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HOUSE BILL NO. 435

Offered January 10, 2018

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A BILL to amend and reenact §§ 38.2-3562 and 38.2-3563 of the Code of Virginia, relating to health carriers; external reviews of adverse coverage determinations; cancer diagnosis.

Patrons—Yancey and Carter

Referred to Committee on Commerce and Labor

Be it enacted by the General Assembly of Virginia:

1. That §§ 38.2-3562 and 38.2-3563 of the Code of Virginia are amended and reenacted as follows:

§ 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 *cancer or* 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 the assigned independent review organization fails to make a decision to uphold or reverse the adverse determination or final adverse determination within 72 hours after the date of receipt of an eligible request for an expedited external review, and if the adverse determination or final adverse determination relates to coverage for treatment of cancer of the covered person, the assigned independent review organization shall be deemed to have decided at the end of such 72-hour period to have reversed the adverse determination or final adverse determination.* If such decision was not in writing*, including a decision deemed to have been made by failing to have made a decision within such 72-hour period,* 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*, or upon being notified that the assigned independent review organization has been deemed to have decided to reverse the adverse determination or final adverse determination as a result of having failed to make a decision within 72 hours after the date of receipt of an eligible request for an expedited external review,* 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*; or*

4. The assigned independent review organization fails to make a decision within 20 days after the date it receives an opinion from all clinical reviewers, and if the recommended or requested health care service or treatment is for a cancer of the covered person, the independent review organization shall be deemed to have decided at the end of such 20-day period to have reversed the adverse determination or final adverse determination.

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 *or, if the independent review organization is deemed to have decided to reverse the adverse determination or final adverse determination as a result of having failed to make a decision within the 20-day period after the date it received an opinion from all clinical reviewers, the notice shall so state.*

N. Upon receipt of a notice of a decision reversing the adverse determination or final adverse determination *or upon being notified that the independent review organization has been deemed to have decided to reverse the adverse determination or final adverse determination as a result of having failed to make a decision within the 20-day period after the date the independent review organization received an opinion from all clinical reviewers,* the health carrier shall promptly approve coverage of the recommended or requested health care service or treatment.