

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:**

- 1 Existing law requires health insurance policies to provide coverage for certain
- 2 medical treatment provided to an insured who participates in certain Phase II, Phase
- 3 III or Phase IV studies or clinical trials for the treatment of cancer or chronic
- 4 fatigue syndrome. (NRS 689A.04033, 689B.0306, 695B.1903, 695C.1693,
- 5 695G.173)
- 6 This bill requires health insurance policies also to provide such coverage for an
- 7 insured who participates in certain Phase I studies or clinical trials for the treatment
- 8 of cancer. To qualify for the coverage required by this bill, the Phase I study or
- 9 clinical trial must be conducted at a facility that meets certain standards and
- 10 requirements for conducting a Phase I study or clinical trial.
- 11 This bill also revises the types of medical treatment that must be covered when
- 12 an insured participates in a study or clinical trial for the treatment of cancer or
- 13 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~~ *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



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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

42 (2) An act or omission by a provider of health care who  
43 provides medical treatment or supervises the provision of medical  
44 treatment to the policyholder or subscriber in connection with his  
45 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



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

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

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

6 (2) A cooperative group;

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

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

10 (5) The United States Department of Defense;

11 (c) ~~The~~ *In the case of:*

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

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

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

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

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

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

33 (1) The procedure to be undertaken;

34 (2) Alternative methods of treatment; and

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

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

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

44 (b) The cost of any ~~reasonably necessary~~ *routine* health care  
45 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) 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





- 1 (2) The Community Clinical Oncology Program.  
2 (b) *“Facility authorized to conduct Phase I clinical trials or*  
3 *studies for the treatment of cancer” means a facility that:*  
4 *(1) Has in place a Phase I program which permits only*  
5 *selective participation in the program and which uses clear-cut*  
6 *criteria to determine eligibility for participation in the program;*  
7 *(2) Operates a protocol review and monitoring system*  
8 *which conforms to the standards set forth in the Policies and*  
9 *Guidelines Relating to the Cancer-Center Support Grant*  
10 *published by the Cancer Centers Branch of the National Cancer*  
11 *Institute;*  
12 *(3) Employs at least two researchers and at least one of*  
13 *those researchers receives funding from a federal grant;*  
14 *(4) Employs at least three clinical investigators who have*  
15 *experience working in Phase I clinical trials or studies conducted*  
16 *at a facility designated as a comprehensive cancer center by the*  
17 *National Cancer Institute;*  
18 *(5) Possesses specialized resources for use in Phase I*  
19 *clinical trials or studies, including, without limitation, equipment*  
20 *that facilitates research and analysis in proteomics, genomics and*  
21 *pharmacokinetics;*  
22 *(6) Is capable of gathering, maintaining and reporting*  
23 *electronic data; and*  
24 *(7) Is capable of responding to audits instituted by federal*  
25 *and state agencies.*

26 (c) “Provider of health care” means:

- 27 (1) A hospital; or  
28 (2) A person licensed pursuant to chapter 630, 631 or 633 of  
29 NRS.

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

31 695B.1903 1. A policy of health insurance issued by a  
32 medical services corporation must provide coverage for medical  
33 treatment which a person insured under the policy receives as part of  
34 a clinical trial or study if:

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

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

- 40 (1) An agency of the National Institutes of Health as set forth  
41 in 42 U.S.C. § 281(b);  
42 (2) A cooperative group;  
43 (3) The Food and Drug Administration as an application for  
44 a new investigational drug;  
45 (4) The United States Department of Veterans Affairs; or



1 (5) The United States Department of Defense;

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

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

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

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

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

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

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

24 (1) The procedure to be undertaken;

25 (2) Alternative methods of treatment; and

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

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

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

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

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

43 (d) Health care services *which are* required for the clinically  
44 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



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

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

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

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

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

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

21 (a) Any injury to the insured caused by:

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

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

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

32 9. As used in this section:

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

37 (1) The Clinical Trials Cooperative Group Program; and

38 (2) The Community Clinical Oncology Program.

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

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

44 *(2) Operates a protocol review and monitoring system  
45 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*



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

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

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

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

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

16 (1) The procedure to be undertaken;

17 (2) Alternative methods of treatment; and

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

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

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

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

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

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

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



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

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

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

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

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

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


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

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

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

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

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

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

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

41 (a) Include in the disclosure required pursuant to NRS 695C.193  
42 notice to each enrollee of the availability of the benefits required by  
43 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;*





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

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

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

9       (c) "Provider of health care" means:

10       (1) A hospital; or

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

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

14       695G.173 1. A health care plan issued by a managed care  
15 organization must provide coverage for medical treatment which a  
16 person insured under the plan receives as part of a clinical trial or  
17 study if:

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

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

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

25       (2) A cooperative group;

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

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

29       (5) The United States Department of Defense;

30       (c) ~~The~~ *In the case of:*

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

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

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

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



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

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

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

7 (1) The procedure to be undertaken;

8 (2) Alternative methods of treatment; and

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

40       7. A health care plan subject to the provisions of this chapter  
41 that is delivered, issued for delivery or renewed on or after  
42 January 1, ~~[2004,]~~ 2006, has the legal effect of including the  
43 coverage required by this section, and any provision of the policy  
44 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 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.*



1       (c) “Provider of health care” means:

2           (1) A hospital; or

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

4 NRS.

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







