WEST VIRGINIA LEGISLATURE

FIRST REGULAR SESSION, 2003

ENROLLED

COMMITTEE SUBSTITUTE FOR House Bill No. 2675

(By Delegates Beane, Amores, Campbell, Craig, Mahan, Michael and Webster)

Passed March 8, 2003

In Effect Ninety Days from Passage

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COMMITTEE SUBSTITUTE

FOR

H. B. 2675

(BY DELEGATES BEANE, AMORES, CAMPBELL,
CRAIG, MAHAN, MICHAEL AND WEBSTER)

[Passed March 8, 2003; in effect ninety days from passage.]

AN ACT to amend article sixteen, chapter five of the code of West Virginia, one thousand nine hundred thirty-one, as amended, by adding thereto two new sections, designated sections seven-d and seven-e; to amend article sixteen-b of said chapter by adding thereto two new sections, designated sections six-a and six-b; to amend article two, chapter nine of said code by adding thereto two new sections, designated sections twelve and twelve-a; to amend article fifteen, chapter thirty-three of said code be by adding thereto a new section, designated section four-h; to amend article sixteen of said chapter by adding thereto a new section, designated section three-q; to amend article twenty-four of said chapter by adding thereto a new section, designated section four-a; to amend and reenact section six, article twenty-five of said chapter; to amend article twenty-five-a of said chapter by adding thereto a new section, designated section twenty-four-a; and to

further amend said chapter by adding thereto a new article, designated article twenty-five-f, all relating to mandating coverage for certain clinical trials under public employees insurance, children's health program, medicaid program, accident and sickness insurance, groups accident and sickness insurance, hospital service corporations, medical service corporations, dental service corporations, health service corporations, healthcare corporations and health maintenance organizations.

Be it enacted by the Legislature of West Virginia:

That article sixteen, chapter five of the code of West Virginia, one thousand nine hundred thirty-one, as amended, be amended by adding thereto two new sections, designated sections seven-d and seven-e; that article sixteen-b of said chapter be amended by adding thereto two new sections, designated sections six-a and six-b; that article two, chapter nine of said code be amended by adding thereto two new sections, designated sections twelve and twelve-a; that article fifteen, chapter thirty-three of said code be amended by adding thereto a new section, designated section four-h; that article sixteen of said chapter be amended by adding thereto a new section, designated section three-q; that article twenty-four of said chapter be amended by adding thereto a new section, designated four-a; that section six, article twenty-five of said chapter be amended and reenacted; that article twenty-five-a of said chapter be amended by adding thereto a new section, designated section twenty-four-a; and that said chapter be further amended by adding thereto a new article, designated article twenty-five-f, all to read as follows:

CHAPTER 5. GENERAL POWERS AND AUTHORITY OF THE GOVERNOR, SECRETARY OF STATE AND ATTORNEY GENERAL; BOARD OF PUBLIC WORKS; MISCELLANEOUS AGENCIES, COMMISSIONS, OFFICES, PROGRAMS, ETC.

ARTICLE 16. WEST VIRGINIA PUBLIC EMPLOYEES INSURANCE ACT.

§5-16-7d. Coverage for patient cost of clinical trials.

(a) The provisions of this section and section seven-e of this article apply to the health plans regulated by this article.

(b) This section does not apply to a policy, plan or contract paid for under Title XVIII of the Social Security Act.

(c) A policy, plan or contract subject to this section shall provide coverage for patient cost to a member in a clinical trial, as a result of:

(1) Treatment provided for a life-threatening condition; or

(2) Prevention of, early detection of or treatment studies on cancer.

(d) The coverage under subsection (c) of this section is required if:

(1)(A) The treatment is being provided or the studies are being conducted in a Phase II, Phase III or Phase IV clinical trial for cancer and has therapeutic intent; or

(B) The treatment is being provided in a Phase II, Phase III or Phase IV clinical trial for any other life-threatening condition and has therapeutic intent;

(2) The treatment is being provided in a clinical trial approved by:

(A) One of the national institutes of health;

(B) An NIH cooperative group or an NIH center;

(C) The FDA in the form of an investigational new drug application or investigational device exemption;

(D) The federal department of veterans affairs; or

(E) An institutional review board of an institution in the state which has a multiple project assurance contract approved by the office of protection from research risks of the national institutes of health;

(3) The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training and volume of patients treated to maintain expertise;

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

(5) The available clinical or preclinical data provide a reasonable expectation that the treatment will be more effective than the noninvestigational treatment alternative;

(6) The treatment is provided in this state: *Provided*, That, if the treatment is provided outside of this state, the treatment must be approved by the payor designated in subsection (a) of this section;

(7) Reimbursement for treatment is subject to all coinsurance, copayment and deductibles and is otherwise subject to all restrictions and obligations of the health plan; and

(8) Reimbursement for treatment by an out of network or noncontracting provider shall be reimbursed at a rate which is no greater than that provided by an in network or contracting provider. Coverage shall not be required if the out of network or noncontracting provider will not accept this level of reimbursement.

(e) Payment for patient costs for a clinical trial is not required by the provisions of this section, if:

(1) The purpose of the clinical trial is designed to extend the patent of any existing drug, to gain approval or coverage of a metabolite of an existing drug, or to gain approval or coverage relating to additional clinical indications for an existing drug; or

(2) The purpose of the clinical trial is designed to keep a generic version of a drug from becoming available on the market; or

(3) The purpose of the clinical trial is to gain approval of or coverage for a reformulated or repackaged version of an existing drug.

(f) Any provider billing a third party payor for services or products provided to a patient in a clinical trial shall provide written notice to the payor that specifically identifies the services as part of a clinical trial.

(g) Notwithstanding any provision in this section to the contrary, coverage is not required for Phase I of any clinical trial.

§5-16-7e. Definitions.

For purposes of section seven-d of this article:

(a) A "clinical trial" is a study that determines whether new drugs, treatments or medical procedures are safe and effective on humans. To determine the efficacy of experimental drugs, treatments or procedures, a study is conducted in four phases including the following:

Phase II: The experimental drug or treatment is given to, or a procedure is performed on, a larger group of people to further measure its effectiveness and safety.

Phase III: Further research is conducted to confirm the effectiveness of the drug, treatment or procedure, to monitor the side effects, to compare commonly used treatments and to collect information on safe use.

Phase IV: After the drug, treatment or medical procedure is marketed, investigators continue testing to determine the effects on various populations and to determine whether there are side effects associated with long-term use.

(b) "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.

(c) "Cooperative group" includes:

(1) The national cancer institute clinical cooperative group;

(2) The national cancer institute community clinical oncology program;

(3) The AIDS clinical trial group; and

(4) The community programs for clinical research in AIDS.

(d) "FDA" means the federal food and drug administration.

(e) "Life-threatening condition" means that the member has a terminal condition or illness that according to current diagnosis has a high probability of death within two years, even with treatment with an existing generally accepted treatment protocol.

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

(g) "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.

(h) "NIH" means the national institutes of health.

(i) "Patient cost" means the routine costs of a medically necessary health care service that is incurred by a member as a result of the treatment being provided pursuant to the protocols of the clinical trial. Routine costs of a clinical trial include all items or services that are otherwise generally available to beneficiaries of the insurance policies. "Patient cost" does not include:

(1) The cost of the investigational drug or device;

(2) The cost of nonhealth care services that a patient may be required to receive as a result of the treatment being provided to the member for purposes of the clinical trial;

(3) Services customarily provided by the research sponsor free of charge for any participant in the trial;

(4) Costs associated with managing the research associated with the clinical trial, including but not limited to, services furnished to satisfy data collection and analysis needs that are not used in the direct clinical management of the participant; or

(5) Costs that would not be covered under the participant's policy, plan, or contract for noninvestigational treatments;

(6) Adverse events during treatment are divided into those that reflect the natural history of the disease, or its progression, and those that are unique in the experimental treatment. Costs

for the former are the responsibility of the payor as provided in section two of this article, and costs for the later are the responsibility of the sponsor. The sponsor shall hold harmless any payor for any losses and injuries sustained by any member as a result of his or her participation in the clinical trial.

ARTICLE 16B. WEST VIRGINIA CHILDREN'S HEALTH PROGRAM.

§5-16B-6a. Coverage for patient cost of clinical trials.

(a) The provisions of this section and section six-b of this article apply to the health plans regulated by this article.

(b) This section does not apply to a policy, plan or contract paid for under Title XVIII of the Social Security Act.

(c) A policy, plan or contract subject to this section shall provide coverage for patient cost to a member in a clinical trial, as a result of:

(1) Treatment provided for a life-threatening condition; or

(2) Prevention of, early detection of or treatment studies on cancer.

(d) The coverage under subsection (c) of this section is required if:

(1)(A) The treatment is being provided or the studies are being conducted in a Phase II, Phase III or Phase IV clinical trial for cancer and has therapeutic intent; or

(B) The treatment is being provided in a Phase II, Phase III or Phase IV clinical trial for any other life-threatening condition and has therapeutic intent;

(2) The treatment is being provided in a clinical trial approved by:

(A) One of the national institutes of health;

(B) An NIH cooperative group or an NIH center;

(C) The FDA in the form of an investigational new drug application or investigational device exemption;

(D) The federal department of veterans affairs; or

(E) An institutional review board of an institution in the state which has a multiple project assurance contract approved by the office of protection from research risks of the national institutes of health;

(3) The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training and volume of patients treated to maintain expertise;

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

(5) The available clinical or preclinical data provide a reasonable expectation that the treatment will be more effective than the noninvestigational treatment alternative;

(6) The treatment is provided in this state: *Provided*, That, if the treatment is provided outside of this state, the treatment must be approved by the payor designated in subsection (a) of this section;

(7) Reimbursement for treatment is subject to all coinsurance, copayment and deductibles and is otherwise subject to all restrictions and obligations of the health plan; and

(8) Reimbursement for treatment by an out of network or noncontracting provider shall be reimbursed at a rate which is no greater than that provided by an in network or contracting provider. Coverage shall not be required if the out of network

or noncontracting provider will not accept this level of reimbursement.

(e) Payment for patient costs for a clinical trial is not required by the provisions of this section, if:

(1) The purpose of the clinical trial is designed to extend the patent of any existing drug, to gain approval or coverage of a metabolite of an existing drug, or to gain approval or coverage relating to additional clinical indications for an existing drug; or

(2) The purpose of the clinical trial is designed to keep a generic version of a drug from becoming available on the market; or

(3) The purpose of the clinical trial is to gain approval of or coverage for a reformulated or repackaged version of an existing drug.

(f) Any provider billing a third party payor for services or products provided to a patient in a clinical trial shall provide written notice to the payor that specifically identifies the services as part of a clinical trial.

(g) Notwithstanding any provision in this section to the contrary, coverage is not required for Phase I of any clinical trial.

§5-16B-6b. Definitions.

For purposes of section six-a of this article:

(a) A "clinical trial" is a study that determines whether new drugs, treatments or medical procedures are safe and effective on humans. To determine the efficacy of experimental drugs,

treatments or procedures, a study is conducted in four phases including the following:

Phase II: The experimental drug or treatment is given to, or a procedure is performed on, a larger group of people to further measure its effectiveness and safety.

Phase III: Further research is conducted to confirm the effectiveness of the drug, treatment or procedure, to monitor the side effects, to compare commonly used treatments and to collect information on safe use.

Phase IV: After the drug, treatment or medical procedure is marketed, investigators continue testing to determine the effects on various populations and to determine whether there are side effects associated with long-term use.

(b) "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.

(c) "Cooperative group" includes:

(1) The national cancer institute clinical cooperative group;

(2) The national cancer institute community clinical oncology program;

(3) The AIDS clinical trial group; and

(4) The community programs for clinical research in AIDS.

(d) "FDA" means the federal food and drug administration.

(e) "Life-threatening condition" means that the member has a terminal condition or illness that according to current diagnosis has a high probability of death within two years, even with

treatment with an existing generally accepted treatment protocol.

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

(g) "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.

(h) "NIH" means the national institutes of health.

(i) "Patient cost" means the routine costs of a medically necessary health care service that is incurred by a member as a result of the treatment being provided pursuant to the protocols of the clinical trial. Routine costs of a clinical trial include all items or services that are otherwise generally available to beneficiaries of the insurance policies. "Patient cost" does not include:

(1) The cost of the investigational drug or device;

(2) The cost of nonhealth care services that a patient may be required to receive as a result of the treatment being provided to the member for purposes of the clinical trial;

(3) Services customarily provided by the research sponsor free of charge for any participant in the trial;

(4) Costs associated with managing the research associated with the clinical trial, including but not limited to, services furnished to satisfy data collection and analysis needs that are not used in the direct clinical management of the participant; or

(5) Costs that would not be covered under the participant's policy, plan, or contract for noninvestigational treatments;

(6) Adverse events during treatment are divided into those that reflect the natural history of the disease, or its progression, and those that are unique in the experimental treatment. Costs for the former are the responsibility of the payor as provided in section two of this article, and costs for the later are the responsibility of the sponsor. The sponsor shall hold harmless any payor for any losses and injuries sustained by any member as a result of his or her participation in the clinical trial.

CHAPTER 9. HUMAN SERVICES.

ARTICLE 2. DEPARTMENT OF HEALTH AND HUMAN RESOURCES, AND OFFICE OF COMMISSIONER OF HUMAN SERVICES; POWERS, DUTIES AND RESPONSIBILITIES GENERALLY.

§9-2-12. Coverage for patient cost of clinical trials.

(a) The provisions of this section and section twelve-a of this article apply to the health plans regulated by this article.

(b) This section does not apply to a policy, plan or contract paid for under Title XVIII of the Social Security Act.

(c) A policy, plan or contract subject to this section shall provide coverage for patient cost to a member in a clinical trial, as a result of:

(1) Treatment provided for a life-threatening condition; or

(2) Prevention of, early detection of or treatment studies on cancer.

(d) The coverage under subsection (c) of this section is required if:

(1)(A) The treatment is being provided or the studies are being conducted in a Phase II, Phase III or Phase IV clinical trial for cancer and has therapeutic intent; or

(B) The treatment is being provided in a Phase II, Phase III or Phase IV clinical trial for any other life-threatening condition and has therapeutic intent;

(2) The treatment is being provided in a clinical trial approved by:

(A) One of the national institutes of health;

(B) An NIH cooperative group or an NIH center;

(C) The FDA in the form of an investigational new drug application or investigational device exemption;

(D) The federal department of veterans affairs; or

(E) An institutional review board of an institution in the state which has a multiple project assurance contract approved by the office of protection from research risks of the national institutes of health;

(3) The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training and volume of patients treated to maintain expertise;

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

(5) The available clinical or preclinical data provide a reasonable expectation that the treatment will be more effective than the noninvestigational treatment alternative;

(6) The treatment is provided in this state: ***Provided***, That, if the treatment is provided outside of this state, the treatment

must be approved by the payor designated in subsection (a) of this section;

(7) Reimbursement for treatment is subject to all coinsurance, copayment and deductibles and is otherwise subject to all restrictions and obligations of the health plan; and

(8) Reimbursement for treatment by an out of network or noncontracting provider shall be reimbursed at a rate which is no greater than that provided by an in network or contracting provider. Coverage shall not be required if the out of network or noncontracting provider will not accept this level of reimbursement.

(e) Payment for patient costs for a clinical trial is not required by the provisions of this section, if:

(1) The purpose of the clinical trial is designed to extend the patent of any existing drug, to gain approval or coverage of a metabolite of an existing drug, or to gain approval or coverage relating to additional clinical indications for an existing drug; or

(2) The purpose of the clinical trial is designed to keep a generic version of a drug from becoming available on the market; or

(3) The purpose of the clinical trial is to gain approval of or coverage for a reformulated or repackaged version of an existing drug.

(f) Any provider billing a third party payor for services or products provided to a patient in a clinical trial shall provide written notice to the payor that specifically identifies the services as part of a clinical trial.

(g) Notwithstanding any provision in this section to the contrary, coverage is not required for Phase I of any clinical trial.

§9-2-12a. Definitions.

For purposes of section twelve of this article:

(a) A "clinical trial" is a study that determines whether new drugs, treatments or medical procedures are safe and effective on humans. To determine the efficacy of experimental drugs, treatments or procedures, a study is conducted in four phases including the following:

Phase II: The experimental drug or treatment is given to, or a procedure is performed on, a larger group of people to further measure its effectiveness and safety.

Phase III: Further research is conducted to confirm the effectiveness of the drug, treatment or procedure, to monitor the side effects, to compare commonly used treatments and to collect information on safe use.

Phase IV: After the drug, treatment or medical procedure is marketed, investigators continue testing to determine the effects on various populations and to determine whether there are side effects associated with long-term use.

(b) "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.

(c) "Cooperative group" includes:

(1) The national cancer institute clinical cooperative group;

(2) The national cancer institute community clinical oncology program;

(3) The AIDS clinical trial group; and

(4) The community programs for clinical research in AIDS.

(d) "FDA" means the federal food and drug administration.

(e) "Life-threatening condition" means that the member has a terminal condition or illness that according to current diagnosis has a high probability of death within two years, even with treatment with an existing generally accepted treatment protocol.

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

(g) "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.

(h) "NIH" means the national institutes of health.

(i) "Patient cost" means the routine costs of a medically necessary health care service that is incurred by a member as a result of the treatment being provided pursuant to the protocols of the clinical trial. Routine costs of a clinical trial include all items or services that are otherwise generally available to beneficiaries of the insurance policies. "Patient cost" does not include:

(1) The cost of the investigational drug or device;

(2) The cost of nonhealth care services that a patient may be required to receive as a result of the treatment being provided to the member for purposes of the clinical trial;

(3) Services customarily provided by the research sponsor free of charge for any participant in the trial;

(4) Costs associated with managing the research associated with the clinical trial, including but not limited to, services furnished to satisfy data collection and analysis needs that are not used in the direct clinical management of the participant; or

(5) Costs that would not be covered under the participant's policy, plan, or contract for noninvestigational treatments;

(6) Adverse events during treatment are divided into those that reflect the natural history of the disease, or its progression, and those that are unique in the experimental treatment. Costs for the former are the responsibility of the payor as provided in section two of this article, and costs for the later are the responsibility of the sponsor. The sponsor shall hold harmless any payor for any losses and injuries sustained by any member as a result of his or her participation in the clinical trial.

CHAPTER 33. INSURANCE.

ARTICLE 15. ACCIDENT AND SICKNESS INSURANCE.

§33-15-4h. Coverage for patient cost of clinical trials.

The provisions relating to clinical trials established in article twenty-five-f of this chapter shall apply to the individual market regulated by this article.

ARTICLE 16. GROUP ACCIDENT AND SICKNESS INSURANCE.

§33-16-3q. Coverage for patient cost of clinical trials.

The provisions relating to clinical trials established in article twenty-five-f of this chapter shall apply to the health benefit plans regulated by this article.

ARTICLE 24. HOSPITAL SERVICE CORPORATIONS, MEDICAL SERVICE CORPORATIONS, DENTAL SERVICE CORPORATIONS AND HEALTH SERVICE CORPORATIONS.

§33-24-4a. Coverage for patient cost of clinical trials.

The provisions relating to clinical trials established in article twenty-five-f of this chapter shall apply to the insurance regulated by this article.

ARTICLE 25. HEALTH CARE CORPORATIONS.

§33-25-6. Supervision and regulation by insurance commissioner; exemption from insurance laws.

Corporations organized under this article are subject to supervision and regulation of the insurance commissioner. The corporations organized under this article, to the same extent these provisions are applicable to insurers transacting similar kinds of insurance and not inconsistent with the provisions of this article, shall be governed by and be subject to the provisions as hereinbelow indicated of the following articles of this chapter: Article four (general provisions), except that section sixteen of said article shall not be applicable thereto; article six-c (guaranteed loss ratio); article seven (assets and liabilities); article eight (investments); article ten (rehabilitation and liquidation); section two-a, article fifteen (definitions); section two-b, article fifteen (guaranteed issue); section two-d, article fifteen (exception to guaranteed renewability); section two-e, article fifteen (discontinuation of coverage); section two-f, article fifteen (certification of creditable coverage); section two-g, article fifteen (applicability); section four-e, article fifteen (benefits for mothers and newborns); section fourteen, article fifteen (individual accident and sickness insurance);

section sixteen, article fifteen (coverage of children); section eighteen, article fifteen (equal treatment of state agency); section nineteen, article fifteen (coordination of benefits with medicaid); article fifteen-c (diabetes insurance); section three, article sixteen (required policy provisions); section three-a, article sixteen (mental health); section three-j, article sixteen (benefits for mothers and newborns); section three-k, article sixteen (preexisting condition exclusions); section three-l, article sixteen (guaranteed renewability); section three-m, article sixteen (creditable coverage); section three-n, article sixteen (eligibility for enrollment); section eleven, article sixteen (coverage of children); section thirteen, article sixteen (equal treatment of state agency); section fourteen, article sixteen (coordination of benefits with medicaid); section sixteen, article sixteen (diabetes insurance); article sixteen-a (group health insurance conversion); article sixteen-c (small employer group policies); article sixteen-d (marketing and rate practices for small employers); article twenty-five-f (coverage for patient cost of clinical trials); article twenty-six-a (West Virginia life and health insurance guaranty association act); article twenty-seven (insurance holding company systems); article thirty-three (annual audited financial report); article thirty-four-a (standards and commissioner's authority for companies deemed to be in hazardous financial condition); article thirty-five (criminal sanctions for failure to report impairment); article thirty-seven (managing general agents); and article forty-one (privileges and immunity)); and no other provision of this chapter may apply to these corporations unless specifically made applicable by the provisions of this article.

ARTICLE 25A. HEALTH MAINTENANCE ORGANIZATION ACT.

§33-25A-24a. Coverage for patient cost of clinical trials.

The provisions relating to clinical trials established in article twenty-five-f of this chapter shall apply to the insurance regulated by this article.

ARTICLE 25F. COVERAGE FOR PATIENT COST OF CLINICAL TRIALS.

§33-25F-1. Definitions.

For purposes of this article:

(a) A "clinical trial" is a study that determines whether new drugs, treatments or medical procedures are safe and effective on humans. To determine the efficacy of experimental drugs, treatments or procedures, a study is conducted in four phases including the following:

Phase II: The experimental drug or treatment is given to, or a procedure is performed on, a larger group of people to further measure its effectiveness and safety.

Phase III: Further research is conducted to confirm the effectiveness of the drug, treatment or procedure, to monitor the side effects, to compare commonly used treatments and to collect information on safe use.

Phase IV: After the drug, treatment or medical procedure is marketed, investigators continue testing to determine the effects on various populations and to determine whether there are side effects associated with long-term use.

(b) "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.

(c) "Cooperative group" includes:

(1) The national cancer institute clinical cooperative group;

(2) The national cancer institute community clinical oncology program;

(3) The AIDS clinical trial group; and

(4) The community programs for clinical research in AIDS.

(d) "FDA" means the federal food and drug administration.

(e) "Life-threatening condition" means that the member has a terminal condition or illness that according to current diagnosis has a high probability of death within two years, even with treatment with an existing generally accepted treatment protocol.

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

(g) "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.

(h) "NIH" means the national institutes of health.

(i) "Patient cost" means the routine costs of a medically necessary health care service that is incurred by a member as a result of the treatment being provided pursuant to the protocols of the clinical trial. Routine costs of a clinical trial include all items or services that are otherwise generally available to beneficiaries of the insurance policies. "Patient cost" does not include:

(1) The cost of the investigational drug or device;

(2) The cost of nonhealth care services that a patient may be required to receive as a result of the treatment being provided to the member for purposes of the clinical trial;

(3) Services customarily provided by the research sponsor free of charge for any participant in the trial;

(4) Costs associated with managing the research associated with the clinical trial, including but not limited to, services furnished to satisfy data collection and analysis needs that are not used in the direct clinical management of the participant; or

(5) Costs that would not be covered under the participant's policy, plan, or contract for noninvestigational treatments;

(6) Adverse events during treatment are divided into those that reflect the natural history of the disease, or its progression, and those that are unique in the experimental treatment. Costs for the former are the responsibility of the payor as provided in section two of this article, and costs for the later are the responsibility of the sponsor. The sponsor shall hold harmless any payor for any losses and injuries sustained by any member as a result of his or her participation in the clinical trial.

§33-25F-2. Coverage applicable under this article.

(a) This section applies to:

(1) Insurers and nonprofit health service plans that provide hospital, medical, surgical or pharmaceutical benefits to individuals or groups on an expense-incurred basis under a health insurance policy or contract issued or delivered in the state; and

(2) Health maintenance organizations that provide hospital, medical, surgical or pharmaceutical benefits to individuals or groups under contracts that are issued or delivered in the state.

(b) This section does not apply to a policy, plan or contract paid for under Title XVIII of the Social Security Act.

(c) A policy, plan or contract subject to this section shall provide coverage for patient cost to a member in a clinical trial, as a result of:

(1) Treatment provided for a life-threatening condition; or

(2) Prevention of, early detection of or treatment studies on cancer.

(d) The coverage under subsection (c) of this section is required if:

(1)(A) The treatment is being provided or the studies are being conducted in a Phase II, Phase III or Phase IV clinical trial for cancer and has therapeutic intent; or

(B) The treatment is being provided in a Phase II, Phase III or Phase IV clinical trial for any other life-threatening condition and has therapeutic intent;

(2) The treatment is being provided in a clinical trial approved by:

(A) One of the national institutes of health;

(B) An NIH cooperative group or an NIH center;

(C) The FDA in the form of an investigational new drug application or investigational device exemption;

(D) The federal department of veterans affairs; or

(E) An institutional review board of an institution in the state which has a multiple project assurance contract approved

by the office of protection from research risks of the national institutes of health;

(3) The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training and volume of patients treated to maintain expertise;

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

(5) The available clinical or preclinical data provide a reasonable expectation that the treatment will be more effective than the noninvestigational treatment alternative;

(6) The treatment is provided in this state: *Provided*, That, if the treatment is provided outside of this state, the treatment must be approved by the payor designated in subsection (a) of this section;

(7) Reimbursement for treatment is subject to all coinsurance, copayment and deductibles and is otherwise subject to all restrictions and obligations of the health plan; and

(8) Reimbursement for treatment by an out of network or noncontracting provider shall be reimbursed at a rate which is no greater than that provided by an in network or contracting provider. Coverage shall not be required if the out of network or noncontracting provider will not accept this level of reimbursement.

(e) Payment for patient costs for a clinical trial is not required by the provisions of this section, if:

(1) The purpose of the clinical trial is designed to extend the patent of any existing drug, to gain approval or coverage of a metabolite of an existing drug, or to gain approval or coverage

relating to additional clinical indications for an existing drug; or

(2) The purpose of the clinical trial is designed to keep a generic version of a drug from becoming available on the market; or

(3) The purpose of the clinical trial is to gain approval of or coverage for a reformulated or repackaged version of an existing drug.

(f) Any provider billing a third party payor for services or products provided to a patient in a clinical trial shall provide written notice to the payor that specifically identifies the services as part of a clinical trial.

(g) Notwithstanding any provision in this section to the contrary, coverage is not required for Phase I of any clinical trial.

That Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.

Chairman Senate Committee

Chairman House Committee

Originating in the House.

In effect ninety days from passage

Clerk of the Senate

Clerk of the House of Delegates

President of the Senate

Speaker of the House of Delegates

The within is approved this the 2nd day of April, 2003.

Governor

PRESENTED TO THE
GOVERNOR
Date 3/26/03
Time 4:10 pm