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FIRST REPRINT **A.B. 502**

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:

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

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

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

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

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

(2) A cooperative group;

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

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

(5) The United States Department of Defense;

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

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

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

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

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

(1) The procedure to be undertaken;

(2) Alternative methods of treatment; and

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

2. The coverage for medical treatment required by this section includes, without limitation:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8. As used in this section:

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

(1) The Clinical Trials Cooperative Group Program; and

(2) The Community Clinical Oncology Program.

(b) "Provider of health care" means:

(1) A hospital; or

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

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

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

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

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

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

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

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

2. The coverage required pursuant to this section:

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

(b) Does not include coverage for any:

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

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

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

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

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

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

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

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

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

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

(2) A cooperative group;

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

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

(5) The United States Department of Defense;

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

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

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

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

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

(1) The procedure to be undertaken;

(2) Alternative methods of treatment; and

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

2. The coverage for medical treatment required by this section includes, without limitation:

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

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

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

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

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

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

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

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

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

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

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

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

4. An insurer who delivers or issues for delivery a policy of group health insurance specified in subsection 1, may require copies of the approval or certification issued pursuant to

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

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

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

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

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

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

(a) Any injury to the insured caused by:

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

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

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

8. As used in this section:

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

(1) The Clinical Trials Cooperative Group Program; and

(2) The Community Clinical Oncology Program.

(b) "Provider of health care" means:

(1) A hospital; or

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

Sec. 5. NRS 689B.0365 is hereby amended to read as follows:

689B.0365 ***Except as otherwise provided in section 4 of this act:***

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

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

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

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

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

2. The coverage required pursuant to this section:

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

(b) Does not include coverage for any:

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

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

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

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

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

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

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

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

(2) A cooperative group;

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

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

(5) The United States Department of Defense;

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

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

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

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

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

(1) The procedure to be undertaken;

(2) Alternative methods of treatment; and

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

2. The coverage for medical treatment required by this section includes, without limitation:

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

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

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

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

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

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

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

(c) Health care services that are specifically excluded from coverage under the insured's policy of health insurance,

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

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

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

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

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

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

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

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

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

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

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

(a) Any injury to the insured caused by:

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

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

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

8. As used in this section:

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

(1) The Clinical Trials Cooperative Group Program; and

(2) The Community Clinical Oncology Program.

(b) "Provider of health care" means:

(1) A hospital; or

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

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

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

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

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

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

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

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

2. The coverage required pursuant to this section:

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

(b) Does not include coverage for any:

(1) Experimental drug used for the treatment of cancer ~~[.]~~ ~~,~~ if that drug has not been approved by the Food and Drug Administration; or

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

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

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

1. A health care plan issued by a health maintenance organization must provide coverage for medical treatment which an enrollee receives as part of a clinical trial or study if:

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

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

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

(2) A cooperative group;

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

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

(5) The United States Department of Defense;

(c) The medical treatment is provided by:

(1) A provider of health care;

(2) If the health maintenance organization has a list of providers of health care given by the health maintenance organization, a provider of health care who is included on that list; and

(3) Facility and personnel who have the experience and training to provide the treatment in a capable manner;

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

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

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

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

(1) The procedure to be undertaken;

(2) Alternative methods of treatment; and

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

2. The coverage for medical treatment required by this section includes, without limitation:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Any injury to an enrollee caused by:

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

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

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

8. As used in this section:

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

(1) The Clinical Trials Cooperative Group Program; and

(2) The Community Clinical Oncology Program.

(b) "Provider of health care" means:

(1) A hospital; or

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

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

695C.050 1. Except as otherwise provided in this chapter or in specific provisions of this title, the provisions of this title are not applicable to any health maintenance organization granted a certificate of authority under this chapter. This provision does not apply to an insurer licensed and regulated pursuant to this title except with respect to its activities as a health maintenance organization authorized and regulated pursuant to this chapter.

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

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

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

5. The provisions of NRS 695C.1694 and 695C.1695 ***and section 8 of this act*** apply to a health maintenance organization that provides health care services through managed care to recipients of Medicaid under the state plan for Medicaid.

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

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

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

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

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

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

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

2. The coverage required pursuant to this section:

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

(b) Does not include coverage for any:

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

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

3. Any evidence of coverage subject to the provisions of this chapter that is delivered, issued for delivery or renewed on or after

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) A cooperative group;

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

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

(5) The United States Department of Defense;

(c) The medical treatment is provided by:

(1) A provider of health care;

(2) If the managed care organization has established a panel of providers of health care for the purpose of offering health care services pursuant this chapter or chapter 689A, 689B, 689C, 695A, 695B or 695C of NRS, a provider of health care who is included on the panel; and

(3) Facility and personnel who have the experience and training to provide the treatment in a capable manner;

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

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

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

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

(1) The procedure to be undertaken;

(2) Alternative methods of treatment; and

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

2. The coverage for medical treatment required by this section includes, without limitation:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Any injury to an insured caused by:

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

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

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

8. As used in this section:

(a) "Cooperative group" means a network of facilities that collaborate on research projects and has established a peer review

program approved by the National Institutes of Health. The term includes:

(1) The Clinical Trials Cooperative Group Program; and

(2) The Community Clinical Oncology Program.

(b) "Provider of health care" means:

(1) A hospital; or

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

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

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

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

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

(c) Provide group life, accident or health coverage through a self-insurance reserve fund and, where necessary, deduct contributions to the maintenance of the fund from the compensation of officers and employees and pay the deductions into the fund. The money accumulated for this purpose through deductions from the compensation of officers and employees and contributions of the governing body must be maintained as an internal service fund as defined by NRS 354.543. The money must be deposited in a state or national bank or credit union authorized to transact business in the State of Nevada. Any independent administrator of a fund created under this section is subject to the licensing requirements of chapter 683A of NRS, and must be a resident of this state. Any contract with an independent administrator must be approved by the Commissioner of Insurance as to the reasonableness of administrative charges in relation to contributions collected and benefits provided. The provisions of NRS 689B.030 to 689B.050, inclusive, and 689B.575 ***and section 4 of this act*** apply to coverage

provided pursuant to this paragraph, except that the provisions of NRS 689B.0359 do not apply to such coverage.

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

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

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

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

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