
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 individual health insurance; requiring policies of health insurance to provide coverage for medical treatment provided in certain Phase I studies and clinical trials for the treatment of cancer; and providing other matters properly relating thereto.

Legislative Counsel’s Digest:

1 Existing law requires health insurance policies to provide coverage for medical
2 treatment of cancer and chronic fatigue syndrome provided in a Phase II, Phase III
3 or Phase IV study or clinical trial. (NRS 689A.04033, 689B.0306, 695B.1903,
4 695C.1693, 695G.173)

5 This bill requires health insurance policies also to provide coverage for medical
6 treatment of cancer provided in a Phase I study or clinical trial.

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

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

3 689A.04033 1. A policy of health insurance must provide
4 coverage for medical treatment which a policyholder or subscriber
5 receives as part of a clinical trial or study if:

6 (a) The medical treatment is provided in a *Phase I*, Phase II,
7 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 medical treatment is provided by a provider of health
12 care and the facility and personnel have the experience and training
13 to provide the treatment in a capable manner;

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

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

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

21 (g) The policyholder or subscriber has signed, before his
22 participation in the clinical trial or study, a statement of consent
23 indicating that he has 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 policyholder or subscriber.

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

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



1 (d) Health care services required for the clinically appropriate
2 monitoring of the policyholder or subscriber during the clinical trial
3 or study.

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

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

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

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

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

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

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

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

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

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

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

42 5. An insurer who delivers or issues for delivery a policy of
43 health insurance specified in subsection 1 ~~(f)~~ may require copies
44 of the approval or certification issued pursuant to paragraph (b) of
45 subsection 1, the statement of consent signed by the policyholder or



1 subscriber, protocols for the clinical trial or study and any other
2 materials related to the scope of the clinical trial or study relevant to
3 the coverage of medical treatment pursuant to this section.

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

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

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

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

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

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

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

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

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

31 9. As used in this section:

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

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

37 (2) The Community Clinical Oncology Program.

38 (b) "Provider of health care" means:

39 (1) A hospital; or

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

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

43 689B.0306 1. A policy of group health insurance must
44 provide coverage for medical treatment which a person insured
45 under the group policy receives as part of a clinical trial or study if:



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

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

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

8 (2) A cooperative group;

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

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

12 (5) The United States Department of Defense;

13 (c) The medical treatment is provided by a provider of health
14 care and the facility and personnel have the experience and training
15 to provide the treatment in a capable manner;

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

19 (e) There is a reasonable expectation based on clinical data that
20 the medical treatment provided in the clinical trial or study will be at
21 least as effective as any other medical treatment;

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

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

26 (1) The procedure to be undertaken;

27 (2) Alternative methods of treatment; and

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

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

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

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

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



1 (d) Health care services required for the clinically appropriate
2 monitoring of the insured during the clinical trial or study.

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

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

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

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

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

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

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

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

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

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

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

41 5. An insurer who delivers or issues for delivery a policy of
42 group health insurance specified in subsection 1 **[5]** may require
43 copies of the approval or certification issued pursuant to paragraph
44 (b) of subsection 1, the statement of consent signed by the insured,
45 protocols for the clinical trial or study and any other materials



1 related to the scope of the clinical trial or study relevant to the
2 coverage of medical treatment pursuant to this section.

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

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

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

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

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

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

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

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

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

31 9. As used in this section:

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

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

37 (2) The Community Clinical Oncology Program.

38 (b) "Provider of health care" means:

39 (1) A hospital; or

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

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

43 695B.1903 1. A policy of health insurance issued by a
44 medical services corporation must provide coverage for medical



1 treatment which a person insured under the policy receives as part of
2 a clinical trial or study if:

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

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

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

10 (2) A cooperative group;

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

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

14 (5) The United States Department of Defense;

15 (c) The medical treatment is provided by a provider of health
16 care and the facility and personnel have the experience and training
17 to provide the treatment in a capable manner;

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

21 (e) There is a reasonable expectation based on clinical data that
22 the medical treatment provided in the clinical trial or study will be at
23 least as effective as any other medical treatment;

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

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

28 (1) The procedure to be undertaken;

29 (2) Alternative methods of treatment; and

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

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

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

39 (b) The cost of any reasonably necessary health care services
40 that are required as a result of the medical treatment provided in the
41 clinical trial or study or as a result of any complication arising out of
42 the medical treatment provided in the clinical trial or study, to the
43 extent that such health care services would otherwise be covered
44 under the policy of health insurance.



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

3 (d) Health care services required for the clinically appropriate
4 monitoring of the insured during the clinical trial or study.

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

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

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

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

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

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

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

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

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

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

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



1 5. A medical services corporation that delivers or issues for
2 delivery a policy of health insurance specified in subsection 1 ~~H~~
3 may require copies of the approval or certification issued pursuant
4 to paragraph (b) of subsection 1, the statement of consent signed by
5 the insured, protocols for the clinical trial or study and any other
6 materials related to the scope of the clinical trial or study relevant to
7 the coverage of medical treatment pursuant to this section.

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

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

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

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

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

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

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

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

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

36 9. As used in this section:

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

- 41 (1) The Clinical Trials Cooperative Group Program; and
42 (2) The Community Clinical Oncology Program.

43 (b) "Provider of health care" means:

- 44 (1) A hospital; or



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

3 **Sec. 4.** NRS 695C.1693 is hereby amended to read as follows:
4 695C.1693 1. Except as otherwise provided in NRS
5 695C.050, a health care plan issued by a health maintenance
6 organization must provide coverage for medical treatment which an
7 enrollee receives as part of a clinical trial or study if:

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

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

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

15 (2) A cooperative group;

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

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

19 (5) The United States Department of Defense;

20 (c) The medical treatment is provided by a provider of health
21 care and the facility and personnel have the experience and training
22 to provide the treatment in a capable manner;

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

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

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

30 (g) The enrollee 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 enrollee.

44 (b) The cost of any reasonably necessary health care services
45 that are required as a result of the medical treatment provided in the



1 clinical trial or study or as a result of any complication arising out of
2 the medical treatment provided in the clinical trial or study, to the
3 extent that such health care services would otherwise be covered
4 under the health care plan.

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

7 (d) Health care services required for the clinically appropriate
8 monitoring of the enrollee during the clinical trial or study.

9 ➔ Except as otherwise provided in NRS 695C.1691, the services
10 provided pursuant to paragraphs (b) and (d) must be covered only if
11 the services are provided by a provider with whom the health
12 maintenance organization has contracted for such services. If the
13 health maintenance organization has not contracted for the provision
14 of such services, the health maintenance organization shall pay the
15 provider the rate of reimbursement that is paid to other providers
16 with whom the health maintenance organization has contracted for
17 similar services and the provider shall accept that rate of
18 reimbursement as payment in full.

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

27 (a) Any injury to an enrollee caused by:

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

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

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

38 9. As used in this section:

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

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

44 (2) The Community Clinical Oncology Program.

45 (b) "Provider of health care" means:



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

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

5 695G.173 1. A health care plan issued by a managed care
6 organization must provide coverage for medical treatment which a
7 person insured under the plan receives as part of a clinical trial or
8 study if:

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

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

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

16 (2) A cooperative group;

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

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

20 (5) The United States Department of Defense;

21 (c) The medical treatment is provided by a provider of health
22 care and the facility and personnel have the experience and training
23 to provide the treatment in a capable manner;

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

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

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

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

34 (1) The procedure to be undertaken;

35 (2) Alternative methods of treatment; and

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

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

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



1 (b) The cost of any reasonably necessary health care services
2 that are required as a result of the medical treatment provided in the
3 clinical trial or study or as a result of any complication arising out of
4 the medical treatment provided in the clinical trial or study, to the
5 extent that such health care services would otherwise be covered
6 under the health care plan.

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

9 (d) Health care services required for the clinically appropriate
10 monitoring of the insured during the clinical trial or study.

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

21 7. A health care plan subject to the provisions of this chapter
22 that is delivered, issued for delivery or renewed on or after
23 January 1, 2004, has the legal effect of including the coverage
24 required by this section ~~§~~ *on the date the plan is delivered, issued*
25 *for delivery or renewed*, and any provision of the plan that conflicts
26 with this section is void.

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

30 (a) Any injury to an insured caused by:

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

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

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

41 9. As used in this section:

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



- 1 (1) The Clinical Trials Cooperative Group Program; and
- 2 (2) The Community Clinical Oncology Program.
- 3 (b) "Provider of health care" means:
- 4 (1) A hospital; or
- 5 (2) A person licensed pursuant to chapter 630, 631 or 633
- 6 of NRS.



