

ASSEMBLY BILL NO. 502—COMMITTEE ON
HEALTH AND HUMAN SERVICES

MARCH 24, 2003

Referred to Committee on Commerce and Labor

SUMMARY—Requires certain policies of health insurance and health care plans to include coverage for certain medical treatment provided in clinical trial or study. (BDR 57-1196)

FISCAL NOTE: Effect on Local Government: Yes.
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 insurance; requiring certain policies of insurance and health plans to provide coverage for certain medical treatment provided in a clinical trial or study; providing immunity from liability for insurers, medical services corporations, health maintenance organizations and managed care organizations for injury and other adverse outcomes occurring in connection with treatment provided in a clinical trial or study for which coverage is required to be provided; and providing other matters properly relating thereto.

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

1 **Section 1.** Chapter 689A of NRS is hereby amended by
2 adding thereto a new section to read as follows:

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

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

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



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- 1 (1) *An agency of the National Institutes of Health as set*
2 *forth in 42 U.S.C. § 281(b);*
- 3 (2) *A cooperative group;*
- 4 (3) *The Food and Drug Administration as an application*
5 *for a new investigational drug;*
- 6 (4) *The United States Department of Veterans Affairs; or*
- 7 (5) *The United States Department of Defense;*
- 8 (c) *The medical treatment is provided by a provider of health*
9 *care and the facility and personnel have the experience and*
10 *training to provide the treatment in a capable manner;*
- 11 (d) *There is no medical treatment available which is*
12 *considered a more appropriate alternative medical treatment than*
13 *the medical treatment provided in the clinical trial or study;*
- 14 (e) *There is a reasonable expectation based on clinical data*
15 *that the medical treatment provided in the clinical trial or study*
16 *will be at least as effective as any other medical treatment;*
- 17 (f) *The clinical trial or study is conducted in this state; and*
- 18 (g) *The policyholder or subscriber has signed, before his*
19 *participation in the clinical trial or study, a statement of consent*
20 *indicating that he has been informed of, without limitation:*
 - 21 (1) *The procedure to be undertaken;*
 - 22 (2) *Alternative methods of treatment; and*
 - 23 (3) *The risks associated with participation in the clinical*
24 *trial or study, including, without limitation, the general nature and*
25 *extent of such risks.*
- 26 2. *The coverage for medical treatment pursuant to this*
27 *section is required only to the extent that the medical treatment is*
28 *not otherwise provided in connection with the clinical trial or*
29 *study, and is limited to:*
 - 30 (a) *Coverage for any drug or device that is approved for sale*
31 *by the Food and Drug Administration without regard to whether*
32 *the approved drug or device has been approved for use in the*
33 *medical treatment of the policyholder or subscriber.*
 - 34 (b) *The cost of any reasonably necessary health care services*
35 *that are required as a result of the medical treatment provided in*
36 *the clinical trial or study or as a result of any complication arising*
37 *out of the medical treatment provided in the clinical trial or study,*
38 *to the extent that such health care services would otherwise be*
39 *covered under the policy of health insurance.*
 - 40 (c) *The initial consultation to determine whether the*
41 *policyholder or subscriber is eligible to participate in the clinical*
42 *trial or study.*
 - 43 (d) *Health care services required for the clinically appropriate*
44 *monitoring of the policyholder or subscriber during the clinical*
45 *trial or study.*



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

9 *3. The coverage for medical treatment required by this*
10 *section does not include:*

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

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

17 *(c) Health care services that are specifically excluded from*
18 *coverage under the policyholder's or subscriber's policy of health*
19 *insurance, regardless of whether such services are provided under*
20 *the clinical trial or study.*

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

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

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

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

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

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

41 *5. An insurer who delivers or issues for delivery a policy*
42 *specified in subsection 1 shall:*

43 *(a) Include in the disclosure required pursuant to NRS*
44 *689A.390 notice to each policyholder and subscriber under the*
45 *policy of the availability of the benefits required by this section.*



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

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

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

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

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

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

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

22 8. *As used in this section:*

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

27 (1) *The Clinical Trials Cooperative Group Program; and*

28 (2) *The Community Clinical Oncology Program.*

29 (b) *"Provider of health care" means:*

30 (1) *A hospital; or*

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

33 **Sec. 2.** NRS 689A.0404 is hereby amended to read as follows:

34 689A.0404 *Except as otherwise provided in section 1 of this*
35 *act:*

36 1. No policy of health insurance that provides coverage for a
37 drug approved by the Food and Drug Administration for use in the
38 treatment of an illness, disease or other medical condition may be
39 delivered or issued for delivery in this state unless the policy
40 includes coverage for any other use of the drug for the treatment of
41 cancer, if that use is:

42 (a) Specified in the most recent edition of or supplement to:

43 (1) *The United States Pharmacopoeia Drug Information; or*

44 (2) *The American Hospital Formulary Service Drug*
45 *Information; or*



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1 (b) Supported by at least two articles reporting the results of
2 scientific studies that are published in scientific or medical journals,
3 as defined in 21 C.F.R. § 99.3.

4 2. The coverage required pursuant to this section:

5 (a) Includes coverage for any medical services necessary to
6 administer the drug to the insured.

7 (b) Does not include coverage for any:

8 (1) Experimental drug used for the treatment of cancer if that
9 drug has not been approved by the Food and Drug Administration;
10 or

11 (2) Use of a drug that is contraindicated by the Food and
12 Drug Administration.

13 3. 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 October 1, 1999, has the legal effect of including the coverage
16 required by this section, and any provision of the policy that
17 conflicts with the provisions of this section is void.

18 **Sec. 3.** NRS 689A.330 is hereby amended to read as follows:

19 689A.330 If any policy is issued by a domestic insurer for
20 delivery to a person residing in another state, and if the insurance
21 commissioner or corresponding public officer of that other state has
22 informed the Commissioner that the policy is not subject to approval
23 or disapproval by that officer, the Commissioner may by ruling
24 require that the policy meet the standards set forth in NRS 689A.030
25 to 689A.320, inclusive ~~§~~, and *section 1 of this act*.

26 **Sec. 4.** Chapter 689B of NRS is hereby amended by adding
27 thereto a new section to read as follows:

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

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

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

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

37 *(2) A cooperative group;*

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

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

41 *(5) The United States Department of Defense;*

42 *(c) The medical treatment is provided by a provider of health*
43 *care and the facility and personnel have the experience and*
44 *training to provide the treatment in a capable manner;*



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- 1 (d) *There is no medical treatment available which is*
2 *considered a more appropriate alternative medical treatment than*
3 *the medical treatment provided in the clinical trial or study;*
4 (e) *There is a reasonable expectation based on clinical data*
5 *that the medical treatment provided in the clinical trial or study*
6 *will be at least as effective as any other medical treatment;*
7 (f) *The clinical trial or study is conducted in this state; and*
8 (g) *The insured has signed, before his participation in the*
9 *clinical trial or study, a statement of consent indicating that he has*
10 *been informed of, without limitation:*
11 (1) *The procedure to be undertaken;*
12 (2) *Alternative methods of treatment; and*
13 (3) *The risks associated with participation in the clinical*
14 *trial or study, including, without limitation, the general nature and*
15 *extent of such risks.*
16 2. *The coverage for medical treatment pursuant to this*
17 *section is required only to the extent that the medical treatment is*
18 *not otherwise provided in connection with the clinical trial or*
19 *study, and is limited to:*
20 (a) *Coverage for any drug or device that is approved for sale*
21 *by the Food and Drug Administration without regard to whether*
22 *the approved drug or device has been approved for use in the*
23 *medical treatment of the insured person.*
24 (b) *The cost of any reasonably necessary health care services*
25 *that are required as a result of the medical treatment provided in*
26 *the clinical trial or study or as a result of any complication arising*
27 *out of the medical treatment provided in the clinical trial or study,*
28 *to the extent that such health care services would otherwise be*
29 *covered under the policy of group health insurance.*
30 (c) *The initial consultation to determine whether the insured is*
31 *eligible to participate in the clinical trial or study.*
32 (d) *Health care services required for the clinically appropriate*
33 *monitoring of the insured during the clinical trial or study.*
34 *The services provided pursuant to paragraphs (b) and (d) must be*
35 *covered only if the services are provided by a provider with whom*
36 *the insurer has contracted for such services. If the insurer has not*
37 *contracted for the provision of such services, the insurer shall pay*
38 *the provider the rate of reimbursement that is paid to other*
39 *providers with whom the insurer has contracted for similar*
40 *services and the provider shall accept that rate of reimbursement*
41 *as payment in full.*
42 3. *The coverage for medical treatment required by this*
43 *section does not include:*



- 1 (a) Any portion of the clinical trial or study that is customarily
2 paid for by a government or a biotechnical, pharmaceutical or
3 medical industry.
- 4 (b) Coverage for a drug or device described in paragraph (a)
5 of subsection 2 which is paid for by the manufacturer, distributor
6 or provider of the drug or device.
- 7 (c) Health care services that are specifically excluded from
8 coverage under the insured's policy of group health insurance,
9 regardless of whether such services are provided under the clinical
10 trial or study.
- 11 (d) Health care services that are customarily provided by the
12 sponsors of the clinical trial or study free of charge to the
13 participants in the trial or study.
- 14 (e) Extraneous expenses related to participation in the clinical
15 trial or study including, without limitation, travel, housing and
16 other expenses that a participant may incur.
- 17 (f) Any expenses incurred by a person who accompanies the
18 insured during the clinical trial or study.
- 19 (g) Any item or service that is provided solely to satisfy a need
20 or desire for data collection or analysis that is not directly related
21 to the clinical management of the insured.
- 22 (h) Any costs for the management of research relating to the
23 clinical trial or study.
- 24 4. An insurer who delivers or issues for delivery a policy of
25 group health insurance specified in subsection 1, may require
26 copies of the approval or certification issued pursuant to
27 paragraph (b) of subsection 1, the statement of consent signed by
28 the insured, protocols for the clinical trial or study and any other
29 materials related to the scope of the clinical trial or study relevant
30 to the coverage of medical treatment pursuant to this section.
- 31 5. An insurer who delivers or issues for delivery a policy of
32 group health insurance specified in subsection 1 shall:
- 33 (a) Include in the disclosure required pursuant to NRS
34 689B.027 notice to each group policyholder of the availability of
35 the benefits required by this section.
- 36 (b) Provide the coverage required by this section subject to the
37 same deductible, copayment, coinsurance and other such
38 conditions for coverage that are required under the policy.
- 39 6. A policy of group health insurance subject to the
40 provisions of this chapter that is delivered, issued for delivery or
41 renewed on or after January 1, 2004, has the legal effect of
42 including the coverage required by this section, and any provision
43 of the policy that conflicts with this section is void.



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

4 (a) *Any injury to the insured caused by:*

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

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

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

15 8. *As used in this section:*

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

20 (1) *The Clinical Trials Cooperative Group Program; and*

21 (2) *The Community Clinical Oncology Program.*

22 (b) *"Provider of health care" means:*

23 (1) *A hospital; or*

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

26 **Sec. 5.** NRS 689B.0365 is hereby amended to read as follows:
27 689B.0365 *Except as otherwise provided in section 4 of this*
28 *act:*

29 1. No group policy of health insurance that provides coverage
30 for a drug approved by the Food and Drug Administration for use in
31 the treatment of an illness, disease or other medical condition may
32 be delivered or issued for delivery in this state unless the policy
33 includes coverage for any other use of the drug for the treatment of
34 cancer, if that use is:

35 (a) Specified in the most recent edition of or supplement to:

36 (1) *The United States Pharmacopoeia Drug Information; or*

37 (2) *The American Hospital Formulary Service Drug*
38 *Information; or*


39 (b) Supported by at least two articles reporting the results of
40 scientific studies that are published in scientific or medical journals,
41 as defined in 21 C.F.R. § 99.3.

42 2. The coverage required pursuant to this section:

43 (a) Includes coverage for any medical services necessary to
44 administer the drug to the employee or member of the insured
45 group.



1 (b) Does not include coverage for any:

2 (1) Experimental drug used for the treatment of cancer  if
3 that drug has not been approved by the Food and Drug
4 Administration; or

5 (2) Use of a drug that is contraindicated by the Food and
6 Drug Administration.

7 3. A policy subject to the provisions of this chapter that is
8 delivered, issued for delivery or renewed on or after October 1,
9 1999, has the legal effect of including the coverage required by this
10 section, and any provision of the policy that conflicts with the
11 provisions of this section is void.

12 **Sec. 6.** Chapter 695B of NRS is hereby amended by adding
13 thereto a new section to read as follows:

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

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

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

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

24 *(2) A cooperative group;*

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

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

28 *(5) The United States Department of Defense;*

29 *(c) The medical treatment is provided by a provider of health*
30 *care and the facility and personnel have the experience and*
31 *training to provide the treatment in a capable manner;*

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

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

38 *(f) The clinical trial or study is conducted in this state; and*

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

42 *(1) The procedure to be undertaken;*

43 *(2) Alternative methods of treatment; and*



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

4 2. *The coverage for medical treatment pursuant to this*
5 *section is required only to the extent that the medical treatment is*
6 *not otherwise provided in connection with the clinical trial or*
7 *study, and is limited to:*

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

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

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

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

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

31 3. *The coverage for medical treatment required by this*
32 *section does not include:*

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

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

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

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



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

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

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

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

11 4. *A medical services corporation that delivers or issues for*
12 *delivery a policy of health insurance specified in subsection 1, may*
13 *require copies of the approval or certification issued pursuant to*
14 *paragraph (b) of subsection 1, the statement of consent signed by*
15 *the insured, protocols for the clinical trial or study and any other*
16 *materials related to the scope of the clinical trial or study relevant*
17 *to the coverage of medical treatment pursuant to this section.*

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

21 (a) *Include in the disclosure required pursuant to NRS*
22 *695B.172 notice to each person insured under the policy of the*
23 *availability of the benefits required by this section.*

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

27 6. *A policy of health insurance subject to the provisions of*
28 *this chapter that is delivered, issued for delivery or renewed on or*
29 *after January 1, 2004, has the legal effect of including the*
30 *coverage required by this section, and any provision of the policy*
31 *that conflicts with this section is void.*

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

35 (a) *Any injury to the insured caused by:*

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

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

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



1 8. *As used in this section:*

2 (a) *“Cooperative group” means a network of facilities that*
3 *collaborate on research projects and has established a peer review*
4 *program approved by the National Institutes of Health. The term*
5 *includes:*

6 (1) *The Clinical Trials Cooperative Group Program; and*
7 (2) *The Community Clinical Oncology Program.*

8 (b) *“Provider of health care” means:*

9 (1) *A hospital; or*

10 (2) *A person licensed pursuant to chapter 630, 631 and 633*
11 *of NRS.*

12 **Sec. 7.** NRS 695B.1908 is hereby amended to read as follows:

13 695B.1908 *Except as otherwise provided in section 6 of this*
14 *act:*

15 1. No contract for hospital or medical services that provides
16 coverage for a drug approved by the Food and Drug Administration
17 for use in the treatment of an illness, disease or other medical
18 condition may be delivered or issued for delivery in this state unless
19 the contract includes coverage for any other use of the drug for the
20 treatment of cancer, if that use is:

21 (a) Specified in the most recent edition of or supplement to:

22 (1) *The United States Pharmacopoeia Drug Information; or*


23 (2) *The American Hospital Formulary Service Drug*
24 *Information; or*

25 (b) Supported by at least two articles reporting the results of
26 scientific studies that are published in scientific or medical journals,
27 as defined in 21 C.F.R. § 99.3.

28 2. The coverage required pursuant to this section:

29 (a) Includes coverage for any medical services necessary to
30 administer the drug to a person covered under the contract.

31 (b) Does not include coverage for any:

32 (1) Experimental drug used for the treatment of cancer  if
33 that drug has not been approved by the Food and Drug
34 Administration; or

35 (2) Use of a drug that is contraindicated by the Food and
36 Drug Administration.

37 3. A contract for hospital or medical services subject to the
38 provisions of this chapter that is delivered, issued for delivery or
39 renewed on or after October 1, 1999, has the legal effect of
40 including the coverage required by this section, and any provision of
41 the contract that conflicts with the provisions of this section is void.

42 **Sec. 8.** Chapter 695C of NRS is hereby amended by adding
43 thereto a new section to read as follows:

44 1. *Except as otherwise provided in NRS 695C.050, a health*
45 *care plan issued by a health maintenance organization must*



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1 *provide coverage for medical treatment which an enrollee receives*
2 *as part of a clinical trial or study if:*

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

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

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

9 *(2) A cooperative group;*

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

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

13 *(5) The United States Department of Defense;*

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

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

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

23 *(f) The clinical trial or study is conducted in this state; and*

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

27 *(1) The procedure to be undertaken;*

28 *(2) Alternative methods of treatment; and*

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

32 *2. The coverage for medical treatment pursuant to this*
33 *section is required only to the extent that the medical treatment is*
34 *not otherwise provided in connection with the clinical trial or*
35 *study, and is limited to:*

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

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



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

3 (d) *Health care services required for the clinically appropriate*
4 *monitoring of the enrollee during the clinical trial or study.*
5 *The services provided pursuant to paragraphs (b) and (d) must be*
6 *covered only if the services are provided by a provider with whom*
7 *the health maintenance organization has contracted for such*
8 *services. If the health maintenance organization has not*
9 *contracted for the provision of such services, the health*
10 *maintenance organization shall pay the provider the rate of*
11 *reimbursement that is paid to other providers with whom the*
12 *health maintenance organization has contracted for similar*
13 *services and the provider shall accept that rate of reimbursement*
14 *as payment in full.*

15 3. *The coverage for medical treatment required by this*
16 *section does not include:*

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

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

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

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

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

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

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

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

40 4. *A health maintenance organization that delivers or issues*
41 *for delivery a health care plan specified in subsection 1, may*
42 *require copies of the approval or certification issued pursuant to*
43 *paragraph (b) of subsection 1, the statement of consent signed by*
44 *the enrollee, protocols for the clinical trial or study and any other*



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

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

5 (a) *Include in the disclosure required pursuant to NRS*
6 *695C.193 notice to each enrollee 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*
10 *conditions for coverage that are required under the plan.*

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

16 7. *A health maintenance organization that delivers or issues*
17 *for delivery a health care plan specified in subsection 1 is immune*
18 *from liability for:*

19 (a) *Any injury to an enrollee caused by:*

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

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

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

30 8. *As used in this section:*

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

35 (1) *The Clinical Trials Cooperative Group Program; and*

36 (2) *The Community Clinical Oncology Program.*

37 (b) *"Provider of health care" means:*

38 (1) *A hospital; or*

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

41 **Sec. 9.** *NRS 695C.050 is hereby amended to read as follows:*

42 695C.050 1. *Except as otherwise provided in this chapter or*
43 *in specific provisions of this title, the provisions of this title are not*
44 *applicable to any health maintenance organization granted a*
45 *certificate of authority under this chapter. This provision does not*



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1 apply to an insurer licensed and regulated pursuant to this title
2 except with respect to its activities as a health maintenance
3 organization authorized and regulated pursuant to this chapter.

4 2. Solicitation of enrollees by a health maintenance
5 organization granted a certificate of authority, or its representatives,
6 must not be construed to violate any provision of law relating to
7 solicitation or advertising by practitioners of a healing art.

8 3. Any health maintenance organization authorized under this
9 chapter shall not be deemed to be practicing medicine and is exempt
10 from the provisions of chapter 630 of NRS.

11 4. The provisions of NRS 695C.110, 695C.170 to 695C.200,
12 inclusive, 695C.250 and 695C.265 *and section 8 of this act* do not
13 apply to a health maintenance organization that provides health care
14 services through managed care to recipients of Medicaid under the
15 state plan for Medicaid or insurance pursuant to the Children's
16 Health Insurance Program pursuant to a contract with the Division
17 of Health Care Financing and Policy of the Department of Human
18 Resources. This subsection does not exempt a health maintenance
19 organization from any provision of this chapter for services
20 provided pursuant to any other contract.

21 5. The provisions of NRS 695C.1694 and 695C.1695 apply to
22 a health maintenance organization that provides health care services
23 through managed care to recipients of Medicaid under the state plan
24 for Medicaid.

25 **Sec. 10.** NRS 695C.1733 is hereby amended to read as
26 follows:

27 695C.1733 *Except as otherwise provided in section 8 of this*
28 *act:*

29 1. No evidence of coverage that provides coverage for a drug
30 approved by the Food and Drug Administration for use in the
31 treatment of an illness, disease or other medical condition may be
32 delivered or issued for delivery in this state unless the evidence of
33 coverage includes coverage for any other use of the drug for the
34 treatment of cancer, if that use is:

35 (a) Specified in the most recent edition of or supplement to:

36 (1) The *United States Pharmacopoeia Drug Information*; or

37 (2) The *American Hospital Formulary Service Drug*
38 *Information*; or

39 (b) Supported by at least two articles reporting the results of
40 scientific studies that are published in scientific or medical journals,
41 as defined in 21 C.F.R. § 99.3.

42 2. The coverage required pursuant to this section:

43 (a) Includes coverage for any medical services necessary to
44 administer the drug to the enrollee.

45 (b) Does not include coverage for any:



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1 (1) Experimental drug used for the treatment of cancer ~~§~~ if
2 that drug has not been approved by the Food and Drug
3 Administration; or

4 (2) Use of a drug that is contraindicated by the Food and
5 Drug Administration.

6 3. Any evidence of coverage subject to the provisions of this
7 chapter that is delivered, issued for delivery or renewed on or after
8 October 1, 1999, has the legal effect of including the coverage
9 required by this section, and any provision of the evidence of
10 coverage that conflicts with the provisions of this section is void.

11 **Sec. 11.** NRS 695C.330 is hereby amended to read as follows:

12 695C.330 1. The Commissioner may suspend or revoke any
13 certificate of authority issued to a health maintenance organization
14 pursuant to the provisions of this chapter if he finds that any of the
15 following conditions exist:

16 (a) The health maintenance organization is operating
17 significantly in contravention of its basic organizational document,
18 its health care plan or in a manner contrary to that described in and
19 reasonably inferred from any other information submitted pursuant
20 to NRS 695C.060, 695C.070 and 695C.140, unless any amendments
21 to those submissions have been filed with and approved by the
22 Commissioner;

23 (b) The health maintenance organization issues evidence of
24 coverage or uses a schedule of charges for health care services
25 which do not comply with the requirements of NRS ~~695C.170~~
26 ~~695C.1694~~ to 695C.200, inclusive, ~~for 695C.1694, 695C.1695~~ or
27 695C.207 ~~§~~ *or section 8 of this act*;

28 (c) The health care plan does not furnish comprehensive health
29 care services as provided for in NRS 695C.060;

30 (d) The State Board of Health certifies to the Commissioner that
31 the health maintenance organization:

32 (1) Does not meet the requirements of subsection 2 of NRS
33 695C.080; or

34 (2) Is unable to fulfill its obligations to furnish health care
35 services as required under its health care plan;

36 (e) The health maintenance organization is no longer financially
37 responsible and may reasonably be expected to be unable to meet its
38 obligations to enrollees or prospective enrollees;

39 (f) The health maintenance organization has failed to put into
40 effect a mechanism affording the enrollees an opportunity to
41 participate in matters relating to the content of programs pursuant to
42 NRS 695C.110;

43 (g) The health maintenance organization has failed to put into
44 effect the system for *resolving* complaints required by NRS
45 695C.260 in a manner reasonably to dispose of valid complaints;



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1 (h) The health maintenance organization or any person on its
2 behalf has advertised or merchandised its services in an untrue,
3 misrepresentative, misleading, deceptive or unfair manner;

4 (i) The continued operation of the health maintenance
5 organization would be hazardous to its enrollees; or

6 (j) The health maintenance organization has otherwise failed to
7 comply substantially with the provisions of this chapter.

8 2. A certificate of authority must be suspended or revoked only
9 after compliance with the requirements of NRS 695C.340.

10 3. If the certificate of authority of a health maintenance
11 organization is suspended, the health maintenance organization shall
12 not, during the period of that suspension, enroll any additional
13 groups or new individual contracts, unless those groups or persons
14 were contracted for before the date of suspension.

15 4. If the certificate of authority of a health maintenance
16 organization is revoked, the organization shall proceed, immediately
17 following the effective date of the order of revocation, to wind up its
18 affairs and shall conduct no further business except as may be
19 essential to the orderly conclusion of the affairs of the organization.
20 It shall engage in no further advertising or solicitation of any kind.
21 The Commissioner may, by written order, permit such further
22 operation of the organization as he may find to be in the best interest
23 of enrollees to the end that enrollees are afforded the greatest
24 practical opportunity to obtain continuing coverage for health care.

25 **Sec. 12.** Chapter 695G of NRS is hereby amended by adding
26 thereto a new section to read as follows:

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

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

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

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

37 *(2) A cooperative group;*

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

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

41 *(5) The United States Department of Defense;*

42 *(c) The medical treatment is provided by a provider of health*
43 *care and the facility and personnel have the experience and*
44 *training to provide the treatment in a capable manner;*



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- 1 (d) *There is no medical treatment available which is*
2 *considered a more appropriate alternative medical treatment than*
3 *the medical treatment provided in the clinical trial or study;*
4 (e) *There is a reasonable expectation based on clinical data*
5 *that the medical treatment provided in the clinical trial or study*
6 *will be at least as effective as any other medical treatment;*
7 (f) *The clinical trial or study is conducted in this state; and*
8 (g) *The insured has signed, before his participation in the*
9 *clinical trial or study, a statement of consent indicating that he has*
10 *been informed of, without limitation:*
11 (1) *The procedure to be undertaken;*
12 (2) *Alternative methods of treatment; and*
13 (3) *The risks associated with participation in the clinical*
14 *trial or study, including, without limitation, the general nature and*
15 *extent of such risks.*
16 2. *The coverage for medical treatment pursuant to this*
17 *section is required only to the extent that the medical treatment is*
18 *not otherwise provided in connection with the clinical trial or*
19 *study, and is limited to:*
20 (a) *Coverage for any drug or device that is approved for sale*
21 *by the Food and Drug Administration without regard to whether*
22 *the approved drug or device has been approved for use in the*
23 *medical treatment of the insured.*
24 (b) *The cost of any reasonably necessary health care services*
25 *that are required as a result of the medical treatment provided in*
26 *the clinical trial or study or as a result of any complication arising*
27 *out of the medical treatment provided in the clinical trial or study,*
28 *to the extent that such health care services would otherwise be*
29 *covered under the health care plan.*
30 (c) *The initial consultation to determine whether the insured is*
31 *eligible to participate in the clinical trial or study.*
32 (d) *Health care services required for the clinically appropriate*
33 *monitoring of the insured during the clinical trial or study.*
34 *The services provided pursuant to paragraphs (b) and (d) must be*
35 *covered only if the services are provided by a provider with whom*
36 *the managed care organization has contracted for such services. If*
37 *the managed care organization has not contracted for the*
38 *provision of such services, the managed care organization shall*
39 *pay the provider the rate of reimbursement that is paid to other*
40 *providers with whom the managed care organization has*
41 *contracted for similar services and the provider shall accept that*
42 *rate of reimbursement as payment in full.*
43 3. *The coverage for medical treatment required by this*
44 *section does not include:*



- 1 (a) Any portion of the clinical trial or study that is customarily
2 paid for by a government or a biotechnical, pharmaceutical or
3 medical industry.
- 4 (b) Coverage for a drug or device described in paragraph (a)
5 of subsection 2 which is paid for by the manufacturer, distributor
6 or provider of the drug or device.
- 7 (c) Health care services that are specifically excluded from
8 coverage under the insured's health care plan, regardless of
9 whether such services are provided under the clinical trial or
10 study.
- 11 (d) Health care services that are customarily provided by the
12 sponsors of the clinical trial or study free of charge to the
13 participants in the trial or study.
- 14 (e) Extraneous expenses related to participation in the clinical
15 trial or study including, without limitation, travel, housing and
16 other expenses that a participant may incur.
- 17 (f) Any expenses incurred by a person who accompanies the
18 insured during the clinical trial or study.
- 19 (g) Any item or service that is provided solely to satisfy a need
20 or desire for data collection or analysis that is not directly related
21 to the clinical management of the insured.
- 22 (h) Any costs for the management of research relating to the
23 clinical trial or study.
- 24 4. A managed care organization that delivers or issues for
25 delivery a health care plan specified in subsection 1, may require
26 copies of the approval or certification issued pursuant to
27 paragraph (b) of subsection 1, the statement of consent signed by
28 the insured, protocols for the clinical trial or study and any other
29 materials related to the scope of the clinical trial or study relevant
30 to the coverage of medical treatment pursuant to this section.
- 31 5. A managed care organization that delivers or issues for
32 delivery a health care plan specified in subsection 1 shall:
- 33 (a) Include in the disclosure required pursuant to NRS
34 695C.193 notice to each person insured under the plan of the
35 availability of the benefits required by this section.
- 36 (b) Provide the coverage required by this section subject to the
37 same deductible, copayment, coinsurance and other such
38 conditions for coverage that are required under the plan.
- 39 6. A health care plan subject to the provisions of this chapter
40 that is delivered, issued for delivery or renewed on or after
41 January 1, 2004, has the legal effect of including the coverage
42 required by this section, and any provision of the plan that
43 conflicts with this section is void.



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

4 (a) *Any injury to an insured caused by:*

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

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

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

15 8. *As used in this section:*

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

20 (1) *The Clinical Trials Cooperative Group Program; and*

21 (2) *The Community Clinical Oncology Program.*

22 (b) *"Provider of health care" means:*

23 (1) *A hospital; or*

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

26 **Sec. 13.** NRS 287.010 is hereby amended to read as follows:

27 287.010 1. The governing body of any county, school
28 district, municipal corporation, political subdivision, public
29 corporation or other public agency of the State of Nevada may:

30 (a) Adopt and carry into effect a system of group life, accident
31 or health insurance, or any combination thereof, for the benefit of its
32 officers and employees, and the dependents of officers and
33 employees who elect to accept the insurance and who, where
34 necessary, have authorized the governing body to make deductions
35 from their compensation for the payment of premiums on the
36 insurance.

37 (b) Purchase group policies of life, accident or health insurance,
38 or any combination thereof, for the benefit of such officers and
39 employees, and the dependents of such officers and employees, as
40 have authorized the purchase, from insurance companies authorized
41 to transact the business of such insurance in the State of Nevada,
42 and, where necessary, deduct from the compensation of officers and
43 employees the premiums upon insurance and pay the deductions
44 upon the premiums.



1 (c) Provide group life, accident or health coverage through a
2 self-insurance reserve fund and, where necessary, deduct
3 contributions to the maintenance of the fund from the compensation
4 of officers and employees and pay the deductions into the fund. The
5 money accumulated for this purpose through deductions from
6 the compensation of officers and employees and contributions of the
7 governing body must be maintained as an internal service fund as
8 defined by NRS 354.543. The money must be deposited in a state or
9 national bank or credit union authorized to transact business in the
10 State of Nevada. Any independent administrator of a fund created
11 under this section is subject to the licensing requirements of chapter
12 683A of NRS, and must be a resident of this state. Any contract
13 with an independent administrator must be approved by the
14 Commissioner of Insurance as to the reasonableness of
15 administrative charges in relation to contributions collected and
16 benefits provided. The provisions of NRS 689B.030 to 689B.050,
17 inclusive, and 689B.575 *and section 4 of this act* apply to coverage
18 provided pursuant to this paragraph, except that the provisions of
19 NRS 689B.0359 do not apply to such coverage.

20 (d) Defray part or all of the cost of maintenance of a self-
21 insurance fund or of the premiums upon insurance. The money for
22 contributions must be budgeted for in accordance with the laws
23 governing the county, school district, municipal corporation,
24 political subdivision, public corporation or other public agency of
25 the State of Nevada.

26 2. If a school district offers group insurance to its officers and
27 employees pursuant to this section, members of the board of trustees
28 of the school district must not be excluded from participating in the
29 group insurance. If the amount of the deductions from compensation
30 required to pay for the group insurance exceeds the compensation to
31 which a trustee is entitled, the difference must be paid by the trustee.

32 **Sec. 14.** NRS 287.04335 is hereby amended to read as
33 follows:

34 287.04335 If the Board provides health insurance through a
35 plan of self-insurance, it shall comply with the provisions of *section*
36 *12 of this act and* NRS 689B.255, 695G.150, 695G.160, 695G.170
37 and 695G.200 to 695G.230, inclusive, in the same manner as an
38 insurer that is licensed pursuant to title 57 of NRS is required to
39 comply with those provisions.

40 **Sec. 15.** This act becomes effective on January 1, 2004.

