
2 Obstetric-Gynecologic Services" prepared by the American College of Obstetricians and
3 Gynecologists. Such coverage shall be provided incorporating any changes in such Guidelines or
4 Standards within six months of the publication of such Guidelines or Standards or any official
5 amendment thereto.
6 4. a. Include an appeals process for resolution of written complaints concerning denials or partial
7 denials of claims that shall provide reasonable procedures for resolution of such written complaints
8 and shall be published and disseminated to all covered state employees. Such appeals process shall
9 include a separate expedited emergency appeals procedure which shall provide resolution within one
10 business day of receipt of a complaint concerning situations requiring immediate medical care. For
11 appeals involving adverse decisions as defined in § 32.1-137.7, the Department shall contract with one
12 or more impartial health entities to review such decisions. Impartial health entities may include
13 medical peer review organizations and independent utilization review companies. The Department
14 shall adopt regulations to assure that the impartial health entity conducting the reviews has adequate
15 standards, credentials and experience for such review. The impartial health entity shall examine the
16 final denial of claims to determine whether the decision is objective, clinically valid, and compatible
17 with established principles of health care. The decision of the impartial health entity shall (i) be in
18 writing, (ii) contain findings of fact as to the material issues in the case and the basis for those
19 findings, and (iii) be final and binding if consistent with law and policy.
20 b. Prior to assigning an appeal to an impartial health entity, the Department shall verify that the
21 impartial health entity conducting the review of a denial of claims has no relationship or association
22 with (i) the covered employee, (ii) the treating health care provider, or any of its employees or
23 affiliates, (iii) the medical care facility at which the covered service would be provided, or any of its
24 employees or affiliates, or (iv) the development or manufacture of the drug, device, procedure or other
25 therapy which is the subject of the final denial of a claim. The impartial health entity shall not be a
26 subsidiary of, nor owned or controlled by, a health plan, a trade association of health plans, or a
27 professional association of health care providers. There shall be no liability on the part of and no
28 cause of action shall arise against any officer or employee of an impartial health entity for any actions
29 taken or not taken or statements made by such officer or employee in good faith in the performance
30 of his powers and duties.
31 5. Include coverage for early intervention services. For purposes of this section, "early intervention
32 services" means medically necessary speech and language therapy, occupational therapy, physical
33 therapy and assistive technology services and devices for dependents from birth to age three who are
34 certified by the Department of Mental Health, Mental Retardation and Substance Abuse Services as
35 eligible for services under Part H of the Individuals with Disabilities Education Act (20 U.S.C. § 1471
36 et seq.). Medically necessary early intervention services for the population certified by the Department
37 of Mental Health, Mental Retardation and Substance Abuse Services shall mean those services
38 designed to help an individual attain or retain the capability to function age-appropriately within his
39 environment, and shall include services which enhance functional ability without effecting a cure.
40 For persons previously covered under the plan, there shall be no denial of coverage due to the
41 existence of a preexisting condition. The cost of early intervention services shall not be applied to any
42 contractual provision limiting the total amount of coverage paid by the insurer to or on behalf of the
43 insured during the insured's lifetime.
44 6. Include coverage for prescription drugs and devices approved by the United States Food and
45 Drug Administration for use as contraceptives.
46 7. Not deny coverage for any drug approved by the United States Food and Drug Administration
47 for use in the treatment of cancer on the basis that the drug has not been approved by the United
48 States Food and Drug Administration for the treatment of the specific type of cancer for which the
49 drug has been prescribed, if the drug has been recognized as safe and effective for treatment of that
50 specific type of cancer in one of the standard reference compendia.
51 8. Not deny coverage for any drug prescribed to treat a covered indication so long as the drug has
52 been approved by the United States Food and Drug Administration for at least one indication and the
53 drug is recognized for treatment of the covered indication in one of the standard reference compendia
54 or in substantially accepted peer-reviewed medical literature.

1 9. Include coverage for equipment, supplies and outpatient self-management training and education,
2 including medical nutrition therapy, for the treatment of insulin-dependent diabetes, insulin-using
3 diabetes, gestational diabetes and noninsulin-using diabetes if prescribed by a health care professional
4 legally authorized to prescribe such items under law. To qualify for coverage under this subdivision,
5 diabetes outpatient self-management training and education shall be provided by a certified, registered
6 or licensed health care professional.
7 10. Include coverage for reconstructive breast surgery. For purposes of this section, "reconstructive
8 breast surgery" means surgery performed on and after July 1, 1998, (i) coincident with a mastectomy
9 performed for breast cancer or (ii) following a mastectomy performed for breast cancer to reestablish
10 symmetry between the two breasts. For persons previously covered under the plan, there may be no
11 denial of coverage due to preexisting conditions.
12 11. Include coverage for annual pap smears, including coverage, on and after July 1, 1999, for
13 annual testing performed by any FDA-approved gynecologic cytology screening technologies.
14 12. Include coverage providing a minimum stay in the hospital of not less than forty-eight hours
15 for a patient following a radical or modified radical mastectomy and twenty-four hours of inpatient
16 care following a total mastectomy or a partial mastectomy with lymph node dissection for treatment
17 of breast cancer. Nothing in this subdivision shall be construed as requiring the provision of inpatient
18 coverage where the attending physician in consultation with the patient determines that a shorter
19 period of hospital stay is appropriate.
20 13. Include coverage (i) to persons age fifty and over and (ii) to persons age forty and over who
21 are at high risk for prostate cancer, according to the most recent published guidelines of the American
22 Cancer Society, for one PSA test in a twelve-month period and digital rectal examinations, all in
23 accordance with American Cancer Society guidelines. For the purpose of this subdivision, "PSA
24 testing" means the analysis of a blood sample to determine the level of prostate specific antigen.
25 14. Permit any individual covered under the plan direct access to the health care services of a
26 participating specialist (i) authorized to provide services under the plan and (ii) selected by the
27 covered individual. The plan shall have a procedure by which an individual who has an ongoing
28 special condition may, after consultation with the primary care physician, receive a referral to a
29 specialist for such condition who shall be responsible for and capable of providing and coordinating
30 the individual's primary and specialty care related to the initial specialty care referral. If such an
31 individual's care would most appropriately be coordinated by such a specialist, the plan shall refer the
32 individual to a specialist. For the purposes of this subdivision, "special condition" means a condition
33 or disease that is (i) life-threatening, degenerative, or disabling and (ii) requires specialized medical
34 care over a prolonged period of time. Within the treatment period authorized by the referral, such
35 specialist shall be permitted to treat the individual without a further referral from the individual's
36 primary care provider and may authorize such referrals, procedures, tests, and other medical services
37 related to the initial referral as the individual's primary care provider would otherwise be permitted to
38 provide or authorize. The plan shall have a procedure by which an individual who has an ongoing
39 special condition that requires ongoing care from a specialist may receive a standing referral to such
40 specialist for the treatment of the special condition. If the primary care provider, in consultation with
41 the plan and the specialist, if any, determines that such a standing referral is appropriate, the plan or
42 issuer shall make such a referral to a specialist. Nothing contained herein shall prohibit the plan from
43 requiring a participating specialist to provide written notification to the covered individual's primary
44 care physician of any visit to such specialist. Such notification may include a description of the health
45 care services rendered at the time of the visit.
46 15. a. Include provisions allowing employees to continue receiving health care services for a
47 period of up to ninety days from the date of the primary care physician's notice of termination from
48 any of the plan's provider panels.
49 b. The plan shall notify any provider at least ninety days prior to the date of termination of the
50 provider, except when the provider is terminated for cause.
51 c. For a period of at least ninety days from the date of the notice of a provider's termination from
52 any of the plan's provider panels, except when a provider is terminated for cause, a provider shall be
53 permitted by the plan to render health care services to any of the covered employees who (i) were in
54 an active course of treatment from the provider prior to the notice of termination and (ii) request to

1 continue receiving health care services from the provider.
2 d. Notwithstanding the provisions of clause a, any provider shall be permitted by the plan to
3 continue rendering health services to any covered employee who has entered the second trimester of
4 pregnancy at the time of the provider's termination of participation, except when a provider is
5 terminated for cause. Such treatment shall, at the covered employee's option, continue through the
6 provision of postpartum care directly related to the delivery.
7 e. Notwithstanding the provisions of clause a, any provider shall be permitted by the plan to
8 continue rendering health services to any covered employee who is determined to be terminally ill (as
9 defined under § 1861 (dd) (3) (A) of the Social Security Act) at the time of a provider's termination
10 of participation, except when a provider is terminated for cause. Such treatment shall, at the covered
11 employee's option, continue for the remainder of the employee's life for care directly related to the
12 treatment of the terminal illness.
13 f. A provider who continues to render health care services pursuant to this subdivision shall be
14 reimbursed in accordance with the carrier's agreement with such provider existing immediately before
15 the provider's termination of participation.
16 16. a. Include coverage for patient costs incurred during participation in clinical trials for treatment
17 studies on cancer, including ovarian cancer trials.
18 b. The reimbursement for patient costs incurred during participation in clinical trials for treatment
19 studies on cancer shall be determined in the same manner as reimbursement is determined for other
20 medical and surgical procedures. Such coverage shall have durational limits, dollar limits, deductibles,
21 copayments and coinsurance factors that are no less favorable than for physical illness generally.
22 c. For purposes of this subdivision:
23 "Cooperative group" means a formal network of facilities that collaborate on research projects and
24 have an established NIH-approved peer review program operating within the group. "Cooperative
25 group" includes (i) the National Cancer Institute Clinical Cooperative Group and (ii) the National
26 Cancer Institute Community Clinical Oncology Program.
27 "FDA" means the Federal Food and Drug Administration.
28 "Multiple project assurance contract" means a contract between an institution and the federal
29 Department of Health and Human Services that defines the relationship of the institution to the federal
30 Department of Health and Human Services and sets out the responsibilities of the institution and the
31 procedures that will be used by the institution to protect human subjects.
32 "NCI" means the National Cancer Institute.
33 "NIH" means the National Institutes of Health.
34 "Patient" means a person covered under the plan established pursuant to this section.
35 "Patient cost" means the cost of a medically necessary health care service that is incurred as a
36 result of the treatment being provided to a patient for purposes of a clinical trial. "Patient cost" does
37 not include (i) the cost of nonhealth care services that a patient may be required to receive as a result
38 of the treatment being provided for purposes of a clinical trial, (ii) costs associated with managing the
39 research associated with the clinical trial, or (iii) the cost of the investigational drug or device.
40 d. Coverage for patient costs incurred during clinical trials for treatment studies on cancer shall be
41 provided if the treatment is being conducted in a Phase II, Phase III, or Phase IV clinical trial. Such
42 treatment may, however, be provided on a case-by-case basis if the treatment is being provided in a
43 Phase I clinical trial.
44 e. The treatment described in clause d shall be provided by a clinical trial approved by:
45 (1) The National Cancer Institute;
46 (2) An NCI cooperative group or an NCI center;
47 (3) The FDA in the form of an investigational new drug application;
48 (4) The federal Department of Veterans Affairs; or
49 (5) An institutional review board of an institution in the Commonwealth that has a multiple project
50 assurance contract approved by the Office of Protection from Research Risks of the NCI.
51 f. The facility and personnel providing the treatment shall be capable of doing so by virtue of their
52 experience, training, and expertise.
53 g. Coverage under this section shall apply only if:
54 (1) There is no clearly superior, noninvestigational treatment alternative;

1 (2) The available clinical or preclinical data provide a reasonable expectation that the treatment
2 will be at least as effective as the noninvestigational alternative; and
3 (3) The patient and the physician or health care provider who provides services to the patient
4 under the plan conclude that the patient's participation in the clinical trial would be appropriate,
5 pursuant to procedures established by the plan.
6 17. Include coverage providing a minimum stay in the hospital of not less than twenty-three hours
7 for a covered employee following a laparoscopy-assisted vaginal hysterectomy and forty-eight hours
8 for a covered employee following a vaginal hysterectomy, as outlined in Milliman & Robertson's
9 nationally recognized guidelines. Nothing in this subdivision shall be construed as requiring the
10 provision of the total hours referenced when the attending physician, in consultation with the covered
11 employee, determines that a shorter hospital stay is appropriate.
12 18. (Effective until July 1, 2004) a. Include coverage for biologically based mental illness.
13 b. For purposes of this subdivision, a "biologically based mental illness" is any mental or nervous
14 condition caused by a biological disorder of the brain that results in a clinically significant syndrome
15 that substantially limits the person's functioning; specifically, the following diagnoses are defined as
16 biologically based mental illness as they apply to adults and children: schizophrenia, schizoaffective
17 disorder, bipolar disorder, major depressive disorder, panic disorder, obsessive-compulsive disorder,
18 attention deficit hyperactivity disorder, autism, and drug and alcoholism addiction.
19 c. Coverage for biologically based mental illnesses shall neither be different nor separate from
20 coverage for any other illness, condition or disorder for purposes of determining deductibles, benefit
21 year or lifetime durational limits, benefit year or lifetime dollar limits, lifetime episodes or treatment
22 limits, copayment and coinsurance factors, and benefit year maximum for deductibles and copayment
23 and coinsurance factors. *Such coverage shall include speech and language therapy, occupational*
24 *therapy, physical therapy and related therapies relevant to the treatment of these illnesses whether or*
25 *not they effect a cure.*
26 d. Nothing shall preclude the undertaking of usual and customary procedures to determine the
27 appropriateness of, and medical necessity for, treatment of biologically based mental illnesses under
28 this option, provided that all such appropriateness and medical necessity determinations are made in
29 the same manner as those determinations made for the treatment of any other illness, condition or
30 disorder covered by such policy or contract.
31 e. In no case, however, shall coverage for mental disorders provided pursuant to this section be
32 diminished or reduced below the coverage in effect for such disorders on January 1, 1999.
33 C. Claims incurred during a fiscal year but not reported during that fiscal year shall be paid from
34 such funds as shall be appropriated by law. Appropriations, premiums and other payments shall be
35 deposited in the employee health insurance fund, from which payments for claims, premiums, cost
36 containment programs and administrative expenses shall be withdrawn from time to time. The funds
37 of the health insurance fund shall be deemed separate and independent trust funds, shall be segregated
38 from all other funds of the Commonwealth, and shall be invested and administered solely in the
39 interests of the employees and beneficiaries thereof. Neither the General Assembly nor any public
40 officer, employee, or agency shall use or authorize the use of such trust funds for any purpose other
41 than as provided in law for benefits, refunds, and administrative expenses, including but not limited to
42 legislative oversight of the health insurance fund.
43 D. For the purposes of this section:
44 "Peer-reviewed medical literature" means a scientific study published only after having been
45 critically reviewed for scientific accuracy, validity, and reliability by unbiased independent experts in
46 a journal that has been determined by the International Committee of Medical Journal Editors to have
47 met the Uniform Requirements for Manuscripts submitted to biomedical journals. Peer-reviewed
48 medical literature does not include publications or supplements to publications that are sponsored to a
49 significant extent by a pharmaceutical manufacturing company or health carrier.
50 "Standard reference compendia" means the American Medical Association Drug Evaluations, the
51 American Hospital Formulary Service Drug Information, or the United States Pharmacopoeia
52 Dispensing Information.
53 "State employee" means state employee as defined in § 51.1-124.3, employee as defined in
54 § 51.1-201, the Governor, Lieutenant Governor and Attorney General, judge as defined in § 51.1-301

1 and judges, clerks and deputy clerks of regional juvenile and domestic relations, county juvenile and
2 domestic relations, and district courts of the Commonwealth, interns and residents employed by the
3 School of Medicine and Hospital of the University of Virginia, and interns, residents, and employees
4 of the Medical College of Virginia Hospitals Authority as provided in § 23-50.16:24.
5 E. Provisions shall be made for retired employees to obtain coverage under the above plan. The
6 Commonwealth may, but shall not be obligated to, pay all or any portion of the cost thereof.
7 F. Any self-insured group health insurance plan established by the Department of Personnel and
8 Training which utilizes a network of preferred providers shall not exclude any physician solely on the
9 basis of a reprimand or censure from the Board of Medicine, so long as the physician otherwise meets
10 the plan criteria established by the Department.
11 G. The plan established by the Department shall include, in each planning district, at least two
12 health coverage options, each sponsored by unrelated entities. In each planning district that does not
13 have an available health coverage alternative, the Department shall voluntarily enter into negotiations
14 at any time with any health coverage provider who seeks to provide coverage under the plan. This
15 section shall not apply to any state agency authorized by the Department to establish and administer
16 its own health insurance coverage plan separate from the plan established by the Department.
17 H. 1. Any self-insured group health insurance plan established by the Department of Personnel that
18 includes coverage for prescription drugs on an outpatient basis may apply a formulary to the
19 prescription drug benefits provided by the plan if the formulary is developed, reviewed at least
20 annually, and updated as necessary in consultation with and with the approval of a pharmacy and
21 therapeutics committee, a majority of whose members are actively practicing licensed (i) pharmacists,
22 (ii) physicians, and (iii) other health care providers.
23 2. If the plan maintains one or more drug formularies, the plan shall establish a process to allow a
24 person to obtain, without additional cost-sharing beyond that provided for formulary prescription drugs
25 in the plan, a specific, medically necessary nonformulary prescription drug if, after reasonable
26 investigation and consultation with the prescribing physician, the formulary drug is determined to be
27 an inappropriate therapy for the medical condition of the person. The plan shall act on such requests
28 within one business day of receipt of the request.
29 I. Any plan established by the Department of Personnel and Training requiring preauthorization
30 prior to rendering medical treatment shall have personnel available to provide authorization at all
31 times when such preauthorization is required.
32 J. Any plan established by the Department of Personnel and Training shall provide to all covered
33 employees written notice of any benefit reductions during the contract period at least thirty days
34 before such reductions become effective.
35 K. No contract between a provider and any plan established by the Department of Personnel and
36 Training shall include provisions which require a health care provider or health care provider group to
37 deny covered services that such provider or group knows to be medically necessary and appropriate
38 that are provided with respect to a covered employee with similar medical conditions.
39 L. 1. The Department of Personnel and Training shall appoint an Ombudsman to promote and
40 protect the interests of covered employees under any state employee's health plan.
41 2. The Ombudsman shall:
42 a. Assist covered employees in understanding their rights and the processes available to them
43 according to their state health plan.
44 b. Answer inquiries from covered employees by telephone and electronic mail.
45 c. Provide to covered employees information concerning the state health plans.
46 d. Develop information on the types of health plans available, including benefits and complaint
47 procedures and appeals.
48 e. Make available, either separately or through an existing Internet web site utilized by the
49 Department of Personnel and Training, information as set forth in clause d and such additional
50 information as he deems appropriate.
51 f. Maintain data on inquiries received, the types of assistance requested, any actions taken and the
52 disposition of each such matter.
53 g. Upon request, assist covered employees in using the procedures and processes available to them
54 from their health plan, including all appeal procedures. Such assistance may require the review of

1 health care records of a covered employee, which shall be done only with that employee's express
2 written consent. The confidentiality of any such medical records shall be maintained in accordance
3 with the confidentiality and disclosure laws of the Commonwealth.
4 h. Ensure that covered employees have access to the services provided by the Ombudsman and
5 that the covered employees receive timely responses from the Ombudsman or his representatives to
6 the inquiries.
7 i. Report annually on his activities to the standing committees of the General Assembly having
8 jurisdiction over insurance and over health and the Joint Commission on Health Care by December 1
9 of each year.
10 M. 1. The plan established by the Department of Personnel and Training shall not refuse to accept
11 or make reimbursement pursuant to an assignment of benefits made to a dentist or oral surgeon by a
12 covered employee.
13 2. For purposes of this subsection, "assignment of benefits" means the transfer of dental care
14 coverage reimbursement benefits or other rights under the plan. The assignment of benefits shall not
15 be effective until the covered employee notifies the plan in writing of the assignment.
16 § 38.2-3412.1:01. (Effective until July 1, 2004) Coverage for biologically based mental illness.
17 A. Notwithstanding the provisions of § 38.2-3419, each insurer proposing to issue individual or
18 group accident and sickness insurance policies providing hospital, medical and surgical, or major
19 medical coverage on an expense-incurred basis; each corporation providing individual or group
20 accident and sickness subscription contracts; and each health maintenance organization providing a
21 health care plan for health care services shall provide coverage for biologically based mental illnesses.
22 B. Benefits for biologically based mental illnesses may be different from benefits for other
23 illnesses, conditions or disorders if such benefits meet the medical criteria necessary to achieve the
24 same outcomes as are achieved by the benefits for any other illness, condition or disorder that is
25 covered by such policy or contract.
26 C. Coverage for biologically based mental illnesses shall neither be different nor separate from
27 coverage for any other illness, condition or disorder for purposes of determining deductibles, benefit
28 year or lifetime durational limits, benefit year or lifetime dollar limits, lifetime episodes or treatment
29 limits, copayment and coinsurance factors, and benefit year maximum for deductibles and copayment
30 and coinsurance factors. *Such coverage shall include speech and language therapy, occupational*
31 *therapy, physical therapy and related therapies relevant to the treatment of these illnesses whether or*
32 *not they effect a cure.*
33 D. Nothing shall preclude the undertaking of usual and customary procedures to determine the
34 appropriateness of, and medical necessity for, treatment of biologically based mental illnesses under
35 this option, provided that all such appropriateness and medical necessity determinations are made in
36 the same manner as those determinations made for the treatment of any other illness, condition or
37 disorder covered by such policy or contract.
38 E. For purposes of this section, a "biologically based mental illness" is any mental or nervous
39 condition caused by a biological disorder of the brain that results in a clinically significant syndrome
40 that substantially limits the person's functioning; specifically, the following diagnoses are defined as
41 biologically based mental illness as they apply to adults and children: schizophrenia, schizoaffective
42 disorder, bipolar disorder, major depressive disorder, panic disorder, obsessive-compulsive disorder,
43 attention deficit hyperactivity disorder, autism, and drug and alcoholism addiction.
44 F. The provisions of this section shall not apply to (i) short-term travel, accident only, limited or
45 specified disease policies, (ii) short-term nonrenewable policies of not more than six months' duration,
46 (iii) policies, contracts, or plans issued in the individual market or small group markets to employers
47 with 25 or fewer employees, or (iv) policies or contracts designed for issuance to persons eligible for
48 coverage under Title XVIII of the Social Security Act, known as Medicare, or any other similar
49 coverage under state or federal governmental plans.

APPENDIX A-2

summary | pdf

SENATE BILL NO. 165

AMENDMENT IN THE NATURE OF A SUBSTITUTE

A BILL to amend and reenact §§ 2.1-20.1 and 38.2-3418.5 of the Code of Virginia, relating to coverage for biologically based mental illness; coverage for speech, occupational, physical and related therapies.

Patrons-- Edwards and Puller

Referred to Committee on Commerce and Labor

Be it enacted by the General Assembly of Virginia:

1. That §§ 2.1-20.1 and 38.2-3412.1:01 of the Code of Virginia are amended and reenacted as follows:

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

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

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

B. The plan shall:

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

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

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

(2) The equipment used to perform the mammogram shall meet the standards set forth by the Virginia Department of Health in its radiation protection regulations; and
(3) The mammography film shall be retained by the radiologic facility performing the examination in accordance with the American College of Radiology guidelines or state law.
2. Include coverage for the treatment of breast cancer by dose-intensive chemotherapy with autologous bone marrow transplants or stem cell support when performed at a clinical program authorized to provide such therapies as a part of clinical trials sponsored by the National Cancer Institute. For persons previously covered under the plan, there shall be no denial of coverage due to the existence of a preexisting condition.
3. Include coverage for postpartum services providing inpatient care and a home visit or visits which shall be in accordance with the medical criteria outlined in the most current version of or an official update to the "Guidelines for Perinatal Care" prepared by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists or the "Standards for Obstetric-Gynecologic Services" prepared by the American College of Obstetricians and Gynecologists. Such coverage shall be provided incorporating any changes in such Guidelines or Standards within six months of the publication of such Guidelines or Standards or any official amendment thereto.
4. a. Include an appeals process for resolution of written complaints concerning denials or partial denials of claims that shall provide reasonable procedures for resolution of such written complaints and shall be published and disseminated to all covered state employees. Such appeals process shall include a separate expedited emergency appeals procedure which shall provide resolution within one business day of receipt of a complaint concerning situations requiring immediate medical care. For appeals involving adverse decisions as defined in § 32.1-137.7, the Department shall contract with one or more impartial health entities to review such decisions. Impartial health entities may include medical peer review organizations and independent utilization review companies. The Department shall adopt regulations to assure that the impartial health entity conducting the reviews has adequate standards, credentials and experience for such review. The impartial health entity shall examine the final denial of claims to determine whether the decision is objective, clinically valid, and compatible with established principles of health care. The decision of the impartial health entity shall (i) be in writing, (ii) contain findings of fact as to the material issues in the case and the basis for those findings, and (iii) be final and binding if consistent with law and policy.
b. Prior to assigning an appeal to an impartial health entity, the Department shall verify that the impartial health entity conducting the review of a denial of claims has no relationship or association with (i) the covered employee, (ii) the treating health care provider, or any of its employees or affiliates, (iii) the medical care facility at which the covered service would be provided, or any of its employees or affiliates, or (iv) the development or manufacture of the drug, device, procedure or other therapy which is the subject of the final denial of a claim. The impartial health entity shall not be a subsidiary of, nor owned or controlled by, a health plan, a trade association of health plans, or a professional association of health care providers. There shall be no liability on the part of and no cause of action shall arise against any officer or employee of an impartial health entity for any actions taken or not taken or statements made by such officer or employee in good faith in the performance of his powers and duties.
5. Include coverage for early intervention services. For purposes of this section, "early intervention services" means medically necessary speech and language therapy, occupational therapy, physical therapy and assistive technology services and devices for dependents from

birth to age three who are certified by the Department of Mental Health, Mental Retardation and Substance Abuse Services as eligible for services under Part H of the Individuals with Disabilities Education Act (20 U.S.C. § 1471 et seq.); and children ages three through 12 with diagnosed developmental disabilities. Medically necessary early intervention services for the population certified by the Department of Mental Health, Mental Retardation and Substance Abuse Services shall mean those services designed to help an individual attain or retain the capability to function age-appropriately within his environment, and shall include services which enhance functional ability without effecting a cure.

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

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

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

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

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

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

11. Include coverage for annual pap smears, including coverage, on and after July 1, 1999, for annual testing performed by any FDA-approved gynecologic cytology screening technologies.

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

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

this subdivision, "PSA testing" means the analysis of a blood sample to determine the level of prostate specific antigen.

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

15. a. Include provisions allowing employees to continue receiving health care services for a period of up to ninety days from the date of the primary care physician's notice of termination from any of the plan's provider panels.

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

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

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

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

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

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

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

c. For purposes of this subdivision:

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

"FDA" means the Federal Food and Drug Administration.

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

"NCI" means the National Cancer Institute.

"NIH" means the National Institutes of Health.

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

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

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

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

(1) The National Cancer Institute;

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

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

(4) The federal Department of Veterans Affairs; or

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

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

g. Coverage under this section shall apply only if:

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

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

(3) The patient and the physician or health care provider who provides services to the patient under the plan conclude that the patient's participation in the clinical trial would be appropriate, pursuant to procedures established by the plan.
17. Include coverage providing a minimum stay in the hospital of not less than twenty-three hours for a covered employee following a laparoscopy-assisted vaginal hysterectomy and forty-eight hours for a covered employee following a vaginal hysterectomy, as outlined in Milliman & Robertson's nationally recognized guidelines. Nothing in this subdivision shall be construed as requiring the provision of the total hours referenced when the attending physician, in consultation with the covered employee, determines that a shorter hospital stay is appropriate.
18. (Effective until July 1, 2004) a. Include coverage for biologically based mental illness.
b. For purposes of this subdivision, a "biologically based mental illness" is any mental or nervous condition caused by a biological disorder of the brain that results in a clinically significant syndrome that substantially limits the person's functioning; specifically, the following diagnoses are defined as biologically based mental illness as they apply to adults and children: schizophrenia, schizoaffective disorder, bipolar disorder, major depressive disorder, panic disorder, obsessive-compulsive disorder, attention deficit hyperactivity disorder, autism, and drug and alcoholism addiction.
c. Coverage for biologically based mental illnesses shall neither be different nor separate from coverage for any other illness, condition or disorder for purposes of determining deductibles, benefit year or lifetime durational limits, benefit year or lifetime dollar limits, lifetime episodes or treatment limits, copayment and coinsurance factors, and benefit year maximum for deductibles and copayment and coinsurance factors. Nothing shall preclude the undertaking of usual and customary procedures to determine the appropriateness of, and medical necessity for, treatment of biologically based mental illnesses under this option, provided that all such appropriateness and medical necessity determinations are made in the same manner as those determinations made for the treatment of any other illness, condition or disorder covered by such policy or contract.
e. In no case, however, shall coverage for mental disorders provided pursuant to this section be diminished or reduced below the coverage in effect for such disorders on January 1, 1999.
C. Claims incurred during a fiscal year but not reported during that fiscal year shall be paid from such funds as shall be appropriated by law. Appropriations, premiums and other payments shall be deposited in the employee health insurance fund, from which payments for claims, premiums, cost containment programs and administrative expenses shall be withdrawn from time to time. The funds of the health insurance fund shall be deemed separate and independent trust funds, shall be segregated from all other funds of the Commonwealth, and shall be invested and administered solely in the interests of the employees and beneficiaries thereof. Neither the General Assembly nor any public officer, employee, or agency shall use or authorize the use of such trust funds for any purpose other than as provided in law for benefits, refunds, and administrative expenses, including but not limited to legislative oversight of the health insurance fund.
D. For the purposes of this section:
"Peer-reviewed medical literature" means a scientific study published only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased independent experts in a journal that has been determined by the International Committee of Medical Journal Editors to have met the Uniform Requirements for Manuscripts submitted to biomedical journals. Peer-reviewed medical literature does not include publications or supplements to

publications that are sponsored to a significant extent by a pharmaceutical manufacturing company or health carrier.

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

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

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

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

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

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

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

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

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

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

appropriate that are provided with respect to a covered employee with similar medical conditions.

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

2. The Ombudsman shall:

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

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

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

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

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

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

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

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

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

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

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

§ 38.2-3418.5. Coverage for early intervention services. A. Notwithstanding the provisions of § 38.2-3419, each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; each corporation providing individual or group accident and sickness subscription contracts; and each health maintenance organization providing a health care plan for health care services shall provide coverage for medically necessary early intervention services under such policy, contract or plan delivered, issued for delivery or renewed in this Commonwealth on and after July 1, 1998. Such coverage shall be limited to a benefit of $5,000 per insured or member per policy or calendar year and, except as set forth in subsection C, shall be subject to such dollar limits, deductibles and coinsurance factors as are no less favorable than for physical illness generally.

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

C. The cost of early intervention services for children birth to age three who are certified by the Department of Mental Health, Mental Retardation and Substance Abuse Services shall not be applied to any contractual provision limiting the total amount of coverage paid by the insurer, corporation or health maintenance organization to or on behalf of the insured or member during the insured's or member's lifetime.

D. "Financial costs," as used in this section, shall mean any copayment, coinsurance, or deductible in the policy or plan for children birth to age three who are certified by the Department of Mental Health, Mental Retardation and Substance Abuse Services. Financial costs may be paid through the use of federal Part H program funds, state general funds, or local government funds appropriated to implement Part H services for families who may refuse the use of their insurance to pay for early intervention services due to a financial cost.

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