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SUBCHAPTER R. UTILIZATION REVIEWS FOR HEALTH CARE PROVIDED UNDER A HEALTH BENEFIT PLAN OR HEALTH INSURANCE POLICY

28 TAC §19.1709 and §19.1711

INTRODUCTION. The Texas Department of Insurance (TDI) adopts amendments to 28 TAC §19.1709 and §19.1711, relating to notice of determinations made in utilization review and written procedures for appeals of adverse determinations by utilization review agents (URAs). The amendments are adopted with nonsubstantive changes to the proposed text published in the January 25, 2019, issue of the *Texas Register* (44 TexReg 406). The department revised §19.709(e)(2) and §19.1711(a)(1)–(3) and (7)(C) to correct capitalization and punctuation.

REASONED JUSTIFICATION. The amendments are necessary to align the rules with statute and implement House Bill 1621, 84th Legislature, Regular Session (2015) and Senate Bill 680, 85th Legislature, Regular Session (2017). The amendment to §19.1711(a)(8) reduces the information a URA must provide to an enrollee when the appeal of an adverse determination is resolved with a favorable outcome for the enrollee. When the outcome is favorable for an enrollee, this information is unnecessary.

The amendment to §19.1709(b)(9) adds the requirements for a URA's notice to the enrollee, an individual acting on behalf of the enrollee, or the provider of record (collectively "enrollee") that must be provided under HB 1621 amendments to Insurance Code §4201.303. The amendment to Insurance Code §4201.303 requires a URA to notify individuals covered by a health insurance policy of their right to an immediate review of the URA's denial of prescription drugs or intravenous infusions for which they are receiving benefits under the health insurance policy.

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The amendment to §19.1711(a)(7) adds a requirement that a URA provide a method for expedited appeals for denials of prescription drugs or intravenous infusions for which a patient is receiving benefits under the health insurance policy, or for denials of a step therapy protocol exception request. The change is needed to implement amendments to Insurance Code §1369.0546 and §4201.357 made in HB 1621 and SB 680.

The amendment to §19.1711(a)(8) is necessary to clarify that a URA is not required to exceed the requirements of Insurance Code §4201.359(b). Section 19.1711(a)(8) states the information that a URA must provide upon resolution of an appeal of an adverse determination. The department determined that when an appeal of a URA's prior adverse determination results in a favorable outcome for the enrollee, providing the information required in §19.1711(a)(8)(A) – (H) is unnecessary. The amended section does not prohibit URAs from sending the additional information or require URAs to amend or change their existing systems. However, they may do so to the extent they remain in compliance with the Insurance Code.

The amendment to §19.1711(a)(10) adds a requirement that a URA's written procedures must provide that an enrollee who is denied the provision of prescription drugs or intravenous infusions for which the patient is receiving benefits under the health insurance policy is entitled to an immediate appeal to an IRO and is not required to comply with the procedures for an appeal of the URA's adverse determination. This change is needed to implement amendments to Insurance Code §4201.3601 made in HB 1621.

In addition, the amendments to both sections include nonsubstantive editorial and formatting changes to conform to the department's current style and to improve the rule's clarity.

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SUMMARY OF COMMENTS AND AGENCY RESPONSE.

Commenters: The department received two written comments. The commenter in support of the proposal was Texas Medical Association. The commenter in support of the proposal with changes was Community Health Choice, Inc.

Comment on §19.1711(a)(7).

One commenter strongly supports the proposed amendment language and agrees with the department that the change is needed to implement amendments to the Insurance Code made in HB 1621 and SB 680. The commenter contends the proposed amendment will aid the regulated community and enrollees in understanding statutory requirements for expedited appeals.

Agency Response to Comment on §19.1711(a)(7).

The department thanks the commenter for its support.

Comment on §19.1711(a)(7) and (a)(10).

One commenter states the phrase "for which a person is receiving benefits under the health insurance policy" can be ambiguous. The commenter asks whether the enrollees entitled to expedited appeals and immediate appeals are those currently receiving prescription drugs or intravenous infusions or those with a proposed course of treatment which has not yet started. The commenter seeks clarification on the meaning of "receiving benefits under the health insurance policy."

Agency Response to Comment on §19.1711(a)(7) and (a)(10).

The department disagrees that the amendment's use of the statutory language of Chapter 4201 is ambiguous and declines to make a change based on the comment. The

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intent of HB 1621 was to address the rights to appeals and intermediate appeals for those enrollees currently receiving prescription drugs or intravenous infusions, not those with a proposed course of treatment that has not yet started. The phrase "receiving benefits under the health insurance policy" refers to those benefits the person is currently receiving.

STATUTORY AUTHORITY. Amendments to §19.1709 and §19.1711 are proposed under Insurance Code §§1369.057, 4201.003, and 36.001.

Insurance Code §1369.057 provides that the Commissioner may adopt rules to implement Insurance Code Chapter 1369, Subchapter B.

Insurance Code §4201.003 provides that the Commissioner may adopt rules to implement Insurance Code Chapter 4201.

Insurance Code §36.001 provides that the Commissioner may adopt any rules necessary and appropriate to implement the powers and duties of the department under the Insurance Code and other laws of this state.

TEXT.

§19.1709 Notice of Determinations Made in Utilization Review

(a) Notice requirements. A URA must send written notification to the enrollee or an individual acting on behalf of the enrollee and the enrollee's provider of record, including the health care provider who rendered the service, of a determination made in a utilization review.

(b) Required notice elements. In all instances of a prospective, concurrent, or retrospective utilization review adverse determination, written notification of the adverse determination by the URA must include:

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- (1) the principal reasons for the adverse determination;
- (2) the clinical basis for the adverse determination;
- (3) a description or the source of the screening criteria that were utilized as guidelines in making the determination;
- (4) the professional specialty of the physician, doctor, or other health care provider that made the adverse determination;
- (5) a description of the procedure for the URA's complaint system as required by §19.1705 of this title (relating to General Standards of Utilization Review);
- (6) a description of the URA's appeal process, as required by §19.1711 of this title (relating to Written Procedures for Appeal of Adverse Determination);
- (7) a copy of the request for a review by an IRO form, available at www.tdi.texas.gov/forms;
- (8) notice of the independent review process with instructions that:
 - (A) request for a review by an IRO form must be completed by the enrollee, an individual acting on behalf of the enrollee, or the enrollee's provider of record and be returned to the insurance carrier or URA that made the adverse determination to begin the independent review process; and
 - (B) the release of medical information to the IRO, which is included as part of the independent review request for a review by an IRO form, must be signed by the enrollee or the enrollee's legal guardian; and
- (9) a description of the enrollee's right to an immediate review by an IRO and of the procedures to obtain that review for an enrollee who has a life-threatening condition or who is denied the provision of prescription drugs or intravenous infusions for which the patient is receiving benefits under the health insurance policy.

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(c) Determination concerning an acquired brain injury. In addition to the notification required by this section, a URA must comply with this subsection in regard to a determination concerning an acquired brain injury as defined by §21.3102 of this title (relating to Definitions). Not later than three business days after the date an individual requests utilization review or requests an extension of coverage based on medical necessity or appropriateness, a URA must provide notification of the determination through a direct telephone contact to the individual making the request. This subsection does not apply to a determination made for coverage under a small employer health benefit plan.

(d) Prospective and concurrent review.

(1) Favorable determinations. The written notification of a favorable determination made in utilization review must be mailed or electronically transmitted as required by Insurance Code §4201.302.

(2) Preauthorization numbers. A URA must ensure that preauthorization numbers assigned by the URA comply with the data and format requirements contained in the standards adopted by the U.S. Department of Health and Human Services in 45 C.F.R. §162.1102, (relating to Standards for Health Care Claims or Equivalent Encounter Information Transaction), based on the type of service in the preauthorization request.

(3) Required time frames. Except as otherwise provided by the Insurance Code, the time frames for notification of the adverse determination begin from the date of the request and must comply with Insurance Code §4201.304. A URA must provide the notice to the provider of record or other health care provider not later than one hour after the time of the request when denying post-stabilization care subsequent to emergency treatment as requested by a provider of record or other health care provider. The URA

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must send written notification within three working days of the telephone or electronic transmission.

(e) Retrospective review.

(1) The URA must develop and implement written procedures for providing the notice of adverse determination for retrospective utilization review, including the time frames for the notice of adverse determination, that comply with Insurance Code §4201.305 and this section.

(2) When a retrospective review of the medical necessity or appropriateness, or the experimental or investigational nature of the health care services is made in relation to health coverage, the URA may not require the submission or review of a mental health therapist's process or progress notes that relate to the mental health therapist's treatment of an enrollee's mental or emotional condition or disorder. This prohibition extends to requiring an oral, electronic, facsimile, or written submission or rendition of a mental health therapist's process or progress notes. This prohibition does not preclude requiring submission of:

(A) an enrollee's mental health medical record summary; or

(B) medical records or process or progress notes that relate to treatment of conditions or disorders other than a mental or emotional condition or disorder.

§19.1711 Written Procedures for Appeal of Adverse Determinations

(a) Appeal of prospective or concurrent review adverse determinations. Each URA must comply with its written procedures for appeals. The written procedures for appeals must comply with Insurance Code Chapter 4201, Subchapter H, concerning Appeal of Adverse Determination, and must include provisions that specify the following:

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(1) Time frames for filing the written or oral appeal, which may not be less than 30 calendar days after the date of issuance of written notification of an adverse determination.

(2) An enrollee, an individual acting on behalf of the enrollee, or the provider of record may appeal the adverse determination orally or in writing.

(3) An appeal acknowledgement letter must:

(A) be sent to the appealing party within five working days from receipt of the appeal;

(B) acknowledge the date the URA received the appeal;

(C) include a list of relevant documents that must be submitted by the appealing party to the URA; and

(D) include a one-page appeal form to be filled out by the appealing party when the URA receives an oral appeal of an adverse determination.

(4) Appeal decisions must be made by a physician who has not previously reviewed the case.

(5) In any instance in which the URA is questioning the medical necessity or appropriateness, or the experimental or investigational nature, of the health care services prior to issuance of an adverse determination, the URA must afford the provider of record a reasonable opportunity to discuss the plan of treatment for the enrollee with a physician. The provision must require that the discussion include, at a minimum, the clinical basis for the URA's decision.

(6) If an appeal is denied and, within 10 working days from the denial, the health care provider sets forth in writing good cause for having a particular type of specialty provider review the case, the denial must be reviewed by a health care provider in the same or similar specialty that typically manages the medical, dental, or specialty

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condition, procedure, or treatment under discussion for review of the adverse determination. The specialty review must be completed within 15 working days of receipt of the request. The provision must state that notification of the appeal under this paragraph must be in writing.

(7) In addition to the written appeal, a method for expedited appeals for emergency care denials, denials of care for life-threatening conditions, denials of continued stays for hospitalized enrollees, denials of prescription drugs or intravenous infusions for which an enrollee is receiving benefits under the health insurance policy, and adverse determinations of a step therapy protocol exception request under Insurance Code §1369.0546 is available. The provision must state that:

(A) the procedure must include a review by a health care provider who has not previously reviewed the case and who is of the same or a similar specialty as the health care provider that typically manages the medical condition, procedure, or treatment under review;

(B) an expedited appeal must be completed based on the immediacy of the medical or dental condition, procedure, or treatment, but may in no event exceed one working day from the date all information necessary to complete the appeal is received; and

(C) an expedited appeal determination may be provided by telephone or electronic transmission but must be followed with a letter within three working days of the initial telephonic or electronic notification.

(8) After the URA has sought review of the appeal of the adverse determination, the URA must issue a response letter to the enrollee or an individual acting on behalf of the enrollee, and the provider of record, explaining the resolution of the appeal. If there is an adverse determination of the appeal, the letter must include:

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(A) a statement of the specific medical, dental, or contractual reasons for the resolution;

(B) the clinical basis for the decision;

(C) a description of or the source of the screening criteria that were utilized in making the determination;

(D) the professional specialty of the physician who made the determination;

(E) notice of the appealing party's right to seek review of the adverse determination by an IRO under §19.1717 of this title (relating to Independent Review of Adverse Determinations);

(F) notice of the independent review process;

(G) a copy of a request for a review by an IRO form; and

(H) procedures for filing a complaint as described in §19.1705(f) of this title (relating to General Standards of Utilization Review).

(9) A statement that the appeal must be resolved as soon as practical, but, under Insurance Code §4201.359 and §1352.006, in no case later than 30 calendar days after the date the URA receives the appeal from the appealing party referenced under paragraph (3) of this subsection.

(10) In a circumstance involving an enrollee's life-threatening condition or the denial of prescription drugs or intravenous infusions for which the enrollee is receiving benefits under the health insurance policy, the enrollee is entitled to an immediate appeal to an IRO and is not required to comply with procedures for an appeal of the URA's adverse determination.

(b) Appeal of retrospective review adverse determinations. A URA must maintain and make available a written description of the appeal procedures involving an adverse

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determination in a retrospective review. The written procedures for appeals must specify that an enrollee, an individual acting on behalf of the enrollee, or the provider of record may appeal the adverse determination orally or in writing. The appeal procedures must comply with:

(1) Chapter 21, Subchapter T, of this title (relating to Submission of Clean Claims), if applicable;

(2) Section 19.1709 of this title (relating to Notice of Determinations Made in Utilization Review), for retrospective utilization review adverse determination appeals; and

(3) Insurance Code §4201.359.

(c) Appeals concerning an acquired brain injury. A URA must comply with this subsection in regard to a determination concerning an acquired brain injury as defined by §21.3102 of this title (relating to Definitions). Not later than three business days after the date on which an individual requests utilization review or requests an extension of coverage based on medical necessity or appropriateness, a URA must provide notification of the determination through a direct telephone contact to the individual making the request. This subsection does not apply to a determination made for coverage under a small employer health benefit plan.

CERTIFICATION. This agency certifies that legal counsel has reviewed the adoption and found it to be within the agency's legal authority to adopt.

Issued at Austin, Texas, on July 3, 2019.

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/s/ James Person _____

James Person

Interim General Counsel

Texas Department of Insurance

The Commissioner adopts amendments to 28 TAC §19.1709 and §19.1711.

By: */s/ Kent C. Sullivan* _____

Kent C. Sullivan

Commissioner of Insurance

Commissioner's Order No. **2019-6010**