

COMMONWEALTH OF VIRGINIA  
STATE CORPORATION COMMISSION  
AT RICHMOND, NOVEMBER 9, 2015

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COMMONWEALTH OF VIRGINIA, *ex rel.*

STATE CORPORATION COMMISSION

CASE NO. INS-2015-00184

*Ex Parte:* In the matter of Amending  
Rules Governing Internal Appeal  
and External Review

ORDER TO TAKE NOTICE

Section 12.1-13 of the Code of Virginia ("Code") provides that the State Corporation Commission ("Commission") shall have the power to promulgate rules and regulations in the enforcement and administration of all laws within its jurisdiction, and § 38.2-223 of the Code provides that the Commission may issue any rules and regulations necessary or appropriate for the administration and enforcement of Title 38.2 of the Code.

The rules and regulations issued by the Commission pursuant to § 38.2-223 of the Code are set forth in Title 14 of the Virginia Administrative Code. A copy may also be found at the Commission's website: <http://www.scc.virginia.gov/boi/laws.aspx>.

The Bureau of Insurance ("Bureau") has submitted to the Commission a proposal to amend certain sections found in Chapter 216 of Title 14 of the Virginia Administrative Code entitled "Rules Governing Internal Appeal and External Review" ("Rules"), which are set out at 14 VAC 5-216-10, 14 VAC 5-216-20, 14 VAC 5-216-40, and 14 VAC 5-216-50, and establish a new section at 14 VAC 5-216-65.

The amendments and the new section are necessary to define an "exception request" for an enrollee to obtain a prescription drug that is not on a health carrier's closed formulary and to describe the requirements for the exception request process that will enhance and further clarify

the process identified in § 38.2-3407.9:01 B 2 and 3 of the Code. The amendments also provide further clarification to the urgent care appeals section.

NOW THE COMMISSION is of the opinion that the proposed amendments to 14 VAC 5-216-10, 14 VAC 5-216-20, 14 VAC 5-216-40, and 14 VAC 5-216-50 and the new section at 14 VAC 5-216-65, as submitted by the Bureau, should be considered for adoption.

Accordingly, IT IS ORDERED THAT:

(1) The proposed amendments to the "Rules Governing Internal Appeal and External Review," which amend the Rules at 14 VAC 5-216-10, 14 VAC 5-216-20, 14 VAC 5-216-40, and 14 VAC 5-216-50 and establish a new section at 14 VAC 5-216-65, are attached hereto and made a part hereof.

(2) All interested persons who desire to comment in support of or in opposition to, or request a hearing to consider the proposed amendments and new section, shall file such comments or hearing request on or before December 18, 2015, with Joel H. Peck, Clerk, State Corporation Commission, c/o Document Control Center, P.O. Box 2118, Richmond, Virginia 23218. Interested persons desiring to submit comments electronically may do so by following the instructions at the Commission's website: <http://www.scc.virginia.gov/case>. All comments shall refer to Case No. INS-2015-00184.

(3) If no written request for a hearing on the proposal to amend and establish new Rules as outlined in this Order is received on or before December 18, 2015, the Commission, upon consideration of any comments submitted in support of or in opposition to the proposal, may adopt the Rules as submitted by the Bureau.

(4) The Bureau forthwith shall provide notice of the proposal to amend and establish new Rules by sending, by e-mail or U.S. mail, a copy of this Order, together with the proposal, to

all insurers, health maintenance organizations and health services plans licensed in Virginia to sell accident and sickness insurance, and to all interested persons.

(5) The Commission's Division of Information Resources forthwith shall cause a copy of this Order, together with the proposal to amend and establish new Rules, to be forwarded to the Virginia Registrar of Regulations for appropriate publication in the *Virginia Register of Regulations*.

(6) The Commission's Division of Information Resources shall make available this Order and the attached proposal on the Commission's website: <http://www.scc.virginia.gov/case>.

(7) The Bureau shall file with the Clerk of the Commission an affidavit of compliance with the notice requirements of Ordering Paragraph (4).

(8) This matter is continued.

AN ATTESTED COPY hereof shall be sent by the Clerk of the Commission to: Kiva B. Pierce, Assistant Attorney General, Division of Consumer Counsel, Office of the Attorney General, 900 East Main Street, Second Floor, Richmond, Virginia 23219; and a copy hereof shall be delivered to the Commission's Office of General Counsel and the Bureau of Insurance in care of Deputy Commissioner Althelia P. Battle.

**STATE CORPORATION COMMISSION, BUREAU OF INSURANCE****Rules Governing Internal Appeal and External Review**

## Part I

## General

**14VAC5-216-10. Scope and purpose.**

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; 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 except that a self-insured employee welfare benefit plan may elect to use the state external review process; any coverage issued under Chapter 55 of Title 10 of the U.S. Code (TRICARE), and any coverage issued as supplemental to that coverage; any coverage issued as supplemental to liability insurance, workers' compensation or similar insurance; and automobile medical payment insurance or any insurance under which benefits are payable with or without regard to fault, whether written on a group or individual basis.

B. The purpose of this chapter is to set forth rules to carry out the provisions of Chapter 35.1 (§ 38.2-3556 et seq.) of Title 38.2 of the Code of Virginia as well as federal law to provide a health carrier with guidelines to assist with establishing a procedure for an internal appeals process under which there will be a full and fair review of any adverse benefit determination. This chapter also sets forth requirements for the external review process.

C. This chapter shall apply to any adverse benefit determination made on or after July 1, 2011, by any health carrier for a grandfathered or non-grandfathered health benefit plan, as defined by the PPACA.

D. This chapter also sets forth requirements for an exception request for plan years beginning on or after January 1, 2016.

**14VAC5-216-20. Definitions.**

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Adverse benefit determination" in the context of the internal appeals process means (i) a determination by a health carrier or its designee utilization review entity that, based on the information provided, a request for, a benefit under the health carrier's health benefit plan upon application of any utilization review technique does not meet the health carrier'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 requested benefit; (ii) the denial, reduction, or termination of, or failure to provide or make payment in whole or in part for, a benefit based on a determination by a health carrier or its designee utilization review entity of a covered person's eligibility to participate in the health carrier's health benefit plan; (iii) any review determination that denies, reduces, or terminates or fails to provide or make payment, in whole or in part, for a benefit; (iv) a rescission of coverage determination as defined in § 38.2-3438 of the Code of Virginia; or (v) any decision to deny individual coverage in an initial eligibility determination.

"Adverse determination" in the context of external review 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 or is determined to be experimental or investigational and the requested service or payment for the service is therefore denied, reduced, or terminated.

"Authorized representative" means (i) a person to whom a covered person has given express written consent to represent the covered person; (ii) a person authorized by law to provide substituted consent for a covered person; (iii) a family member of a covered person or the covered person's treating health care professional when the covered person is unable to provide consent; (iv) a health care professional when the covered person's health benefit plan requires that a request for a benefit under the plan be initiated by the health care professional; or (v) in the case of an urgent care internal appeal, a health care professional with knowledge of the covered person's medical condition.

"Clinical peer reviewer" means a practicing health care professional who holds a nonrestricted license in a state, district, or territory of the United States and in the same or similar specialty as typically manages the medical condition, procedure, or treatment under appeal.

"Commission" means the State Corporation Commission.

"Concurrent review" means utilization review conducted during a patient's stay or course of treatment in a facility, the office of a health care professional, or other inpatient or outpatient health care setting.

"Covered person" means a policyholder, subscriber, enrollee, or other individual participating in a health benefit plan. For purposes of this chapter with respect to the



insurance; coverage of Medicare services or federal employee health plans pursuant to contracts with the United States government; Medicare supplement or long-term care insurance; Medicaid coverage; dental only or vision only insurance; specified disease insurance; hospital indemnity coverage; limited benefit health coverage; coverage issued as a supplement to liability insurance; insurance arising out of a workers' compensation or similar law; automobile medical payment insurance; medical expense and loss of income benefits; or insurance under which benefits are payable with or without regard to fault and that is statutorily required to be contained in any liability insurance policy or equivalent self-insurance.

"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 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 of the Code of Virginia.

"Independent review organization" means an entity that conducts independent external reviews of adverse determinations and final adverse determinations, as well as alleged violations of 14VAC5-216-30 through 14VAC5-216-70 pertaining to internal appeal.

"PPACA" means the Patient Protection and Affordable Care Act (P.L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152).

"Pre-service claim" means a claim for a benefit under a health benefit plan that requires approval of the benefit in whole or in part, in advance of obtaining the service or treatment.

"Post-service claim" means a claim for a benefit under a health benefit plan that is not a pre-service claim, or the service or treatment has been provided to the covered person.

"Self-insured plan" means an "employee welfare benefit plan" that has the meaning set forth in the Employee Retirement Income Security Act of 1974, 29 USC § 1002(1).

"Urgent care appeal" means an appeal for medical care or treatment with respect to which the application of the time periods for making non-urgent care determinations (i) could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function; or (ii) in the opinion of the treating health care professional with knowledge of the covered person's medical condition, would subject the covered person to severe pain that cannot be adequately managed without the care or treatment that is the subject of the appeal. An urgent care appeal shall not be available for any post-service claim or retrospective adverse benefit determination.

"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.

**14VAC5-216-40. Minimum appeal requirements.**

A. Each covered person shall be entitled to a full and fair review of an adverse benefit determination. Within 180 days after the date of receipt of a notice of an adverse benefit determination, a covered person may file an appeal with the health carrier. A health carrier may

designate a utilization review entity to coordinate the review. For purposes of this chapter, "health carrier" may also mean its designated utilization review entity.

B. The health carrier shall conduct the appeal in a manner to ensure the independence and impartiality of the individuals involved in reviewing the appeal. In ensuring the independence and impartiality of such individuals, the health carrier shall not make decisions regarding hiring, compensation, termination, promotion, or other similar matters based upon the likelihood that an individual will support the denial of benefits.

C. 1. In deciding an appeal of any adverse benefit determination that is based in whole or in part on a medical judgment, including determinations with regard to whether a particular treatment, drug, or other service is experimental, investigational, or not medically necessary or appropriate, the health carrier shall designate a clinical peer reviewer to review the appeal. The clinical peer reviewer shall not have been involved in any previous adverse benefit determination with respect to the claim.

2. A reviewer of any other type of adverse benefit determination shall be an appropriate person designated by the health carrier. The reviewer of the appeal shall not be the individual who made any previous adverse benefit determination of the subject appeal nor the subordinate of such individual and shall not defer to any prior adverse benefit determination.

D. A full and fair review shall also provide for:

1. The covered person to have an opportunity to submit written comments, documents, records, and other information relating to the appeal for the reviewer or reviewers to consider when reviewing the appeal.

2. Upon request to the health carrier, the covered person to have reasonable access to and free of charge copies of all documents, records, and other information relevant to

the covered person's request for benefits. This information shall be provided to the covered person as soon as practicable.

3. An appeal process that takes into account all comments, documents, records, and other information submitted by the covered person relating to the appeal, without regard to whether such information was submitted or considered in the initial benefit determination.

4. The identification of medical or vocational experts whose advice was obtained on behalf of the health ~~benefit plan~~ carrier in connection with a covered person's adverse benefit determination, without regard to whether the advice was relied upon in making the benefit determination.

5. An urgent care appeal process.

6. Prior to issuing a final adverse benefit determination, the health carrier to provide free of charge to the covered person any new or additional evidence relied upon or generated by the health carrier or at the direction of the health carrier, in connection with the internal appeal sufficiently in advance of the date the determination is required to be provided to permit the covered person a reasonable opportunity to respond prior to that date.

E. A health carrier shall notify the covered person of the final benefit determination within a reasonable period of time appropriate to the medical circumstances, but not later than the timeframes established in subdivisions 1 and 2 of this subsection.

1. If an internal appeal involves a pre-service claim review request, the health carrier shall notify the covered person of its decision within 30 days after receipt of the appeal.

A health carrier may provide a second level of internal appeal for group health plans

only, provided that a maximum of 15 days is allowed for a benefit determination and notification from each level of the appeal.

2. If an internal appeal involves a post-service claim review request, the health carrier shall notify the covered person of its decision within 60 days after receipt of the appeal.

A health carrier may provide a second level of internal appeal for group health plans only, provided that a maximum of 30 days is allowed for a benefit determination and notification from each level of the appeal.

**14VAC5-216-50. Urgent care appeals.**

A. The health carrier shall notify the covered person of its initial benefit determination as soon as possible taking into account medical exigencies, but not later than 72 hours after receipt of the request, unless the covered person fails to provide sufficient information to determine whether, or to what extent, benefits are covered or payable under the health benefit plan. In the case of such failure, the health carrier shall notify the covered person as soon as possible, but not later than 24 hours after receipt of the request, of the specific information necessary to complete the claim. The covered person shall be afforded a reasonable amount of time, taking into account the circumstances, but not less than 48 hours to provide the specified information. The health carrier shall notify the covered person of its benefit determination not later than 48 hours after the earlier of (i) its receipt of the specified information or (ii) the end of the period afforded to the covered person to provide the specified additional information.

B. The notification of an urgent care adverse benefit determination that is based on a medical necessity, appropriateness, health care setting, level of care, effectiveness, experimental or investigational service or treatment, or similar exclusion or limit, shall include a description of the health carrier's urgent care appeal process including any time limits applicable to those procedures and the availability of and procedures for an expedited external review.

C. Upon receipt of an adverse benefit determination, a covered person may submit a request for an urgent care appeal either orally or in writing to the health carrier. Any appeal request made under this section by a treating health care professional shall be handled as an urgent care appeal. If such request is made by the covered person and not the treating health care professional, an individual acting on behalf of the health carrier shall apply the judgment of a prudent layperson who possesses an average knowledge of health and medicine to determine whether the appeal meets urgent care requirements.

D. All necessary information, including the benefit determination on appeal, shall be transmitted between the health carrier and the covered person by telephone, facsimile, or the most expeditious method available.

E. The health carrier shall notify the covered person and the treating health care professional of its benefit determination as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of an urgent care appeal.

**14VAC5-216-65. Exception request for prescription drugs.**

A. Any appeal request made under this section by a treating health care professional shall be handled as an urgent care appeal. If such request is made by the covered person and not the treating health care professional, an individual acting on behalf of the health carrier shall apply the judgment of a prudent layperson who possesses an average knowledge of health and medicine to determine whether the appeal meets urgent care requirements.

1. A standard exception request shall be reviewed and a coverage determination provided to the covered person and prescribing physician no later than the earlier of one business day or 72 hours following receipt of the request.

2. An expedited exception request may be made when exigent circumstances exist. Exigent circumstances exist when the covered person is suffering from a health

condition that may seriously jeopardize the covered person's life, health, or ability to regain maximum function or when the covered person is undergoing a current course of treatment using a non-formulary drug. An expedited exception request shall be reviewed and a coverage determination provided to the covered person and prescribing physician no later than 24 hours following receipt of the request.

3. If a health carrier denies coverage as a result of a standard exception request or an expedited exception request, the covered person or prescribing physician may submit an external exception request to the health carrier, requiring that the original exception request and subsequent denial be reviewed by an independent review organization. Such request shall be reviewed and a coverage determination provided to the covered person and prescribing physician no later than 72 hours following receipt of the request if the original request was a standard exception request, or 24 hours following receipt of the request if the original request was an expedited exception request.

B. The health carrier shall provide the non-formulary drug or drugs for the duration of the prescription (including refills) if coverage is granted under a standard exception request, or for the duration of the exigency if coverage is granted under an expedited exception request, including those granted through an external exception request. Coverage for each drug approved by an exception request shall be applied as if the drug was part of the prescription formulary.

C. A health carrier shall contract with at least one accredited independent review organization to conduct reviews in accordance with the requirements of subdivision A 3 of this section.