VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 32.1-137.6, 32.1-137.7, 32.1-137.9, 32.1-137.13 through 32.1-137.16, 38.2-4214, 38.2-4319, 38.2-4509, and 38.2-5900 of the Code of Virginia; to amend the Code of Virginia by adding in Title 38.2 a chapter numbered 35.1, consisting of sections numbered 38.2-3556 through 38.2-3571; and to repeal §§ 38.2-5901, 38.2-5902, 38.2-5903, and 38.2-5905 of the Code of Virginia, relating to health insurance; internal and external review process; Office of the Managed Care Ombudsman.

[H 1928]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-137.6, 32.1-137.7, 32.1-137.9, 32.1-137.13 through 32.1-137.16, 38.2-4214, 38.2-4319, 38.2-4509, and 38.2-5900 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding in Title 38.2 a chapter numbered 35.1, consisting of sections numbered 38.2-3556 through 38.2-3571, as follows:

§ 32.1-137.6. Complaint system.

A. Each managed care health insurance plan licensee subject to § 32.1-137.2 shall establish and maintain for each of its managed care health insurance plans a complaint system approved by the Commissioner and the Bureau of Insurance to provide reasonable procedures for the resolution of written complaints in accordance with the requirements established under this article and Title 38.2, and shall include the following:

1. A record of the complaints shall be maintained for the period set forth in § 32.1-137.16 for review by the Commissioner.

2. Each managed care health insurance plan licensee shall provide complaint forms and/or written procedures to be given to covered persons who wish to register written complaints. Such forms or procedures shall include the address and telephone number of the managed care licensee to which complaints shall be directed and the mailing address, telephone number, and the electronic mail address of the Office of the Managed Care Ombudsman established pursuant to § 38.2-5904 and shall also specify any required limits imposed by or on behalf of the managed care health insurance plan. Such forms and written procedures shall include a clear and understandable description of the covered person's right to appeal adverse ~~decisions~~ *determinations* pursuant to § 32.1-137.15.

B. The Commissioner, in cooperation with the Bureau of Insurance, shall examine the complaint system. The effectiveness of the complaint system of the managed care health insurance plan licensee in allowing covered persons, or their duly authorized representatives, to have issues regarding quality of care appropriately resolved under this article shall be assessed by the State Health Commissioner under this article. Compliance by the health carrier and its managed care health insurance plans with the terms and procedures of the complaint system, as well as the provisions of Title 38.2, shall be assessed by the Bureau of Insurance.

C. As part of the renewal of a certificate, each managed care health insurance plan licensee shall submit to the Commissioner and to the Office of the Managed Care Ombudsman an annual complaint report in a form agreed and prescribed by the Board and the Bureau of Insurance. The complaint report shall include, but shall not be limited to (i) a description of the procedures of the complaint system, (ii) the total number of complaints handled through the complaint system, (iii) the disposition of the complaints, (iv) a compilation of the nature and causes underlying the complaints filed, (v) the time it took to process and resolve each complaint, and (vi) the number, amount, and disposition of malpractice claims adjudicated during the year with respect to any of the managed care health insurance plan's health care providers.

The Department of Human Resource Management and the Department of Medical Assistance Services shall file similar periodic reports with the Commissioner, in a form prescribed by the Board, providing appropriate information on all complaints received concerning quality of care and utilization review under their respective health benefits program and managed care health insurance plan licensee contractors.

D. The Commissioner shall examine the complaint system under subsection B for compliance of the complaint system with respect to quality of care and shall require corrections or modifications as deemed necessary.

E. The Commissioner shall have no jurisdiction to adjudicate individual controversies arising under this article.

F. The Commissioner of Health or the nonprofit organization pursuant to § 32.1-276.4 may prepare a summary of the information submitted pursuant to this provision and § 32.1-122.10:01 to be included in the patient level data base.

§ 32.1-137.7. Definitions.

As used in this article:

"Adverse ~~decision~~ *determination*" means a ~~utilization review~~ determination by the *managed care health insurance plan or its designee* utilization review entity that ~~a health service rendered or proposed to be rendered was or is not medically necessary, when such determination may result in noncoverage of the health service or health services~~, *based upon information provided, a request for a benefit upon application of any utilization review technique does not meet the managed care health insurance plan's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness or is determined to be experimental or investigational and the requested benefit is therefore denied, reduced, or terminated or payment is not provided or made, in whole or in part, for the benefit.* When the policy, contract, plan, certificate, or evidence of coverage includes coverage for prescription drugs and the health service rendered or proposed to be rendered is a prescription for the alleviation of cancer pain, any adverse ~~decision~~ *determination* shall be made within ~~twenty-four~~ *24* hours of the request for coverage.

"Commission" means the Virginia State Corporation Commission.

"Covered person" means a subscriber, policyholder, member, enrollee or dependent, as the case may be, under a policy or contract issued or issued for delivery in Virginia by a managed care health insurance plan licensee, insurer, health services plan, or preferred provider organization.

"Evidence of coverage" includes any certificate, individual or group agreement or contract, or identification card or related documents issued in conjunction with the certificate, agreement or contract, issued to a subscriber setting out the coverage and other rights to which a covered person is entitled.

"Final adverse ~~decision~~ *determination*" means ~~a utilization review~~ *an adverse* determination ~~made by a physician advisor or peer of the treating health care provider in a reconsideration of an adverse decision, and upon which a provider or patient may base an appeal~~ *involving a covered benefit that has been upheld by a managed care health insurance plan, or its designee utilization review entity, at the completion of the managed care health insurance plan's internal appeal process.*

"Medical director" means a physician licensed to practice medicine in the Commonwealth of Virginia who is an employee of a utilization review ~~organization~~ *entity* responsible for compliance with the provisions of this article.

"Peer of the treating health care provider" means a physician or other health care professional who holds a nonrestricted license in the Commonwealth of Virginia or under a comparable licensing law of a state of the United States and in the same or similar specialty as typically manages the medical condition, procedure or treatment under review.

"Physician advisor" means a physician licensed to practice medicine in the Commonwealth of Virginia or under a comparable licensing law of a state of the United States who provides medical advice or information to a private review agent or a utilization review entity in connection with its utilization review activities.

"Private review agent" means a person or entity performing utilization reviews, except that the term shall not include the following entities or employees of any such entity so long as they conduct utilization reviews solely for subscribers, policyholders, members or enrollees:

1. A health maintenance organization authorized to transact business in Virginia; or

2. A health insurer, hospital service corporation, health services plan or preferred provider organization authorized to offer health benefits in this Commonwealth.

"Treating health care provider" or "provider" means a licensed health care provider who renders or proposes to render health care services to a covered person.

"Utilization review" means a system for reviewing the necessity, appropriateness and efficiency of hospital, medical or other health care services rendered or proposed to be rendered to a patient or group of patients for the purpose of determining whether such services should be covered or provided by an insurer, health services plan, managed care health insurance plan licensee, or other entity or person. For purposes of this article, "utilization review" shall include, but not be limited to, preadmission, concurrent and retrospective medical necessity determination, and review related to the appropriateness of the site at which services were or are to be delivered. "Utilization review" shall not include (i) any review of issues concerning insurance contract coverage or contractual restrictions on facilities to be used for the provision of services, (ii) any review of patient information by an employee of or consultant to any licensed hospital for patients of such hospital, or (iii) any determination by an insurer as to the reasonableness and necessity of services for the treatment and care of an injury suffered by an insured for which reimbursement is claimed under a contract of insurance covering any classes of insurance defined in §§ 38.2-117 ~~through~~, *38.2-118,* 38.2-119, 38.2-124 ~~through~~, *38.2-125,* 38.2-126, 38.2-130

~~through~~, *38.2-131,* 38.2-132, and 38.2-134.

"Utilization review entity" or "entity" means a person or entity performing utilization review.

"Utilization review plan" or "plan" means a written procedure for performing review.

§ 32.1-137.9. Requirements and standards for utilization review entities.

A. Each entity shall establish reasonable and prudent standards and criteria to be applied in utilization review determinations with input from physician advisors representing major areas of specialty and certified by the boards of the various American medical specialties. Such standards shall be objective, clinically valid, and compatible with established principles of health care. Such standards shall further be established so as to be sufficiently flexible to allow deviations from norms when justified on case-by-case bases.

The entity shall make available to any provider or covered person, upon written request, a list of such physician advisors and their major areas of specialty, as well as the standards and criteria established in accordance with this section except as prohibited in accordance with copyright laws.

B. An adverse ~~decision~~ *determination* shall be made only in accordance with § 32.1-137.13.

C. Each entity shall have a process for reconsideration of an adverse ~~decision~~ *determination* in accordance with § 32.1-137.14 and an appeals process in accordance with § 32.1-137.15.

D. Each entity shall make arrangements to use the services of physician advisors who are specialists in the various categories of health care on "per need" or "as needed" bases in conducting utilization review.

E. Each entity shall have review staff who are properly qualified, trained and supervised, and supported by a physician advisor, to carry out its review determinations.

F. Each entity shall notify its covered persons of the review process, including the appeals process, and shall so notify the covered person's provider upon written request by the provider. An Evidence of Coverage shall contain a clear and complete statement, if a contract, or a reasonably complete summary, if a certificate, of the process for reconsideration of an adverse ~~decision~~ *determination* rendered under § 32.1-137.13, as required by § 32.1-137.14, and the process for *internal* appeal from ~~a final~~ *an* adverse ~~decision~~ *determination* under § 32.1-137.15.

G. Each entity shall communicate its utilization review decision no later than two business days after receipt by the entity of all information necessary to complete the review.

H. Each entity shall have a representative, authorized to approve utilization review determinations, available to covered persons and providers in accordance with § 32.1-137.11.

I. The Commissioner shall have the right to determine that an entity has complied with the requirement that the entity establish reasonable and prudent requirements and standards pursuant to this section.

§ 32.1-137.13. Adverse decision.

A. The treating provider shall be notified in writing of any adverse ~~decision~~ *determination* within two working days of the ~~decision~~ *determination*; however, the treating provider shall be notified orally by telephone within 24 hours of any adverse ~~decision~~ *determination* for a prescription known to be for the alleviation of cancer pain. Any such notification shall include instructions for the provider on behalf of the covered person to (i) seek a reconsideration of the adverse ~~decision~~ *determination* pursuant to § 32.1-137.14, including the contact name, address, and telephone number of the person responsible for making the adverse ~~decision~~ *determination*, and (ii) seek an appeal of the adverse ~~decision~~ *determination* pursuant to § 32.1-137.15, including the contact name, address, and telephone number to file and perfect such appeal.

B. No entity shall render an adverse ~~decision~~ *determination* unless it has made a good faith attempt to obtain information from the provider. At any time before the entity renders its ~~decision~~ *determination*, the provider shall be entitled to review the issue of medical necessity with a physician advisor or peer of the treating health care provider who represents the entity. For any adverse ~~decision~~ *determination* relating to a prescription to alleviate cancer pain, a physician advisor shall review the issue of medical necessity with the provider.

§ 32.1-137.14. Reconsideration of adverse determination.

A. A treating provider may request reconsideration of an adverse ~~decision~~ *determination* pursuant to this section or may appeal an adverse ~~decision~~ *determination* pursuant to § 32.1-137.15. Any reconsideration of an adverse ~~decision~~ *determination* shall only be requested by the treating provider on behalf of the covered person. A ~~decision~~ *determination* on reconsideration shall be made by a physician advisor, peer of the treating health care provider, or a panel of other appropriate health care providers with at least one physician advisor or peer of the treating health care provider on the panel.

B. The treating provider on behalf of the covered person shall be (i) notified verbally at the time of the determination of the reconsideration of the adverse ~~decision~~ *determination* and in writing following the determination of the reconsideration of the adverse ~~decision~~ *determination*, in accordance with § 32.1-137.9, including the criteria used and the clinical reason for the adverse ~~decision~~ *determination*

and the alternate length of treatment of the alternate treatment setting or settings, if any, that the entity deems to be appropriate, and (ii) notified verbally at the time of the determination of the reconsideration of the adverse ~~decision~~ *determination* of the process for an appeal of the determination pursuant to § 32.1-137.15 and the contact name, address, and telephone number to file and perfect an appeal. If the treating provider on behalf of the covered person requests that the adverse ~~decision~~ *determination* be reviewed by a peer of the treating provider at any time during the reconsideration process, the request for reconsideration shall be vacated and considered an appeal pursuant to § 32.1-137.15. In such cases, the covered person shall be notified that the reconsideration has been vacated and an appeal initiated, all documentation and information provided or relied upon during the reconsideration process pursuant to this section shall be converted to the appeal process, and no additional actions shall be required of the treating provider to perfect the appeal.

C. Any reconsideration shall be rendered and the ~~decision~~ *determination* provided to the treating provider and the covered person in writing within 10 working days of receipt of the request for reconsideration.

§ 32.1-137.15. Adverse determination; appeal.

~~A.~~ Each entity shall establish an *internal* appeals process, including a process for ~~expedited~~ *urgent care* appeals, to consider any ~~final~~ adverse ~~decision~~ *determination* that is appealed by a covered person, his representative, or his provider *in accordance with the provisions of § 38.2-3558*. ~~Except as provided in subsection E, notification of the results of the appeal process shall be provided to the appellant no later than 60 working days after receiving the required documentation. The decision shall be in writing and shall state the criteria used and the clinical reason for the decision. If the appeal is denied, such notification shall include a clear and understandable description of the covered person's right to appeal final adverse decisions to the Bureau of Insurance in accordance with Chapter 59 (§ 38.2-5900 et seq.) of Title 38.2, the procedures for making such an appeal, and the binding nature and effect of such an appeal, including all forms prescribed by the Bureau of Insurance pursuant to § 38.2-5901. Such notification shall also include the mailing address, telephone number, and electronic mail address of the Office of the Managed Care Ombudsman. Further, such notification shall advise any such covered person that, except in the instance of fraud, any such appeal herein may preclude such person's exercise of any other right or remedy relating to such adverse decision. An expedited appeals process of no more than 24 hours shall be established and conducted by telephone to consider any final adverse decision that relates to a prescription to alleviate cancer pain.~~

~~B. Any case under appeal shall be reviewed by a peer of the treating health care provider who proposes the care under review or who was primarily responsible for the care under review. With the exception of expedited appeals, a physician advisor who reviews cases under appeal shall be a peer of the treating health care provider, shall be board certified in the same or similar specialty as the treating health care provider, and shall be specialized in a discipline pertinent to the issue under review.~~

~~A physician advisor or peer of the treating health care provider who renders a decision on appeal shall (i) not have participated in the adverse decision or any prior reconsideration thereof; (ii) not be employed by or a director of the utilization review entity; and (iii) be licensed to practice in Virginia, or under a comparable licensing law of a state of the United States, as a peer of the treating health care provider.~~

~~C. The utilization review entity shall provide an opportunity for the appellant to present additional evidence for consideration on appeal. Before rendering an adverse appeal decision, the utilization review entity shall review the pertinent medical records of the covered person's provider and the pertinent records of any facility in which health care is provided to the covered person which have been furnished to the entity.~~

~~D. In the appeals process, due consideration shall be given to the availability or nonavailability of alternative health care services proposed by the entity. No provision herein shall prevent an entity from considering any hardship imposed by the alternative health care on the patient and his immediate family.~~

~~E. When an adverse decision or adverse reconsideration is made and the treating health care provider believes that the decision warrants an immediate appeal, the treating health care provider shall have the opportunity to appeal the adverse decision or adverse reconsideration by telephone on an expedited basis. The treating health care provider shall have the opportunity to appeal immediately, by telephone, on an expedited basis, an adverse decision or adverse reconsideration relating to a prescription to alleviate cancer pain.~~

~~The decision on an expedited appeal shall be made by a physician advisor, peer of the treating health care provider, or a panel of other appropriate health care providers with at least one physician advisor on the panel.~~

~~The utilization review entity shall decide the expedited appeal no later than one business day after receipt by the entity of all necessary information.~~

~~An expedited appeal may be requested only when the regular reconsideration and appeals process~~

~~will delay the rendering of health care in a manner that would be detrimental to the health of the patient or would subject the cancer patient to pain. Both providers and utilization review entities shall attempt to share the maximum information by telephone, facsimile machine, or otherwise to resolve the expedited appeal in a satisfactory manner.~~

~~An expedited appeal decision may be further appealed through the standard appeal process established by the entity unless all material information and documentation were reasonably available to the provider and to the entity at the time of the expedited appeal, and the physician advisor reviewing the case under expedited appeal was a peer of the treating health care provider, was board certified or board eligible, and specialized in a discipline pertinent to the issue under review.~~

~~F. The appeals process required by this section does not apply to any adverse decision, reconsideration, or final adverse decision rendered solely on the basis that a health benefit plan does not provide benefits for the health care rendered or requested to be rendered.~~

~~G. No entity performing utilization review pursuant to this article or Article 2.1 (§ 32.1-138.6 et seq.) of Chapter 5 of this title, shall terminate the employment or other contractual relationship or otherwise penalize a health care provider for advocating the interest of his patient or patients in the appeals process or invoking the appeals process, unless the provider engages in a pattern of filing appeals that are without merit.~~

§ 32.1-137.16. Records.

Every entity subject to Article 1.1 (§ 32.1-137.1 et seq.) of Chapter 5 ~~of this title~~ and this article shall maintain or cause to be maintained, in writing and at a location accessible to employees of the Department, records of review procedures; the health care qualifications of the entity's staff; the criteria used by the entity to make its ~~decisions~~ *determinations*; records of complaints received, including the manner in which the complaints were resolved; the number and type of adverse ~~decisions,~~ *determinations* and reconsiderations; the number and outcome of final adverse ~~decisions~~ *determinations* and appeals thereof, including a separate record for expedited appeals; and procedures to ensure confidentiality of medical records and personal information. Records of complaints under Article 1.1 (§ 32.1-137.1 et seq.) ~~of this chapter~~ shall be maintained from the date of the entity's last examination and for no less than ~~five~~ *six* years.

Every entity subject to utilization review under this article shall provide, upon request of the Commissioner, data and records pertaining to utilization review from which patient and provider identifiers have been removed. Records shall be maintained or caused to be maintained by the utilization review entity for a period of ~~five~~ *six* years, and all such records shall be subject to examination by the Commissioner or his designee.

CHAPTER 35.1.

HEALTH CARRIER INTERNAL APPEAL PROCESS AND EXTERNAL REVIEW.

§ 38.2-3556. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Adverse determination" means a determination by a health carrier or its designee utilization review entity that an admission, availability of care, continued stay, or other health care service that is a covered benefit has been reviewed and, based upon the information provided, does not meet the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness, and the requested service or payment for the service is therefore denied, reduced, or terminated.

"Ambulatory review" means utilization review of health care services performed or provided in an outpatient setting.

"Authorized representative" means (i) a person to whom a covered person has given express written consent to represent the covered person in an external review, (ii) a person authorized by law to provide substituted consent for a covered person, or (iii) a family member of the covered person or the covered person's treating health care professional only when the covered person is unable to provide consent.

"Best evidence" means evidence based on (i) randomized clinical trials; if randomized clinical trials are not available, then (ii) cohort studies or case-control studies; if clauses (i) and (ii) are not available, then (iii) case-series; or if clauses (i), (ii), and (iii) are not available, then (iv) expert opinion.

"Case-control study" means a retrospective evaluation of two groups of patients with different outcomes to determine which specific interventions the patients received.

"Case management" means a coordinated set of activities conducted for individual patient management of serious, complicated, protracted, or other health conditions.

"Case-series" means an evaluation of a series of patients with a particular outcome, without the use of a control group.

"Certification" means a determination by a health carrier or its designee utilization review entity that an admission, availability of care, continued stay, or other health care service has been reviewed and,

based on the information provided, satisfies the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care, and effectiveness.

"Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols, and practice guidelines used by a health carrier to determine the necessity and appropriateness of health care services.

"Cohort study" means a prospective evaluation of two groups of patients with only one group of patients receiving a specific intervention.

"Concurrent review" means utilization review conducted during a patient's hospital stay or course of treatment.

"Covered benefits" or "benefits" means those health care services to which a covered person is entitled under the terms of a health benefit plan.

"Covered person" means a policyholder, subscriber, enrollee, or other individual participating in a health benefit plan.

"Discharge planning" means the formal process for determining, prior to discharge from a facility, the coordination and management of the care that a patient receives following discharge from a facility.

"Emergency medical condition" means the sudden and, at the time, unexpected onset of a health condition or illness that requires immediate medical attention, where failure to provide medical attention would result in a serious impairment to bodily functions or a serious dysfunction of a bodily organ or part, or would place the person's health in serious jeopardy.

"Emergency services" means health care items and services furnished or required to evaluate and treat an emergency medical condition.

"Evidence-based standard" means the conscientious, explicit, and judicious use of the current best evidence based on the overall systematic review of the research in making decisions about the care of individual patients.

"Expert opinion" means a belief or an interpretation by specialists with experience in a specific area about the scientific evidence pertaining to a particular service, intervention, or therapy.

"Facility" means an institution providing health care services or a health care setting, including hospitals and other licensed inpatient centers; ambulatory surgical or treatment centers; skilled nursing centers; residential treatment centers; diagnostic, laboratory, and imaging centers; and rehabilitation and other therapeutic health settings.

"Final adverse determination" means an adverse determination involving a covered benefit that has been upheld by a health carrier, or its designee utilization review entity, at the completion of the health carrier's internal appeal process.

"Health benefit plan" means a policy, contract, certificate, or agreement offered or issued by a health carrier to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services.

"Health care professional" means a physician or other health care practitioner licensed, accredited, or certified to perform specified health care services consistent with the laws of the Commonwealth.

"Health care provider" or "provider" means a health care professional or a facility.

"Health care services" means services for the diagnosis, prevention, treatment, cure, or relief of a health condition, illness, injury, or disease.

"Health carrier" means an entity, subject to the insurance laws and regulations of the Commonwealth or subject to the jurisdiction of the Commission, that contracts or offers to contract to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including an accident and sickness insurance company, a health maintenance organization, a nonprofit hospital and health service corporation, or a nonstock corporation offering or administering a health services plan, a hospital services plan, or a medical or surgical services plan, or any other entity providing a plan of health insurance, health benefits, or health care services except as excluded under § 38.2-3557.

"Independent review organization" means an entity that conducts independent external reviews of adverse determinations and final adverse determinations.

"Medical or scientific evidence" means evidence found in (i) peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff; (ii) peer-reviewed medical literature, including literature relating to therapies reviewed and approved by a qualified institutional review board, biomedical compendia, and other medical literature that meet the criteria of the National Institutes of Health's Library of Medicine for indexing in Index Medicus (Medline) and Elsevier Science Ltd. for indexing in Excerpta Medica (EMBASE); (iii) medical journals recognized by the Secretary of Health and Human Services under § 1861(t)(2) of the federal Social Security Act; (iv) the following standard reference compendia: the American Hospital Formulary Service-Drug Information; Drug Facts and Comparisons; the American Dental Association Accepted Dental Therapeutics; the United States Pharmacopeia-Drug

Information; National Comprehensive Cancer Network's Drugs & Biologics Compendium; and Elsevier Gold Standard's Clinical Pharmacology; (v) findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including the federal Agency for Healthcare Research and Quality, the National Institutes of Health, the National Cancer Institute, the National Academy of Sciences, the Centers for Medicare and Medicaid Services, the federal Food and Drug Administration, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health care services; or (vi) any other medical or scientific evidence that is comparable to the sources listed in clauses (i) through (v).

"NAIC" means the National Association of Insurance Commissioners.

"Prospective review" means utilization review conducted prior to an admission or a course of treatment.

"Randomized clinical trial" means a controlled, prospective study of patients that have been randomized into an experimental group and a control group at the beginning of the study with only the experimental group of patients receiving a specific intervention and includes study of the groups for variables and anticipated outcomes over time.

"Retrospective review" means a review of medical necessity conducted after services have been provided to a patient, but does not include the review of a claim that is limited to an evaluation of reimbursement levels, veracity of documentation, accuracy of coding, or adjudication for payment.

"Second opinion" means an opportunity or requirement to obtain a clinical evaluation by a provider other than the one originally making a recommendation for a proposed health care service to assess the clinical necessity and appropriateness of the initial proposed health care service.

"Utilization review" means a set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings. Techniques may include ambulatory review, prospective review, second opinion, certification, concurrent review, case management, discharge planning, or retrospective review.

"Utilization review entity" means an individual or entity that conducts utilization review.

§ 38.2-3557. Scope of chapter.

A. This chapter shall apply to all health carriers, except that the provisions of this chapter shall not apply to a policy or certificate that provides coverage only for a specified disease, specified accident or accident-only coverage, credit, disability income, hospital indemnity, long-term care insurance, dental, vision care, or any other limited supplemental benefit or to a Medicare supplement policy of insurance, coverage under a plan through Medicare, Medicaid, or the federal employees health benefits program, self-insured plans, any coverage issued under Chapter 55 of Title 10 of the U.S. Code, and any coverage issued as supplemental to that coverage, any coverage issued as supplemental to liability insurance, workers' compensation or similar insurance, automobile medical payment insurance or any insurance under which benefits are payable with or without regard to fault, whether written on a group blanket or individual basis.

B. Notwithstanding the provisions of this section, self-insured employee welfare benefit plans may request a standard external review from the Commission. "Employee welfare benefit plan" has the meaning set forth in the Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1002(1).

§ 38.2-3558. Health carrier's internal appeal process.

Each health carrier shall establish an internal appeals process, including a process for urgent care appeals, to consider a utilization review adverse determination or other adverse benefit determination or decision that is appealed by a covered person, his authorized representative, or his provider. The Commission shall promulgate regulations effectuating the purpose of this section, including timeframes for filing appeals, types of claims that may be appealed including rescissions, notice requirements, rights of the covered person, and reviewer requirements.

§ 38.2-3559. Notice of right to external review.

A. A health carrier shall notify the covered person in writing of an adverse determination or final adverse determination and the covered person's right to request an external review. The notice of the right to request an external review shall include the following, or substantially similar, language: "We have denied your request for the provision of or payment for a health care service or course of treatment. You may have the right to have our decision reviewed by health care professionals who have no association with us if our decision involved making a judgment as to the medical necessity, appropriateness, health care setting, level of care, or effectiveness of the health care service or treatment you requested by submitting a request for external review to the Commission."

B. The notice of the right to request an external review of an adverse determination shall include the following statements informing the covered person that:

1. If the covered person has a medical condition where the time frame for completion of an expedited internal appeal of an adverse determination would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function, the

covered person or his authorized representative may file a request for an expedited external review pursuant to § 38.2-3562;

2. If the adverse determination involves a denial of coverage based on a determination that the recommended or requested health care service or treatment is experimental or investigational and the covered person's treating physician certifies in writing that the recommended or requested health care service or treatment would be significantly less effective if not promptly initiated, the covered person or his authorized representative may file a request for an expedited external review pursuant to § 38.2-3563;

3. If the covered person or his authorized representative files a request for an expedited internal appeal with the health carrier, he may file at the same time a request for an expedited external review of an adverse determination pursuant to § 38.2-3562 or 38.2-3563. The independent review organization assigned to conduct the expedited external review will determine whether the covered person shall be required to complete the expedited internal appeal prior to conducting the expedited external review; and

4. If the covered person or his authorized representative files a standard appeal with the health carrier's internal appeal process, and the health carrier does not issue a written decision within 30 days following the date the appeal requesting a review is filed and the covered person or his authorized representative did not request or agree to a delay, the covered person or his authorized representative may file a request for external review and shall be considered to have exhausted the health carrier's internal appeal process.

C. The notice of the right to request an external review of a final adverse determination shall include the following statements informing the covered person that:

1. If the covered person has a medical condition where the time frame for completion of a standard external review would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function, the covered person or his authorized representative may file a request for an expedited external review pursuant to § 38.2-3562;

2. If the final adverse determination involves an admission, availability of care, continued stay, or health care service for which the covered person received emergency services, but has not been discharged from a facility, the covered person or his authorized representative may request an expedited external review pursuant to § 38.2-3562; and

3. If the final adverse determination involves a denial of coverage based on a determination that the recommended or requested health care service or treatment is experimental or investigational, the covered person or his authorized representative may file a request for a standard external review pursuant to § 38.2-3563; or if the covered person's treating physician certifies in writing that the recommended or requested health care service or treatment would be significantly less effective if not promptly initiated, the covered person or his authorized representative may request an expedited external review pursuant to subsection B of § 38.2-3563.

D. The health carrier shall include the standard and expedited external review procedures and any forms with the notice of the right to an external review.

§ 38.2-3560. Exhaustion of internal appeal process.

A. A request for an external review shall not be made until the covered person has exhausted the health carrier's internal appeal process.

B. A covered person shall be considered to have exhausted the health carrier's internal appeal process if the covered person or his authorized representative has filed an appeal requesting a review of an adverse determination, and, except to the extent the covered person or his authorized representative requested or agreed to a delay, has not received a written decision from the health carrier within 30 days following the date the appeal was filed with the health carrier.

C. If a covered person or his authorized representative files a request for an expedited internal appeal of an adverse determination with the health carrier, the covered person or his authorized representative is deemed to have exhausted the internal appeal process and may file a request for an expedited external review of the adverse determination at the same time. Upon receipt of a request for an expedited external review of an adverse determination, the independent review organization conducting the external review shall determine whether the covered person shall be required to complete the health carrier's expedited internal appeal process before it conducts the expedited external review. The independent review organization shall promptly notify the covered person and his authorized representative, if any, of this determination, and either proceed with the expedited external review or wait until completion of the internal expedited appeal process.

D. A request for an external review of an adverse determination may be made before the covered person has exhausted the health carrier's internal appeal process whenever the health carrier agrees to waive the exhaustion requirement. If the exhaustion requirement is waived, the covered person or his authorized representative may file a request in writing for a standard external review.

§ 38.2-3561. Standard external review.

A. Within 120 days after the date of receipt of a notice of the right to an external review of a final adverse determination or an adverse determination if the internal appeal process has been deemed to be exhausted or waived, a covered person or his authorized representative may file a request for an external review in writing with the Commission. Within one business day after the date of receipt of a request for external review, the Commission shall send a copy of the request to the health carrier.

B. Within five business days following the date of receipt of the external review request from the Commission, the health carrier shall complete a preliminary review of the request to determine whether:

1. The individual is or was a covered person at the time the health care service was requested or, in the case of a retrospective review, was a covered person at the time the health care service was provided;

2. The health care service is a covered service, except as excluded for not meeting the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness;

3. The covered person has exhausted or is deemed to have exhausted the health carrier's internal appeal process; and

4. All the information and forms required to process the external review are complete.

C. Within one business day after completion of the preliminary review, the health carrier shall notify in writing the Commission, the covered person, and his authorized representative, if any, whether the request is complete and eligible for external review and, if ineligible, the reasons for ineligibility. If the request is not complete, the notice shall include what information or materials are needed to make the request complete. Such notice shall include a statement informing the covered person and his authorized representative, if any, that the health carrier's determination of ineligibility may be appealed to the Commission. If the health carrier makes an ineligibility determination, the Commission may determine that a request is eligible for external review and require that it be referred for external review. In making this determination, the Commission's decision shall be made in accordance with the terms of the covered person's health benefit plan and the requirements of subsection B.

D. Within one business day after the date of receipt of the notice described in subsection C, the Commission shall assign an independent review organization to conduct the external review and notify in writing the health carrier, the covered person, and his authorized representative, if any, of the request's eligibility and acceptance for external review and the name of the assigned independent review organization. The Commission shall include in such notice a statement that the covered person or his authorized representative may submit in writing to the assigned independent review organization, within five business days following the date of receipt, additional information that the independent review organization shall consider when conducting the external review.

E. Within five business days after the date of receipt of the notice from the Commission, the health carrier or its designee utilization review entity shall provide to the assigned independent review organization the documents and any information considered in making the adverse determination or final adverse determination. Failure by the health carrier or its utilization review entity to provide the documents and information within the time specified shall not delay the conduct of the external review. If the health carrier or its utilization review entity fails to provide the documents and information within the time specified, the assigned independent review organization may terminate the external review and make a decision to reverse the adverse determination or final adverse determination. Within one business day after making such decision, the independent review organization shall notify the covered person, his authorized representative, if any, the health carrier, and the Commission.

F. The assigned independent review organization shall review all of the information and documents timely received from the health carrier and any other information submitted in writing by the covered person or his authorized representative. The independent review organization is not required to, but may, accept and consider information submitted late from the covered person or his authorized representative, if any. Upon receipt of any information submitted by the covered person or his authorized representative, the assigned independent review organization shall within one business day forward the information to the health carrier.

G. Upon receipt of the information from the assigned independent review organization, the health carrier may reconsider its adverse determination or final adverse determination. Reconsideration by the health carrier of its adverse determination or final adverse determination shall not delay or terminate the external review. The external review may only be terminated if the health carrier decides to reverse its adverse determination or final adverse determination and provide coverage or payment for the health care service. Within one business day after making the decision to reverse its adverse determination or final adverse determination, the health carrier shall notify the covered person, his authorized representative, if any, the assigned independent review organization, and the Commission in writing of its decision. Upon receipt of the notice of the health carrier's decision to reverse its adverse

determination or final adverse determination, the assigned independent review organization shall terminate the external review.

H. The assigned independent review organization, to the extent the information or documents are available and the independent review organization considers them appropriate, shall also consider the following in reaching a decision:

1. The covered person's medical records;

2. The attending health care professional's recommendation;

3. Consulting reports from appropriate health care professionals and other documents submitted by the health carrier, covered person, his authorized representative, or the covered person's treating provider;

4. The terms of coverage under the covered person's health benefit plan;

5. The most appropriate practice guidelines, which shall include applicable evidence-based standards and may include any other practice guidelines developed by the federal government or national or professional medical societies, boards, and associations;

6. Any applicable clinical review criteria developed and used by the health carrier or its designee utilization review entity; and

7. The opinion of the independent review organization's clinical reviewer or reviewers after considering the information or documents described in subdivisions 1 through 6 to the extent the information or documents are available and the clinical reviewer or reviewers consider appropriate.

In reaching a decision, the assigned independent review organization shall not be bound by any decisions or conclusions reached during the health carrier's utilization review process or the internal appeal process.

I. Within 45 days after the date of receipt of the request for an external review, the assigned independent review organization shall provide written notice of its decision to uphold or reverse the adverse determination or the final adverse determination to the covered person, his authorized representative, if any, the health carrier, and the Commission. The independent review organization shall include in such notice: a general description of the reason for the request for external review; the date the independent review organization received the assignment from the Commission to conduct the external review; the date the external review was conducted; the date of its decision; the principal reason or reasons for its decision, including what applicable, if any, evidence-based standards were a basis for its decision; the rationale for its decision; and references to the evidence or documentation, including evidence-based standards, considered in reaching its decision.

J. Upon receipt of a notice reversing the adverse determination or final adverse determination, the health carrier promptly shall approve the coverage.

§ 38.2-3562. Expedited external review.

A. A covered person or his authorized representative may make a request for an expedited external review with the Commission at the time the covered person receives:

1. An adverse determination if the adverse determination involves a medical condition of the covered person for which the time frame for completion of an expedited internal appeal involving an adverse determination would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function, and the covered person or his authorized representative has filed a request for an expedited internal appeal of the adverse determination; or

2. A final adverse determination if the covered person has a medical condition where the time frame for completion of a standard external review would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function, or if the final adverse determination concerns an admission, availability of care, continued stay, or health care service for which the covered person received emergency services, but has not been discharged from a facility.

B. Upon receipt of a request for an expedited external review, the Commission shall promptly send a copy of the request to the health carrier. Promptly upon receipt of such request, the health carrier shall determine whether the request meets the eligibility requirements in subsection B of § 38.2-3561. The health carrier shall promptly notify the Commission, the covered person, and his authorized representative, if any, of its eligibility determination. Such notice shall include a statement informing the covered person and his authorized representative, if any, that the health carrier's determination of ineligibility may be appealed to the Commission. If the health carrier makes an ineligibility determination, the Commission may determine that a request is eligible for external review and require that it be referred for external review. In making such determination, the Commission decision shall be made in accordance with the terms of the covered person's health benefit plan and the requirements of subsection B of § 38.2-3561.

Upon receipt of the notice that the request meets the eligibility requirements, the Commission shall promptly assign an independent review organization to conduct the expedited external review. The Commission shall promptly notify the health carrier of the name of the assigned independent review

organization.

C. Promptly upon receipt of the notice from the Commission of the name of the independent review organization assigned, the health carrier or its designee utilization review entity shall provide or transmit all necessary documents and information considered in making the adverse determination or final adverse determination to the assigned independent review organization electronically, by telephone, facsimile, or any other available expeditious method.

D. The assigned independent review organization, to the extent the information or documents are available and the independent review organization considers them appropriate, shall also consider the following in reaching a decision:

1. The covered person's pertinent medical records;

2. The attending health care professional's recommendation;

3. Consulting reports from appropriate health care professionals and other documents submitted by the health carrier, covered person, his authorized representative, or the covered person's treating provider;

4. The terms of coverage under the covered person's health benefit plan;

5. The most appropriate practice guidelines, which shall include evidence-based standards, and may include any other practice guidelines developed by the federal government or national or professional medical societies, boards, and associations;

6. Any applicable clinical review criteria developed and used by the health carrier or its designee utilization review entity in making adverse determinations; and

7. The opinion of the independent review organization's clinical reviewer or reviewers after considering the information and documents described in clauses 1 through 6 to the extent the information and documents are available and the clinical reviewer or reviewers consider appropriate.

In reaching a decision, the assigned independent review organization is not bound by any decisions or conclusions reached during the health carrier's utilization review process or internal appeal process.

E. As expeditiously as the covered person's medical condition or circumstances requires, but in no event more than 72 hours after the date of receipt of an eligible request for an expedited external review, the assigned independent review organization shall make a decision to uphold or reverse the adverse determination or final adverse determination and notify the covered person, his authorized representative, if any, the health carrier, and the Commission. If such decision was not in writing, within 48 hours after the date of providing such decision, the assigned independent review organization shall provide written confirmation of the decision to the covered person, his authorized representative, if any, the health carrier, and the Commission and include the information set forth in subsection I of § 38.2-3561.

F. Upon receipt of a decision reversing the adverse determination or final adverse determination, the health carrier shall promptly approve the coverage.

G. An expedited external review shall not be available for retrospective adverse determinations or retrospective final adverse determinations.

§ 38.2-3563. External review of experimental or investigational treatment adverse determinations.

A. Within 120 days after the date of receipt of a notice of the right to an external review of an adverse determination or final adverse determination that involves a denial of coverage based on a determination that the health care service or treatment recommended or requested is experimental or investigational, a covered person or his authorized representative may file a request for external review with the Commission.

B. A covered person or his authorized representative may make an oral request for an expedited external review of the adverse determination or final adverse determination if the covered person's treating physician certifies, in writing, that the recommended or requested health care service or treatment would be significantly less effective if not promptly initiated. The following shall apply with regard to such requests for an expedited external review:

1. Upon receipt of a request for an expedited external review, the Commission shall promptly notify the health carrier;

2. Upon notice of the request for expedited external review, the health carrier shall promptly determine whether the request meets the eligibility requirements in subsection D. The health carrier shall promptly notify the Commission and the covered person and his authorized representative, if any, of its eligibility determination. Such notice shall include a statement informing the covered person and his authorized representative, if any, that a health carrier's ineligibility determination may be appealed to the Commission;

3. If the health carrier makes an ineligibility determination, the Commission may determine that a request is eligible for external review and require that it be referred for external review. The Commission shall make such determination in accordance with the terms of the covered person's health benefit plan and the requirements of subsection D;

4. Upon receipt of the notice that the expedited external review request meets the eligibility requirements, the Commission shall promptly assign an independent review organization to review the expedited request and notify the health carrier of the name of the assigned independent review organization;

5. Promptly upon receipt of the notice of the assigned independent review organization, the health carrier or its designee utilization review entity shall provide or transmit all necessary documents and information considered in making the adverse determination or final adverse determination to the assigned independent review organization electronically, by telephone, facsimile, or any other available expeditious method;

6. Upon receipt of the notice from the Commission, the assigned independent review organization shall promptly assign one or more clinical reviewers in accordance with the provisions of subdivision F 3 to conduct the external review;

7. In reaching an opinion, each clinical reviewer shall also consider the documents listed in subsection J. Each clinical reviewer shall provide an opinion orally or in writing to the assigned independent review organization as expeditiously as the covered person's medical condition or circumstances require, but in no event more than five calendar days after being selected. If the opinion provided was not in writing, within 48 hours following the date of the opinion the clinical reviewer shall provide a written opinion to the assigned independent review organization. The written opinion shall include the information described in subsection K. Recommendations from more than one clinical reviewer shall meet the provisions of subsection L; and

8. Within 48 hours after the date it receives an opinion from all clinical reviewers, the assigned independent review organization shall make a decision and provide notice of the decision orally or in writing to the covered person, his authorized representative, if any, the health carrier, and the Commission. If the notice was not in writing, within 48 hours after the date of the notice, the assigned independent review organization shall provide written confirmation of the decision to the covered person, his authorized representative, if any, the health carrier, and the Commission. The decision shall include the information described in subsection M.

C. Within one business day after the date of receipt of the request for a standard external review, the Commission shall notify the health carrier.

D. Within five business days following the date of receipt of such notice, the health carrier shall conduct and complete a preliminary review of the request to determine whether:

1. The individual is or was a covered person in the health benefit plan at the time the health care service or treatment was recommended or requested or, in the case of a retrospective review, was a covered person in the health benefit plan at the time the health care service or treatment was provided;

2. The recommended or requested health care service or treatment is a covered service except for the health carrier's determination that the service or treatment is experimental or investigational for the particular medical condition and is not explicitly listed as an excluded benefit under the covered person's health benefit plan;

3. The covered person's treating physician has certified that one of the following situations is applicable:

a. Standard health care services or treatments have not been effective in improving the condition of the covered person;

b. Standard health care services or treatments are not medically appropriate for the covered person; or

c. There is no available standard health care service or treatment covered that is more beneficial than the recommended or requested health care service or treatment;

4. The covered person's treating physician:

a. Has recommended a health care service or treatment that the physician certifies, in writing, is likely to be more beneficial to the covered person, in the physician's opinion, than any available standard health care services or treatments; or

b. Who is a licensed, board certified, or board eligible physician qualified to practice in the area of medicine appropriate to treat the covered person's condition, has certified in writing that scientifically valid studies using accepted protocols demonstrate that the health care service or treatment requested is likely to be more beneficial to the covered person than any available standard health care services or treatments;

5. The covered person has exhausted or is deemed to have exhausted the health carrier's internal appeal process; and

6. The covered person has provided all the required information and forms that are necessary to process an external review.

E. Within one business day after completion of the preliminary review, the health carrier shall notify in writing the Commission and the covered person and his authorized representative, if any, whether the

request is complete and eligible for external review. The following shall apply with regard to such requests:

1. If the request is not complete, the health carrier shall inform in writing the Commission, the covered person, and his authorized representative, if any, and include in the notice what information or materials are needed to make the request complete. If the request is not eligible for external review, the health carrier shall inform the covered person, his authorized representative, if any, and the Commission in writing and include in the notice the reasons for its ineligibility. Such notice shall include a statement informing the covered person and his authorized representative, if any, that the health carrier's determination of ineligibility may be appealed to the Commission; and

2. If the health carrier makes an ineligibility determination, the Commission may determine that a request is eligible for external review and require that it be referred for external review. In making this determination, the Commission's decision shall be made in accordance with the terms of the covered person's health benefit plan and the requirements of subsection D.

F. Within one business day after the receipt of the notice from the health carrier, the Commission shall assign an independent review organization to conduct the external review and notify in writing the health carrier, the covered person, and his authorized representative, if any, of the request's eligibility and acceptance for external review, and the name of the assigned independent review organization. The following shall apply with regard to such an external review:

1. The Commission shall include in such notice a statement that the covered person or his authorized representative, if any, may submit in writing to the assigned independent review organization, within five business days following the date of receipt, additional information that the independent review organization shall consider when conducting the external review;

2. Within one business day after the receipt of such notice, the assigned independent review organization shall select one or more clinical reviewers, as it determines is appropriate, to conduct the external review; and

3. In selecting clinical reviewers, the assigned independent review organization shall select physicians or other health care professionals who meet the minimum qualifications of § 38.2-3565 and, through clinical experience in the past three years, are experts in the treatment of the covered person's condition and knowledgeable about the recommended or requested health care service or treatment. Neither the covered person, his authorized representative, if any, nor the health carrier shall choose or control the choice of the physicians or other health care professionals to be selected to conduct the external review.

G. Within five business days after the date of receipt of the notice from the Commission, the health carrier or its designee utilization review entity shall provide to the assigned independent review organization the documents and any information considered in making the adverse determination or the final adverse determination. Failure by the health carrier or its designee utilization review entity to provide the documents and information within the required time specified shall not delay the conduct of the external review. If the health carrier or its designee utilization review entity has failed to provide the documents and information within the required time specified, the assigned independent review entity may terminate the external review and make a decision to reverse the adverse determination or final adverse determination. Promptly upon making such decision, the independent review organization shall notify the covered person, his authorized representative, if any, the health carrier, and the Commission.

H. Each clinical reviewer selected shall review all of the information and documents timely received from the health carrier and any other information submitted in writing by the covered person or his authorized representative. The assigned independent review organization is not required to, but may, accept and consider information submitted late from the covered person or his authorized representative, if any. Upon receipt of any information submitted by the covered person or his authorized representative, within one business day after the receipt of the information, the assigned independent review organization shall forward the information to the health carrier.

I. Upon receipt of the information from the assigned independent review organization, the health carrier may reconsider its adverse determination or final adverse determination. Reconsideration by the health carrier of its adverse determination or final adverse determination shall not delay or terminate the external review. The external review may be terminated only if the health carrier decides to reverse its adverse determination or final adverse determination and provide coverage or payment for the recommended or requested health care service or treatment. Promptly upon making the decision to reverse its adverse determination or final adverse determination, the health carrier shall notify the covered person, his authorized representative, if any, the assigned independent review organization, and the Commission in writing of its decision. Upon receipt of notice of the health carrier's decision to reverse its adverse determination or final adverse determination, the assigned independent review organization shall terminate the external review.

J. To the extent the information or documents are available and the reviewer considers appropriate,

each clinical reviewer shall also consider the following in reaching an opinion:

1. The covered person's pertinent medical records;

2. The attending physician's or health care professional's recommendation;

3. Consulting reports from appropriate health care professionals and other documents submitted by the health carrier, covered person, his authorized representative, or the covered person's treating physician or health care professional;

4. Whether the recommended or requested health care service or treatment is a covered service except for the health carrier's determination that the service or treatment is experimental or investigational; and

5. Whether the recommended or requested health care service or treatment has been approved by the federal Food and Drug Administration, if applicable, for the condition, or medical or scientific evidence or evidence-based standards demonstrate that the expected benefits of the recommended or requested health care service or treatment is more likely than not to be beneficial to the covered person than any available standard health care service or treatment and the adverse risks of the recommended or requested health care service or treatment would not be substantially increased over those of available standard health care services or treatments.

K. Within 20 days after being selected to conduct a standard external review, each clinical reviewer shall provide an opinion to the assigned independent review organization on whether the recommended or requested health care service or treatment should be covered. Each clinical reviewer's opinion shall be in writing and include the following information: a description of the covered person's medical condition; a description of the indicators relevant to determining whether there is sufficient evidence to demonstrate that the recommended or requested health care service or treatment is more likely than not to be more beneficial to the covered person than any available standard health care services or treatments and the adverse risks of the recommended or requested health care service or treatment would not be substantially increased over those of available standard health care services or treatments; a description and analysis of any medical or scientific evidence considered in reaching the opinion; a description and analysis of any evidence-based standard; and information on the extent, if any, to which the reviewer's rationale for the opinion regarding the recommended or requested health care service or treatment is based on (i) whether the health care service or treatment has been approved by the federal Food and Drug Administration for the condition or (ii) medical or scientific evidence or evidence-based standards that demonstrate the recommended or requested health care service or treatment is more likely than not to be more beneficial to the covered person than any available standard health care service or treatment and the adverse risks of the recommended or requested health care service or treatment would not be substantially increased over those of available standard health care services or treatments.

L. Within 20 days after the date it receives an opinion from all clinical reviewers, the assigned independent review organization shall make a decision and provide written notice to the covered person, his authorized representative, if any, the health carrier, and the Commission. If:

1. A majority of the clinical reviewers recommend that the recommended or requested health care service or treatment should be covered, the independent review organization shall make a decision to reverse the health carrier's adverse determination or final adverse determination;

2. A majority of the clinical reviewers recommend that the recommended or requested health care service or treatment should not be covered, the independent review organization shall make a decision to uphold the health carrier's adverse determination or final adverse determination; or

3. The clinical reviewers are evenly split as to whether the recommended or requested health care service or treatment should be covered, the independent review organization shall obtain the opinion of an additional clinical reviewer. The additional clinical reviewer selected shall use the same information as the original clinical reviewers. The selection of the additional clinical reviewer shall not extend the time within which the assigned independent review organization is required to make a decision.

M. The independent review organization shall include in the notice required pursuant to subsection L a general description of the reason for the request for external review; the written opinion of each clinical reviewer, including the recommendation of each clinical reviewer as to whether the recommended or requested health care service or treatment should be covered and the rationale for the reviewer's recommendation; the date the independent review organization was assigned by the Commission to conduct the external review; the date the external review was conducted; the date of its decision; the principal reason or reasons for its decision; and the rationale for its decision.

N. Upon receipt of a notice of a decision reversing the adverse determination or final adverse determination, the health carrier shall promptly approve coverage of the recommended or requested health care service or treatment.

§ 38.2-3564. Binding nature of external review decision.

A. An external review decision is binding on the health carrier. Failure to comply with the assigned

independent review organization's external review decision shall be a knowing and willful violation of this section and subject to one or more of the following: (i) punishment as provided in § 38.2-218, (ii) the suspension or revocation of any license issued by the Commission, or (iii) any order that may be issued by the Commission pursuant to § 38.2-219.

B. An external review decision is binding on the covered person except to the extent the covered person has other remedies available under applicable federal or state law.

C. A covered person or his authorized representative may not file a subsequent request for external review involving the same adverse determination or final adverse determination for which the covered person has already received an external review decision.

§ 38.2-3565. Minimum qualifications for independent review organizations.

A. An independent review organization shall have and maintain written policies and procedures that govern all aspects of both the standard external review process and the expedited external review process and that include, at a minimum:

1. A quality assurance mechanism in place that: ensures that external reviews are conducted within the specified time frames and required notices are provided in a timely manner, ensures the selection of qualified and impartial clinical reviewers to conduct external reviews on behalf of the independent review organization and suitable matching of reviewers to specific cases and that the independent review organization employs or contracts with an adequate number of clinical reviewers to meet this objective, ensures the confidentiality of medical and treatment records and clinical review criteria, and ensures that any person employed by or under contract with the independent review organization adheres to the requirements of this chapter;

2. A toll-free telephone service to receive information on a 24-hour-a-day, seven-day-a-week basis that is capable of accepting, recording, or providing appropriate instruction to incoming telephone callers; and

3. Provisions for maintaining records and providing reports to the Commission in accordance with the requirements set out in § 38.2-3568.

B. All clinical reviewers assigned by an independent review organization to conduct external reviews shall be physicians or other appropriate health care providers who shall meet the following minimum qualifications:

1. Be an expert in the treatment of the covered person's medical condition that is the subject of the external review;

2. Be knowledgeable about the recommended health care service or treatment through recent or current actual clinical experience treating patients with the same or similar medical condition of the covered person;

3. Hold a nonrestricted license in their health care field in a state and, for physicians, a current certification by a recognized American medical specialty board in the area or areas appropriate to the subject of the external review; and

4. Have no history of disciplinary actions or sanctions, including loss of staff privileges or participation restrictions, that have been taken or are pending by any hospital, governmental agency or unit, or regulatory body that raise a substantial question as to the clinical reviewer's physical, mental, or professional competence or moral character.

C. An independent review organization may not own or control, be a subsidiary of, or in any way be owned or controlled by, or exercise control with, a health benefit plan, a national, state, or local trade association of health benefit plans, or a national, state, or local trade association of health care providers.

D. Neither the assigned independent review organization nor any clinical reviewer assigned by the independent organization may have a material professional, familial, or financial conflict of interest with any of the following that is the subject of the external review:

1. The health carrier;

2. The covered person or his authorized representative;

3. Any officer, director, or management employee of the health carrier;

4. The health care provider, the health care provider's medical group, or the independent practice association recommending the health care service or treatment;

5. The facility at which the recommended health care service or treatment would be provided; or

6. The developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended.

E. An independent review organization shall be accredited by a nationally recognized private accrediting entity that has standards that the Commission has determined are equivalent to or exceed the minimum qualifications of this section. The following shall apply with regard to accrediting entities:

1. Upon request, a nationally recognized private accrediting entity shall make its current accreditation standards available to the Commission or the NAIC. The Commission shall initially and

periodically review the accreditation standards of the nationally recognized private accrediting entity to determine whether the entity's standards are, and continue to be, equivalent to or exceed the minimum qualifications established under this section;

2. The Commission may accept a review conducted by the NAIC for the purpose of this determination. The Commission may exclude any private accrediting entity that is not reviewed by the NAIC; and

3. The Commission may approve independent review organizations that are not accredited by a nationally recognized private accrediting entity only if there are no acceptable nationally recognized private accrediting entities providing independent review organization accreditation.

F. An independent review organization shall be unbiased. An independent review organization shall establish and maintain written procedures to ensure that it is unbiased.

§ 38.2-3566. Approval of independent review organizations.

A. Each independent review organization that wishes to be eligible to conduct external reviews shall submit an application to the Commission for approval or reapproval. The Commission may charge a reasonable fee for initial approval and each reapproval.

B. The Commission shall approve independent review organizations that meet the minimum qualifications to conduct external reviews. Such approval is not subject to the Virginia Public Procurement Act (§ 2.2-4300 et seq.).

C. An independent review organization is eligible for approval if it is accredited by a nationally recognized private accrediting entity that the Commission has determined has standards that are equivalent to or at least meet the minimum qualifications for independent review organizations.

D. An approval or reapproval is effective for two years, unless the Commission determines before its expiration that the independent review organization is not satisfying the minimum qualifications or its decisions have been consistently unclear or incomplete. Whenever the Commission determines that an independent review organization has lost its accreditation or does not meet the requirements of this subsection, the Commission shall terminate the approval of the independent review organization and remove it from the list of independent review organizations approved to conduct external reviews.

E. The Commission shall maintain and periodically update a list of approved independent review organizations.

F. The assignment by the Commission of an approved independent review organization shall be done on a random basis, taking into consideration the nature of the health care service or treatment.

§ 38.2-3567. Independent review organizations to be held harmless.

No independent review organization or clinical reviewer working on behalf of an independent review organization or an employee, agent, or contractor of an independent review organization shall be liable in damages to any person for any opinions rendered or acts or omissions performed within the scope of the organization's or person's duties under the law during or upon completion of an external review, unless the opinion was rendered or act or omission performed in bad faith or involved gross negligence.

§ 38.2-3568. External review reporting requirements.

A. An independent review organization shall maintain written records, in the aggregate by state and by health carrier, on all external review requests and external reviews conducted during each calendar year. Each independent review organization shall submit a report to the Commission. The report shall be submitted to the Commission by April 1 of the following calendar year. The report shall include in the aggregate by state, and for each health carrier: the total number of requests for external review; the number of requests for external review resolved and, of those resolved, the number upholding the adverse determination or final adverse determination, and the number reversing the adverse determination or final adverse determination; the average length of time for resolution; a summary of the types of coverages or cases for which an external review was sought; the number of external reviews that were terminated as the result of a reconsideration by the health carrier; and any other information the Commission may request or require. The independent review organization shall retain required written records for at least three years.

B. Each health carrier shall maintain written records, in the aggregate by state and for each type of health benefit plan offered, on all requests for external review. Each health carrier shall submit a report to the Commission. The report shall be submitted to the Commission by April 1 of the following calendar year. The report shall include in the aggregate by state, and by type of health benefit plan: the total number of requests for external review, the number of requests determined eligible for external review, the number of external reviews completed, and any other information the Commission may request or require. The health carrier shall retain required written record for at least three years.

§ 38.2-3569. Funding of external review.

The health carrier against which a request for an external review is filed shall pay the cost incurred by the independent review organization in conducting the external review.

§ 38.2-3570. Disclosure requirements.

Each health carrier shall include a description of the external review procedures in or attached to the policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to covered persons. The description shall include a statement that informs the covered person of his right to file a request for an external review of an adverse determination or final adverse determination with the Commission. The statement shall explain that external review is available when the adverse determination or final adverse determination involves an issue of medical necessity, appropriateness, health care setting, level of care, or effectiveness. The statement shall include the telephone number and address of the Commission. The statement shall inform the covered person that, when filing a request for an external review, the covered person will be required to authorize the release of any medical records of the covered person that may be required to be reviewed for the purpose of reaching a decision on the external review.

§ 38.2-3571. Regulations.

Pursuant to the authority granted by § 38.2-223, the Commission may adopt such rules and regulations as it may deem necessary to implement this chapter.

§ 38.2-4214. Application of certain provisions of law.

No provision of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-218 through 38.2-225, 38.2-230, 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, 38.2-700 through 38.2-705, 38.2-900 through 38.2-904, 38.2-1017, 38.2-1018, 38.2-1038, 38.2-1040 through 38.2-1044, Articles 1 (§ 38.2-1300 et seq.) and 2 (§ 38.2-1306.2 et seq.) of Chapter 13, §§ 38.2-1312, 38.2-1314, 38.2-1315.1, 38.2-1317 through 38.2-1328, 38.2-1334, 38.2-1340, 38.2-1400 through 38.2-1444, 38.2-1800 through 38.2-1836, 38.2-3400, 38.2-3401, 38.2-3404, 38.2-3405, 38.2-3405.1, 38.2-3406.1, 38.2-3406.2, 38.2-3407.1 through 38.2-3407.6:1, 38.2-3407.9 through 38.2-3407.17, 38.2-3409, 38.2-3411 through 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3501, 38.2-3502, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, §§ 38.2-3516 through 38.2-3520 as they apply to Medicare supplement policies, §§ 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3541~~,~~ ~~38.2-3541.1,~~ ~~38.2-3541.2,~~ *through* 38.2-3542, 38.2-3543.2, Article 5 (§ 38.2-3551 et seq.) of Chapter 35, *Chapter 35.1 (§ 38.2-3556 et seq.),* §§ 38.2-3600 through 38.2-3607, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), *and* Chapter 58 (§ 38.2-5800 et seq.) ~~and~~ ~~§ 38.2-5903~~ of this title shall apply to the operation of a plan.

§ 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, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 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.), §§ 38.2-1016.1 through 38.2-1023, 38.2-1057, Article 2 (§ 38.2-1306.2 et seq.), § 38.2-1306.1, § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 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, 38.2-3406.1, 38.2-3407.2 through 38.2-3407.6:1, 38.2-3407.9 through 38.2-3407.17, 38.2-3411.2, 38.2-3411.3, 38.2-3411.4, 38.2-3412.1:01, 38.2-3414.1, 38.2-3418.1 through 38.2-3418.16, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3540.2, 38.2-3541.1, 38.2-3541.2, 38.2-3542, 38.2-3543.2, Article 5 (§ 38.2-3551 et seq.) of Chapter 35, *Chapter 35.1 (§ 38.2-3556 et seq.),* Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), *and* Chapter 58 (§ 38.2-5800 et seq.) ~~and~~ ~~§ 38.2-5903~~ 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.) except with respect to the activities of its health maintenance organization.

B. For plans administered by the Department of Medical Assistance Services that provide benefits pursuant to Title XIX or Title XXI of the Social Security Act, as amended, no provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 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.), §§ 38.2-1016.1 through 38.2-1023, 38.2-1057, § 38.2-1306.1, Article 2 (§ 38.2-1306.2 et seq.), § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 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, §§ 38.2-3401, 38.2-3405, 38.2-3407.2 through 38.2-3407.5, 38.2-3407.6 and 38.2-3407.6:1, 38.2-3407.9, 38.2-3407.9:01, and 38.2-3407.9:02, subdivisions 1, 2, and 3 of subsection F of § 38.2-3407.10, 38.2-3407.11, 38.2-3407.11:3, 38.2-3407.13, 38.2-3407.13:1, and 38.2-3407.14,

38.2-3411.2, 38.2-3418.1, 38.2-3418.2, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3540.2, 38.2-3541.2, 38.2-3542, 38.2-3543.2, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), *and* Chapter 58 (§ 38.2-5800 et seq.) ~~and § 38.2-5903~~ 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.) except with respect to the activities of its health maintenance organization.

C. 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.

D. 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.

E. 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.

F. For purposes of applying this section, "insurer" when used in a section cited in subsections A and B shall be construed to mean and include "health maintenance organizations" unless the section cited clearly applies to health maintenance organizations without such construction.

§ 38.2-4509. Application of certain laws.

A. No provision of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-218 through 38.2-225, 38.2-229, 38.2-316, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, 38.2-900 through 38.2-904, 38.2-1038, 38.2-1040 through 38.2-1044, Articles 1 (§ 38.2-1300 et seq.) and 2 (§ 38.2-1306.2 et seq.) of Chapter 13, §§ 38.2-1312, 38.2-1314, 38.2-1315.1, Article 4 (§ 38.2-1317 et seq.) of Chapter 13, §§ 38.2-1400 through 38.2-1444, 38.2-1800 through 38.2-1836, 38.2-3401, 38.2-3404, 38.2-3405, 38.2-3407.10, 38.2-3407.13, 38.2-3407.14, 38.2-3407.15, 38.2-3407.17, 38.2-3415, 38.2-3541, Article 5 (§ 38.2-3551 et seq.) of Chapter 35, §§ 38.2-3600 through 38.2-3603, Chapter 55 (§ 38.2-5500 et seq.), *and* Chapter 58 (§ 38.2-5800 et seq.) ~~and § 38.2-5903~~ of this title shall apply to the operation of a plan.

B. The provisions of subsection A of § 38.2-322 shall apply to an optometric services plan. The provisions of subsection C of § 38.2-322 shall apply to a dental services plan.

C. The provisions of Article 1.2 (§ 32.1-137.7 et seq.) of Chapter 5 of Title 32.1 shall not apply to either an optometric or dental services plan.

CHAPTER 59.
~~INDEPENDENT EXTERNAL REVIEW OF ADVERSE UTILIZATION REVIEW DECISIONS~~ *OFFICE OF THE MANAGED CARE OMBUDSMAN.*

§ 38.2-5900. Definitions.

As used in this chapter:

"Covered person" means an individual, whether a policyholder, subscriber, enrollee, covered dependent, or member of a managed care health insurance plan, who is entitled to health care services or benefits provided, arranged for, paid for or reimbursed pursuant to a managed care health insurance plan as defined in and subject to regulation under Chapter 58, when such coverage is provided under a contract issued in this Commonwealth.

~~"Final adverse decision" means a utilization review determination denying benefits or coverage, and concerning which all internal appeals available to the covered person pursuant to Title 32.1 have been exhausted.~~

~~"Treating health care provider" means a licensed health care provider who renders or proposes to render health care services to a covered person.~~

~~"Utilization review" means a system for reviewing the necessity, appropriateness and efficiency of hospital, medical or other health care services rendered or proposed to be rendered to a patient or group of patients for the purpose of determining whether such services should be covered or provided by an insurer, health services plan, managed care health insurance plan licensee, or other entity or person. For purposes of this chapter, "utilization review" shall include, but not be limited to, preadmission, concurrent and retrospective medical necessity determination, and review related to the appropriateness of the site at which services were or are to be delivered. "Utilization review" shall also include determinations of medical necessity based upon contractual limitations regarding "experimental" or "investigational" procedures, by whatever terms designated in the evidence of coverage. "Utilization review" shall not include (i) any denial of benefits or services for a procedure which is explicitly~~

~~excluded pursuant to the terms of the contract or evidence of coverage, (ii) any review of issues concerning contractual restrictions on facilities to be used for the provision of services, or (iii) any determination by an insurer as to the reasonableness and necessity of services for the treatment and care of an injury suffered by an insured for which reimbursement is claimed under a contract in insurance covering any classes of insurance defined in §§ 38.2-117, 38.2-118, 38.2-119, 38.2-124, 38.2-125, 38.2-126, 38.2-130, 38.2-131, 38.2-132, and 38.2-134.~~

~~"Utilization review entity" means an insurer or managed care health insurance plan licensee that performs utilization review or upon whose behalf utilization review is performed with regard to the health care or proposed health care that is the subject of the final adverse decision.~~

2. That §§ 38.2-5901, 38.2-5902, 38.2-5903, and 38.2-5905 of the Code of Virginia are repealed.

3. That the provisions of this act shall expire on July 1, 2014.