SENATE BILL NO. 29–SENATORS MATHEWS AND TOWNSEND

PREFILED FEBRUARY 3, 2005

Referred to Committee on Commerce and Labor

SUMMARY—Requires policies of health insurance to provide coverage for certain treatments for cancer. (BDR 57-265)

FISCAL NOTE: Effect on Local Government: May have Fiscal Impact.
Effect on the State: Yes.

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EXPLANATION – Matter in ***bolded italics*** is new; matter between brackets [~~omitted material~~] is material to be omitted.

AN ACT relating to health insurance; requiring policies of health insurance to provide coverage for certain medical treatment provided to an insured who participates in certain Phase I studies or clinical trials for the treatment of cancer; revising the types of medical treatment that must be covered when an insured participates in certain studies or clinical trials for the treatment of cancer or chronic fatigue syndrome; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires health insurance policies to provide coverage for certain medical treatment provided to an insured who participates in certain Phase II, Phase III or Phase IV studies or clinical trials for the treatment of cancer or chronic fatigue syndrome. (NRS 689A.04033, 689B.0306, 695B.1903, 695C.1693, 695G.173)

This bill requires health insurance policies also to provide such coverage for an insured who participates in certain Phase I studies or clinical trials for the treatment of cancer. To qualify for the coverage required by this bill, the Phase I study or clinical trial must be conducted at a facility that meets certain standards and requirements for conducting a Phase I study or clinical trial.

This bill also revises the types of medical treatment that must be covered when an insured participates in a study or clinical trial for the treatment of cancer or chronic fatigue syndrome.

THE PEOPLE OF THE STATE OF NEVADA, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. NRS 689A.04033 is hereby amended to read as follows:

689A.04033 1. A policy of health insurance must provide coverage for medical treatment which a policyholder or subscriber receives as part of a clinical trial or study if:

(a) The medical treatment is provided in a ***Phase I,*** Phase II, Phase III or Phase IV study or clinical trial for the treatment of cancer or ***in a Phase II, Phase III or Phase IV study or clinical trial for the treatment of*** chronic fatigue syndrome;

(b) The clinical trial or study is approved by:

(1) An agency of the National Institutes of Health as set forth in 42 U.S.C. § 281(b);

(2) A cooperative group;

(3) The Food and Drug Administration as an application for a new investigational drug;

(4) The United States Department of Veterans Affairs; or

(5) The United States Department of Defense;

(c) ~~[The]~~ ***In the case of:***

(1) A Phase I clinical trial or study for the treatment of cancer, the medical treatment is provided at a facility authorized to conduct Phase I clinical trials or studies for the treatment of cancer; or

(2) A Phase II, Phase III or Phase IV study or clinical trial for the treatment of cancer or chronic fatigue syndrome, the medical treatment is provided by a provider of health care and the facility and personnel ***for the clinical trial or study*** have the experience and training to provide the treatment in a capable manner;

(d) There is no medical treatment available which is considered a more appropriate alternative medical treatment than the medical treatment provided in the clinical trial or study;

(e) There is a reasonable expectation based on clinical data that the medical treatment provided in the clinical trial or study will be at least as effective as any other medical treatment ~~[,]~~ ***and the clinical trial or study is therapeutic in nature;***

(f) The clinical trial or study is conducted in this State; and

(g) The policyholder or subscriber has signed, before his participation in the clinical trial or study, a statement of consent indicating that he has been informed of, without limitation:

(1) The procedure to be undertaken;

(2) Alternative methods of treatment; and

(3) The risks associated with participation in the clinical trial or study, including, without limitation, the general nature and extent of such risks.

2. Except as otherwise provided in subsection 3, the coverage for medical treatment required by this section is limited to:

(a) Coverage for any drug or device that is approved for sale by the Food and Drug Administration without regard to whether the approved drug or device has been approved for use in the medical treatment of the policyholder or subscriber.

(b) The cost of any ~~[reasonably necessary]~~ ***routine*** health care services that ~~[are required as a result of the medical treatment provided in the clinical trial or study or as a result of any complication arising out of the medical treatment provided in the clinical trial or study, to the extent that such health care services]~~ would otherwise be covered under the policy of health insurance.

(c) The initial consultation to determine whether the policyholder or subscriber is eligible to participate in the clinical trial or study.

(d) Health care services ***which are*** required for the clinically appropriate monitoring of the policyholder or subscriber during the clinical trial or study ~~[.]~~ ***and which are not directly related to the clinical trial or study.***

➥ Except as otherwise provided in NRS 689A.04036, the services provided pursuant to paragraphs (b) and (d) must be covered only if the services are provided by a provider with whom the insurer has contracted for such services. If the insurer has not contracted for the provision of such services, the insurer shall pay the provider the rate of reimbursement that is paid to other providers with whom the insurer has contracted for similar services and the provider shall accept that rate of reimbursement as payment in full.

3. Particular medical treatment described in subsection 2 and provided to a policyholder or subscriber is not required to be covered pursuant to this section if that particular medical treatment is provided by the sponsor of the clinical trial or study free of charge to the policyholder or subscriber.

4. The coverage for medical treatment required by this section does not include:

(a) Any portion of the clinical trial or study that is customarily paid for by a government or a biotechnical, pharmaceutical or medical industry.

(b) Coverage for a drug or device described in paragraph (a) of subsection 2 which is paid for by the manufacturer, distributor or provider of the drug or device.

(c) Health care services that are specifically excluded from coverage under the policyholder's or subscriber's policy of health

insurance, regardless of whether such services are provided under the clinical trial or study.

(d) Health care services that are customarily provided by the sponsors of the clinical trial or study free of charge to the participants in the trial or study.

(e) Extraneous expenses related to participation in the clinical trial or study including, without limitation, travel, housing and other expenses that a participant may incur.

(f) Any expenses incurred by a person who accompanies the policyholder or subscriber during the clinical trial or study.

(g) Any item or service that is provided solely to satisfy a need or desire for data collection or analysis that is not directly related to the clinical management of the policyholder or subscriber.

(h) Any costs for the management of research relating to the clinical trial or study.

5. An insurer who delivers or issues for delivery a policy of health insurance specified in subsection 1 ~~[,]~~ may require copies of the approval or certification issued pursuant to paragraph (b) of subsection 1, the statement of consent signed by the policyholder or subscriber, protocols for the clinical trial or study and any other materials related to the scope of the clinical trial or study relevant to the coverage of medical treatment pursuant to this section.

6. An insurer who delivers or issues for delivery a policy specified in subsection 1 shall:

(a) Include in the disclosure required pursuant to NRS 689A.390 notice to each policyholder and subscriber under the policy of the availability of the benefits required by this section.

(b) Provide the coverage required by this section subject to the same deductible, copayment, coinsurance and other such conditions for coverage that are required under the policy.

7. A policy of health insurance subject to the provisions of this chapter that is delivered, issued for delivery or renewed on or after January 1, ~~[2004,]~~ ***2006,*** has the legal effect of including the coverage required by this section, and any provision of the policy that conflicts with this section is void.

8. An insurer who delivers or issues for delivery a policy specified in subsection 1 is immune from liability for:

(a) Any injury to a policyholder or subscriber caused by:

(1) Any medical treatment provided to the policyholder or subscriber in connection with his participation in a clinical trial or study described in this section; or

(2) An act or omission by a provider of health care who provides medical treatment or supervises the provision of medical treatment to the policyholder or subscriber in connection with his participation in a clinical trial or study described in this section.

(b) Any adverse or unanticipated outcome arising out of a policyholder's or subscriber's participation in a clinical trial or study described in this section.

9. As used in this section:

(a) "Cooperative group" means a network of facilities that collaborate on research projects and has established a peer review program approved by the National Institutes of Health. The term includes:

(1) The Clinical Trials Cooperative Group Program; and

(2) The Community Clinical Oncology Program.

(b) ***"Facility authorized to conduct Phase I clinical trials or studies for the treatment of cancer" means a facility that:***

(1) Has in place a Phase I program which permits only selective participation in the program and which uses clear-cut criteria to determine eligibility for participation in the program;

(2) Operates a protocol review and monitoring system which conforms to the standards set forth in the Policies and Guidelines Relating to the Cancer-Center Support Grant published by the Cancer Centers Branch of the National Cancer Institute;

(3) Employs at least two researchers and at least one of those researchers receives funding from a federal grant;

(4) Employs at least three clinical investigators who have experience working in Phase I clinical trials or studies conducted at a facility designated as a comprehensive cancer center by the National Cancer Institute;

(5) Possesses specialized resources for use in Phase I clinical trials or studies, including, without limitation, equipment that facilitates research and analysis in proteomics, genomics and pharmacokinetics;

(6) Is capable of gathering, maintaining and reporting electronic data; and

(7) Is capable of responding to audits instituted by federal and state agencies.

(c) "Provider of health care" means:

(1) A hospital; or

(2) A person licensed pursuant to chapter 630, 631 or 633 of NRS.

Sec. 2. NRS 689B.0306 is hereby amended to read as follows:

689B.0306 1. A policy of group health insurance must provide coverage for medical treatment which a person insured under the group policy receives as part of a clinical trial or study if:

(a) The medical treatment is provided in a ***Phase I,*** Phase II, Phase III or Phase IV study or clinical trial for the treatment of

cancer or ***in a Phase II, Phase III or Phase IV study or clinical trial for the treatment of*** chronic fatigue syndrome;

(b) The clinical trial or study is approved by:

(1) An agency of the National Institutes of Health as set forth in 42 U.S.C. § 281(b);

(2) A cooperative group;

(3) The Food and Drug Administration as an application for a new investigational drug;

(4) The United States Department of Veterans Affairs; or

(5) The United States Department of Defense;

(c) ~~[The]~~ ***In the case of:***

(1) A Phase I clinical trial or study for the treatment of cancer, the medical treatment is provided at a facility authorized to conduct Phase I clinical trials or studies for the treatment of cancer; or

(2) A Phase II, Phase III or Phase IV study or clinical trial for the treatment of cancer or chronic fatigue syndrome, the medical treatment is provided by a provider of health care and the facility and personnel ***for the clinical trial or study*** have the experience and training to provide the treatment in a capable manner;

(d) There is no medical treatment available which is considered a more appropriate alternative medical treatment than the medical treatment provided in the clinical trial or study;

(e) There is a reasonable expectation based on clinical data that the medical treatment provided in the clinical trial or study will be at least as effective as any other medical treatment ~~[;]~~ ***and the clinical trial or study is therapeutic in nature;***

(f) The clinical trial or study is conducted in this State; and

(g) The insured has signed, before his participation in the clinical trial or study, a statement of consent indicating that he has been informed of, without limitation:

(1) The procedure to be undertaken;

(2) Alternative methods of treatment; and

(3) The risks associated with participation in the clinical trial or study, including, without limitation, the general nature and extent of such risks.

2. Except as otherwise provided in subsection 3, the coverage for medical treatment required by this section is limited to:

(a) Coverage for any drug or device that is approved for sale by the Food and Drug Administration without regard to whether the approved drug or device has been approved for use in the medical treatment of the insured person.

(b) The cost of any ~~[reasonably necessary]~~ ***routine*** health care services that ~~[are required as a result of the medical treatment~~

~~provided in the clinical trial or study or as a result of any complication arising out of the medical treatment provided in the clinical trial or study, to the extent that such health care services~~] would otherwise be covered under the policy of group health insurance.

(c) The initial consultation to determine whether the insured is eligible to participate in the clinical trial or study.

(d) Health care services ***which are*** required for the clinically appropriate monitoring of the insured during the clinical trial or study ~~[.]~~ ***and which are not directly related to the clinical trial or study.***

➥ Except as otherwise provided in NRS 689B.0303, the services provided pursuant to paragraphs (b) and (d) must be covered only if the services are provided by a provider with whom the insurer has contracted for such services. If the insurer has not contracted for the provision of such services, the insurer shall pay the provider the rate of reimbursement that is paid to other providers with whom the insurer has contracted for similar services and the provider shall accept that rate of reimbursement as payment in full.

3. Particular medical treatment described in subsection 2 and provided to a person insured under the group policy is not required to be covered pursuant to this section if that particular medical treatment is provided by the sponsor of the clinical trial or study free of charge to the person insured under the group policy.

4. The coverage for medical treatment required by this section does not include:

(a) Any portion of the clinical trial or study that is customarily paid for by a government or a biotechnical, pharmaceutical or medical industry.

(b) Coverage for a drug or device described in paragraph (a) of subsection 2 which is paid for by the manufacturer, distributor or provider of the drug or device.

(c) Health care services that are specifically excluded from coverage under the insured's policy of group health insurance, regardless of whether such services are provided under the clinical trial or study.

(d) Health care services that are customarily provided by the sponsors of the clinical trial or study free of charge to the participants in the trial or study.

(e) Extraneous expenses related to participation in the clinical trial or study including, without limitation, travel, housing and other expenses that a participant may incur.

(f) Any expenses incurred by a person who accompanies the insured during the clinical trial or study.

(g) Any item or service that is provided solely to satisfy a need or desire for data collection or analysis that is not directly related to the clinical management of the insured.

(h) Any costs for the management of research relating to the clinical trial or study.

5. An insurer who delivers or issues for delivery a policy of group health insurance specified in subsection 1 ~~[,]~~ may require copies of the approval or certification issued pursuant to paragraph (b) of subsection 1, the statement of consent signed by the insured, protocols for the clinical trial or study and any other materials related to the scope of the clinical trial or study relevant to the coverage of medical treatment pursuant to this section.

6. An insurer who delivers or issues for delivery a policy of group health insurance specified in subsection 1 shall:

(a) Include in the disclosure required pursuant to NRS 689B.027 notice to each group policyholder of the availability of the benefits required by this section.

(b) Provide the coverage required by this section subject to the same deductible, copayment, coinsurance and other such conditions for coverage that are required under the policy.

7. A policy of group health insurance subject to the provisions of this chapter that is delivered, issued for delivery or renewed on or after January 1, ~~[2004,]~~ ***2006,*** has the legal effect of including the coverage required by this section, and any provision of the policy that conflicts with this section is void.

8. An insurer who delivers or issues for delivery a policy of group health insurance specified in subsection 1 is immune from liability for:

(a) Any injury to the insured caused by:

(1) Any medical treatment provided to the insured in connection with his participation in a clinical trial or study described in this section; or

(2) An act or omission by a provider of health care who provides medical treatment or supervises the provision of medical treatment to the insured in connection with his participation in a clinical trial or study described in this section.

(b) Any adverse or unanticipated outcome arising out of an insured's participation in a clinical trial or study described in this section.

9. As used in this section:

(a) "Cooperative group" means a network of facilities that collaborate on research projects and has established a peer review program approved by the National Institutes of Health. The term includes:

(1) The Clinical Trials Cooperative Group Program; and

(2) The Community Clinical Oncology Program.

(b) ***"Facility authorized to conduct Phase I clinical trials or studies for the treatment of cancer" means a facility that:***

(1) Has in place a Phase I program which permits only selective participation in the program and which uses clear-cut criteria to determine eligibility for participation in the program;

(2) Operates a protocol review and monitoring system which conforms to the standards set forth in the Policies and Guidelines Relating to the Cancer-Center Support Grant published by the Cancer Centers Branch of the National Cancer Institute;

(3) Employs at least two researchers and at least one of those researchers receives funding from a federal grant;

(4) Employs at least three clinical investigators who have experience working in Phase I clinical trials or studies conducted at a facility designated as a comprehensive cancer center by the National Cancer Institute;

(5) Possesses specialized resources for use in Phase I clinical trials or studies, including, without limitation, equipment that facilitates research and analysis in proteomics, genomics and pharmacokinetics;

(6) Is capable of gathering, maintaining and reporting electronic data; and

(7) Is capable of responding to audits instituted by federal and state agencies.

(c) "Provider of health care" means:

(1) A hospital; or

(2) A person licensed pursuant to chapter 630, 631 or 633 of NRS.

Sec. 3. NRS 695B.1903 is hereby amended to read as follows:

695B.1903 1. A policy of health insurance issued by a medical services corporation must provide coverage for medical treatment which a person insured under the policy receives as part of a clinical trial or study if:

(a) The medical treatment is provided in a ***Phase I,*** Phase II, Phase III or Phase IV study or clinical trial for the treatment of cancer or ***in a Phase II, Phase III or Phase IV study or clinical trial for the treatment of*** chronic fatigue syndrome;

(b) The clinical trial or study is approved by:

(1) An agency of the National Institutes of Health as set forth in 42 U.S.C. § 281(b);

(2) A cooperative group;

(3) The Food and Drug Administration as an application for a new investigational drug;

(4) The United States Department of Veterans Affairs; or

(5) The United States Department of Defense;

(c) ~~[~~The~~]~~ ***In the case of:***

(1) A Phase I clinical trial or study for the treatment of cancer, the medical treatment is provided at a facility authorized to conduct Phase I clinical trials or studies for the treatment of cancer; or

(2) A Phase II, Phase III or Phase IV study or clinical trial for the treatment of cancer or chronic fatigue syndrome, the medical treatment is provided by a provider of health care and the facility and personnel ***for the clinical trial or study*** have the experience and training to provide the treatment in a capable manner;

(d) There is no medical treatment available which is considered a more appropriate alternative medical treatment than the medical treatment provided in the clinical trial or study;

(e) There is a reasonable expectation based on clinical data that the medical treatment provided in the clinical trial or study will be at least as effective as any other medical treatment ~~[~~,~~]~~ ***and the clinical trial or study is therapeutic in nature;***

(f) The clinical trial or study is conducted in this State; and

(g) The insured has signed, before his participation in the clinical trial or study, a statement of consent indicating that he has been informed of, without limitation:

(1) The procedure to be undertaken;

(2) Alternative methods of treatment; and

(3) The risks associated with participation in the clinical trial or study, including, without limitation, the general nature and extent of such risks.

2. Except as otherwise provided in subsection 3, the coverage for medical treatment required by this section is limited to:

(a) Coverage for any drug or device that is approved for sale by the Food and Drug Administration without regard to whether the approved drug or device has been approved for use in the medical treatment of the insured person.

(b) The cost of any ~~[~~reasonably necessary~~]~~ ***routine*** health care services that ~~[~~are required as a result of the medical treatment provided in the clinical trial or study or as a result of any complication arising out of the medical treatment provided in the clinical trial or study, to the extent that such health care services~~]~~ would otherwise be covered under the policy of health insurance.

(c) The initial consultation to determine whether the insured is eligible to participate in the clinical trial or study.

(d) Health care services ***which are*** required for the clinically appropriate monitoring of the insured during the clinical trial or

study ~~[.]~~ ***and which are not directly related to the clinical trial or study.***

➥ Except as otherwise provided in NRS 695B.1901, the services provided pursuant to paragraphs (b) and (d) must be covered only if the services are provided by a provider with whom the medical services corporation has contracted for such services. If the medical services corporation has not contracted for the provision of such services, the medical services corporation shall pay the provider the rate of reimbursement that is paid to other providers with whom the medical services corporation has contracted for similar services and the provider shall accept that rate of reimbursement as payment in full.

3. Particular medical treatment described in subsection 2 and provided to a person insured under the policy is not required to be covered pursuant to this section if that particular medical treatment is provided by the sponsor of the clinical trial or study free of charge to the person insured under the policy.

4. The coverage for medical treatment required by this section does not include:

(a) Any portion of the clinical trial or study that is customarily paid for by a government or a biotechnical, pharmaceutical or medical industry.

(b) Coverage for a drug or device described in paragraph (a) of subsection 2 which is paid for by the manufacturer, distributor or provider of the drug or device.

(c) Health care services that are specifically excluded from coverage under the insured's policy of health insurance, regardless of whether such services are provided under the clinical trial or study.

(d) Health care services that are customarily provided by the sponsors of the clinical trial or study free of charge to the participants in the trial or study.

(e) Extraneous expenses related to participation in the clinical trial or study including, without limitation, travel, housing and other expenses that a participant may incur.

(f) Any expenses incurred by a person who accompanies the insured during the trial or study.

(g) Any item or service that is provided solely to satisfy a need or desire for data collection or analysis that is not directly related to the clinical management of the insured.

(h) Any costs for the management of research relating to the clinical trial or study.

5. A medical services corporation that delivers or issues for delivery a policy of health insurance specified in subsection 1 ~~[,]~~ may require copies of the approval or certification issued pursuant

to paragraph (b) of subsection 1, the statement of consent signed by the insured, protocols for the clinical trial or study and any other materials related to the scope of the clinical trial or study relevant to the coverage of medical treatment pursuant to this section.

6. A medical services corporation that delivers or issues for delivery a policy of health insurance specified in subsection 1 shall:

(a) Include in the disclosure required pursuant to NRS 695B.172 notice to each person insured under the policy of the availability of the benefits required by this section.

(b) Provide the coverage required by this section subject to the same deductible, copayment, coinsurance and other such conditions for coverage that are required under the policy.

7. A policy of health insurance subject to the provisions of this chapter that is delivered, issued for delivery or renewed on or after January 1, ~~[2004,]~~ ***2006,*** has the legal effect of including the coverage required by this section, and any provision of the policy that conflicts with this section is void.

8. A medical services corporation that delivers or issues for delivery a policy of health insurance specified in subsection 1 is immune from liability for:

(a) Any injury to the insured caused by:

(1) Any medical treatment provided to the insured in connection with his participation in a clinical trial or study described in this section; or

(2) An act or omission by a provider of health care who provides medical treatment or supervises the provision of medical treatment to the insured in connection with his participation in a clinical trial or study described in this section.

(b) Any adverse or unanticipated outcome arising out of an insured's participation in a clinical trial or study described in this section.

9. As used in this section:

(a) "Cooperative group" means a network of facilities that collaborate on research projects and has established a peer review program approved by the National Institutes of Health. The term includes:

(1) The Clinical Trials Cooperative Group Program; and

(2) The Community Clinical Oncology Program.

(b) ***"Facility authorized to conduct Phase I clinical trials or studies for the treatment of cancer" means a facility that:***

(1) Has in place a Phase I program which permits only selective participation in the program and which uses clear-cut criteria to determine eligibility for participation in the program;

(2) Operates a protocol review and monitoring system which conforms to the standards set forth in the Policies and

Guidelines Relating to the Cancer-Center Support Grant published by the Cancer Centers Branch of the National Cancer Institute;

(3) Employs at least two researchers and at least one of those researchers receives funding from a federal grant;

(4) Employs at least three clinical investigators who have experience working in Phase I clinical trials or studies conducted at a facility designated as a comprehensive cancer center by the National Cancer Institute;

(5) Possesses specialized resources for use in Phase I clinical trials or studies, including, without limitation, equipment that facilitates research and analysis in proteomics, genomics and pharmacokinetics;

(6) Is capable of gathering, maintaining and reporting electronic data; and

(7) Is capable of responding to audits instituted by federal and state agencies.

(c) "Provider of health care" means:

(1) A hospital; or

(2) A person licensed pursuant to chapter 630, 631 ~~[and]~~ ***or*** 633 of NRS.

Sec. 4. NRS 695C.1693 is hereby amended to read as follows:

695C.1693 1. Except as otherwise provided in NRS 695C.050, a health care plan issued by a health maintenance organization must provide coverage for medical treatment which an enrollee receives as part of a clinical trial or study if:

(a) The medical treatment is provided in a ***Phase I,*** Phase II, Phase III or Phase IV study or clinical trial for the treatment of cancer or ***in a Phase II, Phase III or Phase IV study or clinical trial for the treatment of*** chronic fatigue syndrome;

(b) The clinical trial or study is approved by:

(1) An agency of the National Institutes of Health as set forth in 42 U.S.C. § 281(b);

(2) A cooperative group;

(3) The Food and Drug Administration as an application for a new investigational drug;

(4) The United States Department of Veterans Affairs; or

(5) The United States Department of Defense;

(c) ~~[The]~~ ***In the case of:***

(1) A Phase I clinical trial or study for the treatment of cancer, the medical treatment is provided at a facility authorized to conduct Phase I clinical trials or studies for the treatment of cancer; or

(2) A Phase II, Phase III or Phase IV study or clinical trial for the treatment of cancer or chronic fatigue syndrome, the

medical treatment is provided by a provider of health care and the facility and personnel ***for the clinical trial or study*** have the experience and training to provide the treatment in a capable manner;

(d) There is no medical treatment available which is considered a more appropriate alternative medical treatment than the medical treatment provided in the clinical trial or study;

(e) There is a reasonable expectation based on clinical data that the medical treatment provided in the clinical trial or study will be at least as effective as any other medical treatment ~~[.]~~ ***and the clinical trial or study is therapeutic in nature;***

(f) The clinical trial or study is conducted in this State; and

(g) The enrollee has signed, before his participation in the clinical trial or study, a statement of consent indicating that he has been informed of, without limitation:

(1) The procedure to be undertaken;

(2) Alternative methods of treatment; and

(3) The risks associated with participation in the clinical trial or study, including, without limitation, the general nature and extent of such risks.

2. Except as otherwise provided in subsection 3, the coverage for medical treatment required by this section is limited to:

(a) Coverage for any drug or device that is approved for sale by the Food and Drug Administration without regard to whether the approved drug or device has been approved for use in the medical treatment of the enrollee.

(b) The cost of any ~~[reasonably necessary]~~ ***routine*** health care services that ~~[are required as a result of the medical treatment provided in the clinical trial or study or as a result of any complication arising out of the medical treatment provided in the clinical trial or study, to the extent that such health care services]~~ would otherwise be covered under the health care plan.

(c) The initial consultation to determine whether the enrollee is eligible to participate in the clinical trial or study.

(d) Health care services ***which are*** required for the clinically appropriate monitoring of the enrollee during the clinical trial or study ~~[.]~~ ***and which are not directly related to the clinical trial or study.***

➥ Except as otherwise provided in NRS 695C.1691, the services provided pursuant to paragraphs (b) and (d) must be covered only if the services are provided by a provider with whom the health maintenance organization has contracted for such services. If the health maintenance organization has not contracted for the provision of such services, the health maintenance organization shall pay the provider the rate of reimbursement that is paid to other providers

with whom the health maintenance organization has contracted for similar services and the provider shall accept that rate of reimbursement as payment in full.

3. Particular medical treatment described in subsection 2 and provided to an enrollee is not required to be covered pursuant to this section if that particular medical treatment is provided by the sponsor of the clinical trial or study free of charge to the enrollee.

4. The coverage for medical treatment required by this section does not include:

(a) Any portion of the clinical trial or study that is customarily paid for by a government or a biotechnical, pharmaceutical or medical industry.

(b) Coverage for a drug or device described in paragraph (a) of subsection 2 which is paid for by the manufacturer, distributor or provider of the drug or device.

(c) Health care services that are specifically excluded from coverage under the enrollee's health care plan, regardless of whether such services are provided under the clinical trial or study.

(d) Health care services that are customarily provided by the sponsors of the clinical trial or study free of charge to the participants in the trial or study.

(e) Extraneous expenses related to participation in the clinical trial or study including, without limitation, travel, housing and other expenses that a participant may incur.

(f) Any expenses incurred by a person who accompanies the enrollee during the clinical trial or study.

(g) Any item or service that is provided solely to satisfy a need or desire for data collection or analysis that is not directly related to the clinical management of the enrollee.

(h) Any costs for the management of research relating to the clinical trial or study.

5. A health maintenance organization that delivers or issues for delivery a health care plan specified in subsection 1 ~~[,]~~ may require copies of the approval or certification issued pursuant to paragraph (b) of subsection 1, the statement of consent signed by the enrollee, protocols for the clinical trial or study and any other materials related to the scope of the clinical trial or study relevant to the coverage of medical treatment pursuant to this section.

6. A health maintenance organization that delivers or issues for delivery a health care plan specified in subsection 1 shall:

(a) Include in the disclosure required pursuant to NRS 695C.193 notice to each enrollee of the availability of the benefits required by this section.

(b) Provide the coverage required by this section subject to the same deductible, copayment, coinsurance and other such conditions for coverage that are required under the plan.

7. A health care plan subject to the provisions of this chapter that is delivered, issued for delivery or renewed on or after January 1, ~~[~~2004,~~]~~ ***2006,*** has the legal effect of including the coverage required by this section, and any provision of the policy that conflicts with this section is void.

8. A health maintenance organization that delivers or issues for delivery a health care plan specified in subsection 1 is immune from liability for:

(a) Any injury to an enrollee caused by:

(1) Any medical treatment provided to the enrollee in connection with his participation in a clinical trial or study described in this section; or

(2) An act or omission by a provider of health care who provides medical treatment or supervises the provision of medical treatment to the enrollee in connection with his participation in a clinical trial or study described in this section.

(b) Any adverse or unanticipated outcome arising out of an enrollee's participation in a clinical trial or study described in this section.

9. As used in this section:

(a) "Cooperative group" means a network of facilities that collaborate on research projects and has established a peer review program approved by the National Institutes of Health. The term includes:

(1) The Clinical Trials Cooperative Group Program; and

(2) The Community Clinical Oncology Program.

(b) ***"Facility authorized to conduct Phase I clinical trials or studies for the treatment of cancer" means a facility that:***

(1) Has in place a Phase I program which permits only selective participation in the program and which uses clear-cut criteria to determine eligibility for participation in the program;

(2) Operates a protocol review and monitoring system which conforms to the standards set forth in the Policies and Guidelines Relating to the Cancer-Center Support Grant published by the Cancer Centers Branch of the National Cancer Institute;

(3) Employs at least two researchers and at least one of those researchers receives funding from a federal grant;

(4) Employs at least three clinical investigators who have experience working in Phase I clinical trials or studies conducted at a facility designated as a comprehensive cancer center by the National Cancer Institute;

(5) Possesses specialized resources for use in Phase I clinical trials or studies, including, without limitation, equipment that facilitates research and analysis in proteomics, genomics and pharmacokinetics;

(6) Is capable of gathering, maintaining and reporting electronic data; and

(7) Is capable of responding to audits instituted by federal and state agencies.

(c) "Provider of health care" means:

(1) A hospital; or

(2) A person licensed pursuant to chapter 630, 631 or 633 of NRS.

Sec. 5. NRS 695G.173 is hereby amended to read as follows:

695G.173 1. A health care plan issued by a managed care organization must provide coverage for medical treatment which a person insured under the plan receives as part of a clinical trial or study if:

(a) The medical treatment is provided in a ***Phase I,*** Phase II, Phase III or Phase IV study or clinical trial for the treatment of cancer or ***in a Phase II, Phase III or Phase IV study or clinical trial for the treatment of*** chronic fatigue syndrome;

(b) The clinical trial or study is approved by:

(1) An agency of the National Institutes of Health as set forth in 42 U.S.C. § 281(b);

(2) A cooperative group;

(3) The Food and Drug Administration as an application for a new investigational drug;

(4) The United States Department of Veterans Affairs; or

(5) The United States Department of Defense;

(c) ~~[The]~~ ***In the case of:***

(1) A Phase I clinical trial or study for the treatment of cancer, the medical treatment is provided at a facility authorized to conduct Phase I clinical trials or studies for the treatment of cancer; or

(2) A Phase II, Phase III or Phase IV study or clinical trial for the treatment of cancer or chronic fatigue syndrome, the medical treatment is provided by a provider of health care and the facility and personnel ***for the clinical trial or study*** have the experience and training to provide the treatment in a capable manner;

(d) There is no medical treatment available which is considered a more appropriate alternative medical treatment than the medical treatment provided in the clinical trial or study;

(e) There is a reasonable expectation based on clinical data that the medical treatment provided in the clinical trial or study will be at

least as effective as any other medical treatment ~~[,]~~ ***and the clinical trial or study is therapeutic in nature;***

(f) The clinical trial or study is conducted in this State; and

(g) The insured has signed, before his participation in the clinical trial or study, a statement of consent indicating that he has been informed of, without limitation:

(1) The procedure to be undertaken;

(2) Alternative methods of treatment; and

(3) The risks associated with participation in the clinical trial or study, including, without limitation, the general nature and extent of such risks.

2. Except as otherwise provided in subsection 3, the coverage for medical treatment required by this section is limited to:

(a) Coverage for any drug or device that is approved for sale by the Food and Drug Administration without regard to whether the approved drug or device has been approved for use in the medical treatment of the insured.

(b) The cost of any ~~[reasonably necessary]~~ ***routine*** health care services that ~~[are required as a result of the medical treatment provided in the clinical trial or study or as a result of any complication arising out of the medical treatment provided in the clinical trial or study, to the extent that such health care services]~~ would otherwise be covered under the health care plan.

(c) The initial consultation to determine whether the insured is eligible to participate in the clinical trial or study.

(d) Health care services ***which are*** required for the clinically appropriate monitoring of the insured during the clinical trial or study ~~[.]~~ ***and which are not directly related to the clinical trial or study.***

➥ Except as otherwise provided in NRS 695G.164, the services provided pursuant to paragraphs (b) and (d) must be covered only if the services are provided by a provider with whom the managed care organization has contracted for such services. If the managed care organization has not contracted for the provision of such services, the managed care organization shall pay the provider the rate of reimbursement that is paid to other providers with whom the managed care organization has contracted for similar services and the provider shall accept that rate of reimbursement as payment in full.

3. Particular medical treatment described in subsection 2 and provided to a person insured under the plan is not required to be covered pursuant to this section if that particular medical treatment is provided by the sponsor of the clinical trial or study free of charge to the person insured under the plan.

4. The coverage for medical treatment required by this section does not include:

(a) Any portion of the clinical trial or study that is customarily paid for by a government or a biotechnical, pharmaceutical or medical industry.

(b) Coverage for a drug or device described in paragraph (a) of subsection 2 which is paid for by the manufacturer, distributor or provider of the drug or device.

(c) Health care services that are specifically excluded from coverage under the insured's health care plan, regardless of whether such services are provided under the clinical trial or study.

(d) Health care services that are customarily provided by the sponsors of the clinical trial or study free of charge to the participants in the trial or study.

(e) Extraneous expenses related to participation in the clinical trial or study including, without limitation, travel, housing and other expenses that a participant may incur.

(f) Any expenses incurred by a person who accompanies the insured during the clinical trial or study.

(g) Any item or service that is provided solely to satisfy a need or desire for data collection or analysis that is not directly related to the clinical management of the insured.

(h) Any costs for the management of research relating to the clinical trial or study.

5. A managed care organization that delivers or issues for delivery a health care plan specified in subsection 1 ~~[,]~~ may require copies of the approval or certification issued pursuant to paragraph (b) of subsection 1, the statement of consent signed by the insured, protocols for the clinical trial or study and any other materials related to the scope of the clinical trial or study relevant to the coverage of medical treatment pursuant to this section.

6. A managed care organization that delivers or issues for delivery a health care plan specified in subsection 1 shall:

(a) Include in the disclosure required pursuant to NRS 695C.193 notice to each person insured under the plan of the availability of the benefits required by this section.

(b) Provide the coverage required by this section subject to the same deductible, copayment, coinsurance and other such conditions for coverage that are required under the plan.

7. A health care plan subject to the provisions of this chapter that is delivered, issued for delivery or renewed on or after January 1, ~~[2004,]~~ ***2006,*** has the legal effect of including the coverage required by this section, and any provision of the policy that conflicts with this section is void.

8. A managed care organization that delivers or issues for delivery a health care plan specified in subsection 1 is immune from liability for:

(a) Any injury to an insured caused by:

(1) Any medical treatment provided to the insured in connection with his participation in a clinical trial or study described in this section; or

(2) An act or omission by a provider of health care who provides medical treatment or supervises the provision of medical treatment to the insured in connection with his participation in a clinical trial or study described in this section.

(b) Any adverse or unanticipated outcome arising out of an insured's particiapation in a clinical trial or study described in this section.

9. As used in this section:

(a) "Cooperative group" means a network of facilities that collaborate on research projects and has established a peer review program approved by the National Institutes of Health. The term includes:

(1) The Clinical Trials Cooperative Group Program; and

(2) The Community Clinical Oncology Program.

(b) ***"Facility authorized to conduct Phase I clinical trials or studies for the treatment of cancer" means a facility that:***

(1) Has in place a Phase I program which permits only selective participation in the program and which uses clear-cut criteria to determine eligibility for participation in the program;

(2) Operates a protocol review and monitoring system which conforms to the standards set forth in the Policies and Guidelines Relating to the Cancer-Center Support Grant published by the Cancer Centers Branch of the National Cancer Institute;

(3) Employs at least two researchers and at least one of those researchers receives funding from a federal grant;

(4) Employs at least three clinical investigators who have experience working in Phase I clinical trials or studies conducted at a facility designated as a comprehensive cancer center by the National Cancer Institute;

(5) Possesses specialized resources for use in Phase I clinical trials or studies, including, without limitation, equipment that facilitates research and analysis in proteomics, genomics and pharmacokinetics;

(6) Is capable of gathering, maintaining and reporting electronic data; and

(7) Is capable of responding to audits instituted by federal and state agencies.

(c) "Provider of health care" means:

(1) A hospital; or

(2) A person licensed pursuant to chapter 630, 631 or 633 of NRS.

Sec. 6. This act becomes effective on January 1, 2006.

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