REPORT OF THE
SPECIAL ADVISORY COMMISSION ON
MANDATED HEALTH INSURANCE BENEFITS

MANDATED COVERAGE FOR CLINICAL TRIALS FOR LIFE-THREATENING DISEASES

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

SENATE DOCUMENT NO. 39

COMMONWEALTH OF VIRGINIA
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COMMONWEALTH OF VIRGINIA

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SENATE

January 13, 2000

To: The Honorable James S. Gilmore, III
Governor of Virginia
and
The General Assembly of Virginia

The report contained herein has been prepared pursuant to §§ 9-298 and 9-299 of the Code of Virginia.

This report documents a study conducted by the Special Advisory Commission on mandated Health Insurance Benefits (Advisory Commission) to assess the social and financial impact and the medical efficacy of Senate Bill 1033 regarding mandated coverage for clinical trials for life-threatening diseases.

Respectfully submitted,

Stephen H. Martin
Chairman
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INTRODUCTION

Senate Bill 1033 was referred to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) by the Senate Committee on Commerce and Labor. The patron of the bill is Senator Emily Couric. The bill amends § 38.2-4319 and adds § 38.2-3418.8 in the Code of Virginia.

The Advisory Commission held a hearing to receive comments on the bill on June 30, 1999, in Richmond. In addition to the patron, two physicians and a citizen spoke in support of coverage for clinical trials. Representatives of the Virginia Association of Health Plans (VAHP) and the Health Insurance Association of America (HIAA) spoke about their concerns with the bill. Written comments were received from two physicians who support coverage for clinical trials. Written comments opposed to the bill were received from the HIAA, the VAHP, and the Virginia Manufacturers Association (VMA).

Senator Couric acknowledged that the concerns that prompted the introduction of the legislation were addressed by the passage of language from House Bill 2404 that was incorporated into House Bill 871. The enactment of the bill addressed the Senator's concerns, and she does not believe that passage of Senate Bill 1033 is necessary.

SUMMARY OF PROPOSED LEGISLATION

The bill requires insurers proposing to issue individual or group accident and sickness policies providing hospital, medical and surgical, or major medical coverage on an expense incurred basis; corporations providing individual or group subscription contracts and health maintenance organizations (HMOs) providing health care plans for health care services to provide coverage for clinical trials for life-threatening diseases. The bill applies to policies, contracts or plans delivered, issued for delivery or renewal in the Commonwealth, on and after July 1, 1999.

The bill requires that reimbursement for participation in clinical trials for life-threatening diseases shall be determined according to the same formula as charges are developed for other medical and surgical procedures.

The coverage is to have durational limits, dollar limits, deductible and coinsurance factors that are not less favorable than for physical illness generally.

The bill defines the terms "cooperative group," "FDA," "Member," "Multiple project assurance contract," "NIH" and "patient cost" in subsection C.

Subsection D of the bill requires that coverage for clinical trials for life-threatening diseases shall be provided for participation in a clinical trial as a result of (i) a life-threatening condition or (ii) prevention, early detection and treatment studies on cancer. The coverage shall be required if (i) the treatment is being conducted in a Phase I, II, III, or IV clinical trial for cancer or (ii) the treatment is being conducted in a Phase II, III, or IV clinical trial for any other life-threatening condition. The treatment may be provided on a case-by-case basis, if the treatment is being provided in a Phase I clinical trial for any life-threatening condition other than cancer.

Subsection E provides that the treatment described in subsection D shall be provided by a clinical trial approved by either one of the National Institutes of Health (NIH); an NIH cooperative group or an NIH center; the Food and Drug Administration (FDA) in the form of an investigational new drug application; the Federal Department of Veterans Affairs; or an institutional review board of an institution in Virginia that has a multiple project assurance contract approved by the Office of Protection from Research Risks of the NIH.

The bill provides, in subsection F, that the facility and personnel providing the treatment shall be capable of doing so by virtue of their experience, training, and expertise.

The coverage under this bill applies only if (i) there is no clearly superior, noninvestigational treatment alternative and (ii) the available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the noninvestigational alternative.

The bill does not apply to short-term travel, accident-only, limited or specified disease policies or contracts designed for issuance to persons eligible for coverage under Medicare, or other similar coverage under state or governmental plans, or to short-term nonrenewable policies of not more than six months' duration.

TECHNICAL CONCERNS WITH BILL LANGUAGE

Senate Bill 1033 includes the phrase "life-threatening diseases." However, the phrase is not defined in the bill. The bill is not defined in Title 38.2 and was not located elsewhere in the Code of Virginia. Information from the National Institutes of Health's Office of Communications and Public Liaison Office indicates that each institute has its own guidelines and protocols, and a single definition of "life-threatening diseases" is not available. The Food and Drug Administration also indicated that there is no single definition for the term used by that agency. The term is used and defined in the Code of Federal Regulations, Title 21, Volume 5, Section 312.81. The section defines the term for investigation for new drug applications. The section appears below:

Sec. 323.81 Scope.

This section applies to new drug and biological products that are being studied for their safety and effectiveness in treating life-threatening or severely-debilitating diseases.

(a) For purposes of this section, the term "life-threatening" means:

(1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted; and

(2) Diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival.

(b) For purposes of this section, the term "severely debilitating" means diseases or conditions that cause major irreversible morbidity.

(c) Sponsors are encouraged to consult with FDA on the applicability of these procedures to specific products.

CLINICAL TRIALS

The term "clinical trial" denotes the clinical evaluation where new interventions against disease are tested prospectively on people. When a new drug, for example, is produced in a laboratory and is ready for testing, the first trials (Phase I) are usually conducted to define the toxicity and pharmacology and the safe dosage. The Phase I trials are small studies with usually 36 or less participants. The Phase I studies are often performed in specialized centers. If the new drug is proven to be tolerable, larger collaborative Phase II studies begin to assess the efficacy. These studies often involve a number of centers.

The Phase III trials include the more definitive studies and focus on the relative efficacy and tolerability of the treatment compared to the standard of care. This phase can include hundreds or thousands of patients in numerous locations across the United States. Studies of this type are usually sponsored by agencies of the government or drug companies. Physicians and nurses serve as clinicians and investigators. Statisticians, data managers, and quality control monitors are also included to accurately collect and analyze data.

The NIH is currently running more than 1,000 clinical research studies on many different diseases. There are clinical trials on heart disease, Acquired Immune Deficiency Syndrome, cancer, and a wide range of other diseases.

Before a new drug or device is approved for sale, the FDA requires evidence of the safety and effectiveness of the drug or device. The evidence of the safety and effectiveness comes from tests with laboratory animals and then from humans, who volunteer for clinical trials.

Individuals taking part in clinical trials are not always patients in hospitals and institutions. Many are patients of private practitioners that are conducting clinical research.

SOCIAL IMPACT

Senate Bill 1033 would require coverage for clinical trials for "life-threatening" diseases. Life-threatening diseases could be interpreted broadly to include cancer, heart disease, AIDS, and many other conditions. A number of Virginians could be included in the approximately 1,000 current NIH clinical trials. Over 20,000 new patients are included in treatment trials each year.

It is highly unlikely that the majority of the clinical trials participants would reside in Virginia or any single state.

FINANCIAL IMPACT

According to information from the National Institute of General Medical Sciences, it has been estimated that basic research costs in the United States were less than 1% of total health care costs. Investment in basic biomedical research is viewed as providing savings, benefits, and sometimes profits. Selma J. Mushkin, author of "Biomedical Research: Costs and Benefits," performed an economic analysis of biomedical research that was performed from 1900 to 1975. Her analysis determined that for every $1 invested in research, there was a return of from $10 to $16 in increased productivity due to longer life and a reduction in illnesses.

MEDICAL EFFICACY

The FDA issued regulations in 1976 that require Institutional Review Boards (IRBs) for all institutionalized subjects. The regulations were amended in 1981 to require that all studies needing a FDA research permit be reviewed and approved by an IRB before tests on humans begin. The IRB is composed of at least five people with varying backgrounds that are knowledgeable by virtue of training or experience in the research areas likely to be conducted. Racial, ethnic, and other interests must be represented; at least one member must come from a nonscientific discipline and at least one must not be affiliated with the research institution. The IRBs review research before it is conducted to protect the rights of the participants and to safeguard their welfare.

A 1967 FDA policy statement outlined the consent process for clinical trials and required that consent be obtained, in writing, for the early stages of research. The FDA revised its regulations in 1981 to require that all studies of products obtain written informed consent.

The FDA relies on the review of responsible IRBs to ensure that research studies are not unnecessarily risky and that the studies are valid. The IRBs and the informed consent process are believed to adequately protect the welfare of participants.

INSURANCE COVERAGE

The State Corporation Commission's Bureau of Insurance surveyed 50 of the top writers of accident and sickness insurance in Virginia regarding the bills referred to the Advisory Commission for review. Twenty-nine companies responded by April 9, 1999. Five indicated that they have little applicable health insurance business in force in Virginia and could not provide the requested information. Twenty-four companies completed the survey. Twenty of the responding companies indicated that they do not provide coverage for participation in clinical trials for life-threatening diseases in their standard contracts. Two companies indicated that they do provide the coverage proposed by Senate Bill 1033. The remaining two companies determine coverage on a case-by-case basis.

SIMILAR LEGISLATION IN OTHER STATES

According to information available from the National Insurance Law Service and individual insurance department responses, the State of Maryland has legislation in place requiring coverage for participation in clinical trials for cancer and for other life-threatening conditions. Rhode Island requires coverage for clinical trials for cancer treatment, and Georgia requires coverage for clinical trials for treatment of children's cancer. Legislation was passed in 1999 in Illinois to require the offer of coverage for clinical trials for cancer treatment. A clinical trials mandate was proposed in Arizona but was not passed. Legislation has also been proposed in Louisiana. Legislation in Georgia requires clinical trials coverage for routine patient care costs incurred in connection with the provision of goods, services, and benefits to dependent children in connection with approved clinical trial programs for the treatment of children's cancer.

Rhode Island requires coverage for new cancer therapies still under investigation when the treatment is being provided in connection with a Phase II, III, or IV clinical trial approved by the NIH in cooperation with the NCI Community oncology programs, the FDA, the Department of Veteran's Affairs, or a qualified

nongovernmental research entity as identified in NCI guidelines for support grants. The provision also includes requirements that the therapy be reviewed and approved by a qualified IRB; the facility and personnel are capable; the patients meet all protocol requirements; there is no clearly superior, noninvestigational alternative; the available clinical or preclinical data provide a reasonable expectation that the protocol treatment will be at least as efficacious as the noninvestigational alternative; and the coverage for the treatment for a Phase II trial is not required for only that part of the treatment. The parts of a Phase II trial customarily funded by government, biotechnical and/or pharmaceutical or medical device industry must continue. This coverage does not "supplant" other customary funding.

Maryland requires coverage for patient costs for clinical trials as a result of treatment for a life-threatening condition or prevention, early detection, and treatment studies on cancer. The coverage is required if the treatment is being conducted in a Phase I, Phase II, or Phase III, or Phase IV clinical trial for cancer or a Phase II, Phase III, or Phase IV clinical trial for any other life-threatening condition. The treatment must also be in a trial approved by one of the NIHs; an NIH cooperative group or an NIH center; the FDA in the form of an investigational new drug application; the Federal Department of Veteran's Affairs; or an institutional review with a multiple project assurance contract approved by the Office of Protection from Research Risks of the NIH. The facility and personnel providing the treatment must be capable; there must be no clearly superior, noninvestigational treatment alternative; and the available clinical or preclinical data must provide a reasonable expectation that the treatment will be at least as effective as the noninvestigational alternative. The coverage may be provided on a case-by-case basis for treatment in Phase I clinical trials, for a life-threatening condition other than cancer. The insurer must provide coverage for patient costs for drugs and devices approved for sale by the FDA, whether the FDA has approved the drug or device for the patient's particular condition.

REVIEW CRITERIA

SOCIAL IMPACT

a. *The extent to which the treatment or service is generally utilized by a significant portion of the population.*

There are over 1,000 clinical research studies being run by the National Institutes of Health on different diseases. Over 20,000 new patients are included in treatment trials each year.

b. The extent to which insurance coverage for the treatment or service is already generally available.

The Bureau of Insurance surveyed the top fifty writers of accident and sickness in Virginia regarding proposals for mandated benefits. Twenty-four companies completed the survey. Twenty of the companies do not provide coverage for participation for clinical trials for life-threatening diseases in their standard contracts. Two companies indicated that they provide the coverage proposed by Senate Bill 1033. Two companies determine coverage on a case-by-case basis.

c. If coverage is not generally available, the extent to which the lack of coverage results in persons being unable to obtain necessary health care treatments.

The American Cancer Society believes that enrollment in clinical trials is dropping because of reasons that include lack of coverage by health plans for routine patient costs, complex enrollment and treatment approval processes, and limited access to medical centers that conduct trials.

d. If the coverage is not generally available, the extent to which the lack of coverage results in unreasonable financial hardship on those persons needing treatment.

Proponents believe that a lack of coverage is believed to result in patients receiving standard treatments and not enrolling in clinical trials.

e. The level of public demand for the treatment or service.

The exact level of demand from the public to participate in clinical trials for life-threatening diseases is not known.

f. The level of public demand and the level of demand from providers for individual or group insurance coverage of the treatment or service.

Two providers spoke at the public hearing in support of Senate Bill 1033. They believe that many people feel threatened that they may "lose insurance coverage" if they participate in clinical trials. They believe that more patients would enter trials if they could feel secure about insurance coverage and that the expansion of trials would benefit many others.

g. *The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts.*

The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts is not known.

h. *Any relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.*

No information or findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit were presented to the Advisory Commission.

FINANCIAL IMPACT

a. *The extent to which the proposed insurance coverage would increase or decrease the cost of treatment or service over the next five years.*

Coverage for participation in clinical trials for life-threatening diseases is not expected to impact the cost of treatment in the next five years.

b. *The extent to which the proposed insurance coverage might increase the appropriate or inappropriate use of the treatment or service.*

Proponents of the bill believe that the bill will increase appropriate use of clinical trials.

The VAHP commented that Senate Bill 1033 requires coverage for Phase I clinical trials for cancer and that side effects for these treatments are not known ahead of time. Because of possible significant risks to patients, VAHP member plans are concerned about their enrollees. They believe that coverage for Phase I trials should be on a case-by-case basis as required by House Bill 871.

The VAHP is also concerned about the broadening of coverage to include prevention and early detection studies. They are concerned about the expansion because it is open-ended. Insurers and HMOs could be responsible for numerous studies that may not benefit the patients. This could include behavioral research studies such as smoking cessation and diet modification. They believe the trials may involve risk to the patient and higher health care premiums.

c. *The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.*

The clinical trials participation would provide health care in place of the standard treatment for the illness. Proponents of the bill cited the results of the Mayo Clinic study of patients treated from 1988 to 1994. The study's results appeared in the May 19, 1999 issue of the Journal of the National Cancer Institute. The study found an average cost per patient in clinical cancer trials of $46,424 and an average cost of $44,133 for patients receiving standard treatment.

d. *The extent to which the insurance coverage may affect the number and types of providers of the mandated treatment or service over the next five years.*

The number of providers and types of providers is not expected to be affected by coverage for clinical trials for life-threatening diseases.

e. *The extent to which insurance coverage might be expected to increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.*

Six insurers provided estimates on the impact of the coverage required by Senate Bill 1033 on individual contracts. The insurers provided estimates that ranged from $.44 to $8 per month to include the coverage in a standard contract. One insurer estimated .2%. Ten insurers provided estimates of the impact on group premiums. The ten estimates included a range of $1 to $16 per month; 1.01% and 5% per month; $.08 per member per month and $1.65 per member per month.

f. *The impact of coverage on the total cost of health care.*

Proponents believe that because the bill is limited to patient costs, it will not greatly impact total health care. They believe that the majority of the costs for trials are for the investigational drugs, devises, data management, and other administrative costs that are not included in the bill and are addressed by the health care institution and pharmaceutical company.

MEDICAL EFFICACY

a. *The contribution of the benefit to the quality of patient care and the health status of the population, including the results of any research demonstrating*

the medical efficacy of the treatment or service compared to alternatives or not providing the treatment or service.

Proponents cited the impact of clinical trials on cancers in children. According to their information, in the 1970s and 1980s approximately 70% of all children who were cancer patients were treated in clinical trials. They believe that the current rate of curable cancer for children, 75%, is the result of the trials in those years.

The VAHP acknowledged that clinical research is vital and well designed, and high quality clinical trials expand knowledge about the safety and efficacy of new treatments. However, they believe that not all clinical trials are well designed. They believe insurers and health plans should be able to assess clinical trials individually. They believe that some clinical trials "offer limited benefits to patients, may not be innovative, or are too small-scale to provide a meaningful answer to questions of safety and efficacy."

The VAHP pointed to the agreement between the American Association of Health Plans (AAHP) and the National Institutes of Health. They believe that it is more appropriate to expand coverage for clinical trials through this type of agreement.

b. *If the legislation seeks to mandate coverage of an additional class of practitioners:*

1) *The results of any professionally acceptable research demonstrating the medical results achieved by the additional class of practitioners relative to those already covered.*

Not applicable.

2) *The methods of the appropriate professional organization that assure clinical proficiency.*

Not applicable.

EFFECTS OF BALANCING THE SOCIAL, FINANCIAL, AND MEDICAL EFFICACY CONSIDERATIONS

a. *The extent to which the benefit addresses a medical or a broader social need and whether it is consistent with the role of health insurance.*

The HIAA made the point that insurance and HMO plans generally provide coverage for specific medical services that are deemed medically necessary and appropriate and in accordance with the acceptable standards of medical practice in the community.

b. The extent to which the need to coverage outweighs the costs of mandating the benefit for all policyholders.

VAHP noted that "life-threatening" conditions can include a plethora of diseases including cardiovascular disease, hypertension, and diabetes. They believe that the number of potential enrollees would directly impact health care premiums.

VMA states that "life-threatening conditions" is not defined in the bill. Phase I clinical trials coverage may encourage more clinical trials that increase premiums and result in more uninsureds when employers and employees are unable to afford health insurance.

HIAA commented that mandated coverage for clinical trials will pass along costs that have been paid traditionally by government and private research funds to health care insurance. They believe that with the exemption of self-insured plans from mandates because of ERISA, the mandate will shift the cost of medical research to small employers and individuals.

c. The extent to which the need for coverage may be solved by mandating the availability of the coverage as an option for policyholders.

It is expected that a mandated offer of coverage would be higher because the cost would be paid by only those selecting the benefit. Group contract holders would make the coverage selection and not the individual insured.

RECOMMENDATION

The Advisory Commission recognized the positive impact of clinical trials on health care. However, there are a number of concerns with the bill, including the lack of a definition for "life-threatening" diseases. The recent passage of legislation in Virginia mandating coverage for cancer trials, the 1999 agreement between the NIH and the AAHP, and the statement by the bill's patron indicate that enactment of the bill is not necessary at this time.

CONCLUSION

The Advisory Commission voted on Senate Bill 1033 at its July 28, 1999 meeting. The vote was unanimous to recommend that Senate Bill 1033 not be enacted.

The Advisory Commission believes that the enactment of House Bill 871 and its requirement of coverage of participation in cancer trials will address the majority of the concerns advocated by the parties that supported Senate Bill 1033.

993312635

SENATE BILL NO. 1033

Offered January 20, 1999

A BILL to amend and reenact § 38.2-4319 of the Code of Virginia, and to amend the Code of Virginia by adding a section numbered 38.2-3418.8, relating to accident and sickness insurance; coverage for clinical trials for life-threatening diseases.

Patrons—Couric, Colgan, Edwards, Gartlan, Holland, Houck, Howell, Lambert, Lucas, Marsh, Marye, Maxwell, Miller, Y.B., Puckett, Reynolds, Saslaw, Ticer, Walker and Whipple; Delegate: Keating

Referred to Committee on Commerce and Labor

Be it enacted by the General Assembly of Virginia:

1. That § 38.2-4319 of the Code of Virginia is amended and reenacted, and that the Code of Virginia is amended by adding a section numbered 38.2-3418.8, as follows:

§ 38.2-3418.8. Coverage for clinical trials for life-threatening diseases.

A. Notwithstanding the provisions of § 38.2-3419, each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; each corporation providing individual or group accident and sickness subscription contracts; and each health maintenance organization providing a health care plan for health care services shall provide coverage for clinical trials for life-threatening diseases under any such policy, contract or plan delivered, issued for delivery, or renewed in this Commonwealth on and after July 1, 1999.

B. The reimbursement for the participation in clinical trials for life-threatening diseases shall be determined according to the same formula by which charges are developed for other medical and surgical procedures. Such coverage shall have durational limits, dollar limits, deductibles and coinsurance factors that are no less favorable than for physical illness generally.

C. For purposes of this section:

"Cooperative group" means a formal network of facilities that collaborate on research projects and have an established NIH-approved peer review program operating within the group. "Cooperative group" includes (i) the National Cancer Institute Clinical Cooperative group, (ii) the National Cancer Institute Community Clinical Oncology Program, (iii) the AIDS Clinical Trials Group, and (iv) the Community Programs for Clinical Research in AIDS.

"FDA" means the Federal Food and Drug Administration.

"Member" means a policyholder, subscriber, insured, or certificate holder or a covered dependent of a policyholder, subscriber, insured or certificate holder.

"Multiple project assurance contract" means a contract between an institution and the federal Department of Health and Human Services that defines the relationship of the institution to the federal Department of Health and Human Services and sets out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects.

"NIH" means the National Institutes of Health.

"Patient cost" means the cost of a medically necessary health care service that is incurred as a result of the treatment being provided to the member for purposes of a clinical trial. "Patient cost" does not include (i) the cost of nonhealth care services that a patient may be required to receive as a result of the treatment being provided for purposes of a clinical trial, (ii) costs associated with managing the research associated with the clinical trial, or (iii) costs that would not be covered under the patient's policy, plan, or contract for noninvestigational treatments.

D. Coverage for clinical trials for life-threatening diseases shall be provided for participation in a clinical trial as a result of (i) a life-threatening condition or (ii) prevention, early detection, and treatment studies on cancer. Such coverage shall be required if:

1. The treatment is being conducted in a Phase I, Phase II, Phase III, or Phase IV clinical trial for cancer; or

2. The treatment is being conducted in a Phase II, Phase III, or Phase IV clinical trial for any other life-threatening condition. Such treatment may, however, be provided on a case-by-case basis if the treatment is being provided in a Phase I clinical trial for any life-threatening condition other than

cancer.

E. The treatment described in subsection D shall be provided by a clinical trial approved by:

1. One of the National Institutes of Health;

2. An NIH cooperative group or an NIH center;

3. The FDA in the form of an investigational new drug application;

4. The Federal Department of Veterans Affairs; or

5. An institutional review board of an institution in the Commonwealth that has a multiple project assurance contract approved by the Office of Protection from Research Risks of the NIH.

F. The facility and personnel providing the treatment shall be capable of doing so by virtue of their experience, training, and expertise.

G. Coverage under this section shall apply only if:

1. There is no clearly superior, noninvestigational treatment alternative; and

2. The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the noninvestigatonal alternative.

H. The provisions of this section shall not apply to short-term travel, accident-only, limited or specified disease policies or contracts designed for issuance to persons eligible for coverage under Title XVIII of the Social Security Act, known as Medicare, or any other similar coverage under state or governmental plans or to short-term nonrenewable policies of not more than six months' duration.

§ 38.2-4319. Statutory construction and relationship to other laws.

A. No provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-200, 38.2-203, 38.2-210 through 38.2-213, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-305, 38.2-316, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.) of this title, 38.2-1057, 38.2-1306.2 through 38.2-1309, Articles 4 (§ 38.2-1317 et seq.) and 5 (§ 38.2-1322 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.) and 2 (§ 38.2-1412 et seq.) of Chapter 14, §§ 38.2-1800 through 38.2-1836, 38.2-3401, 38.2-3405, 38.2-3405.1, 38.2-3407.2 through 38.2-3407.6, 38.2-3407.9, 38.2-3407.10, 38.2-3407.11, 38.2-3407.12, 38.2-3411.2, 38.2-3414.1, 38.2-3418.1 through ~~38.2-3418.7~~ *38.2-3418.8*, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3542, 38.2-3543.2, Chapter 53 (§ 38.2-5300 et seq.) and Chapter 58 (§ 38.2-5800 et seq.) of this title shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§ 38.2-4200 et seq.) of this title except with respect to the activities of its health maintenance organization.

B. Solicitation of enrollees by a licensed health maintenance organization or by its representatives shall not be construed to violate any provisions of law relating to solicitation or advertising by health professionals.

C. A licensed health maintenance organization shall not be deemed to be engaged in the unlawful practice of medicine. All health care providers associated with a health maintenance organization shall be subject to all provisions of law.

D. Notwithstanding the definition of an eligible employee as set forth in § 38.2-3431, a health maintenance organization providing health care plans pursuant to § 38.2-3431 shall not be required to offer coverage to or accept applications from an employee who does not reside within the health maintenance organization's service area.