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 proposes amendments to Title 28, Texas Administrative Code §19.1709 and §19.1711, concerning notice of determinations made in utilization review and written procedures for appeals of adverse determinations by utilization review agents (URAs). The amendments to §19.1709 implement House Bill 1621, 84th Legislature, Regular Session (2015). The amendments to §19.1711 implement HB 1621 and SB 680, 85th Legislature, Regular Session (2017). The amendments to §19.1709 also reduce existing requirements in the rule to conform to Insurance Code §4201.359.

EXPLANATION. The proposal amends §§19.1709, 19.1711(b)(9), and 19.1711(a)(10) to include new requirements that HB 1621 and SB 680 added to Insurance Code Chapters 1369 and 4201. The amendments are necessary to align the rules with statute and implement HB 1621 and SB 680. The proposal also amends §19.1711(a)(8) to reduce 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.

Section 19.1709(b)(9). The proposal amends §19.1709(b)(9) to add 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.

Section 19.1711(a)(7). The proposal amends §19.1711(a)(7) to include 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.

Section 19.1711(a)(8). The proposed 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. TDI 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 proposal 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.

Section 19.1711(a)(10). The proposal amends §19.1711(a)(10) to include 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 proposed amendments include non-substantive editorial and formatting changes to conform the amended rules to the department's current style.

FISCAL NOTE AND LOCAL EMPLOYMENT IMPACT STATEMENT. Debra Diaz-Lara, Director of the Managed Care Quality Assurance Office, has determined that during each year of the first five years the proposed amendments are in effect, there will be no measurable fiscal impact on state and local governments as a result of enforcing or administering the sections, other than that imposed by the statute. This determination was made because the proposed amendments do not add to or decrease state revenues or expenditures, and because local governments are not involved in enforcing or complying with the proposed amendments.

Ms. Diaz-Lara does not anticipate any measurable effect on local employment or the local economy as a result of this proposal.

PUBLIC BENEFIT AND COST NOTE. Ms. Diaz-Lara has also determined that for each year of the first five years the proposed sections are in effect, public benefits are expected as a result of enforcing the proposed amendments. Public benefits resulting from the adoption of the rules will be the implementation of HB 1621 and SB 680. The benefits include conforming §§19.1709(b)(9), 19.1711(a)(7), and 19.1711(a)(10) to include applicable statutory requirements, which will result in consistent utilization review and appeal processes, and the ability of individuals to have notice of their rights to appeal URA adverse determinations. In addition, the amendment to §19.1711(a)(8) will reduce the administrative burden on URAs by limiting the amount of information that a URA must

send if an appeal of the URA's prior adverse determination is resolved with a favorable outcome for the enrollee.

Ms. Diaz-Lara expects that the proposed amendments will not increase the cost of compliance with Insurance Code §§4201.303, 4201.357, and 4201.3601, because the proposal does not impose requirements beyond those in the statute.

The amendment to \$19.1711(a)(8) will reduce the amount of information that a URA must send enrollees if the appeal of the URA's prior adverse determination is resolved with a favorable outcome for the enrollee. This may result in less cost to URAs over time in both actual expense and responding to inquiries concerning the information. TDI recognizes that implementing such a change may result in costs to change existing systems if the change were required. For that reason, TDI has not proposed a requirement for URAs to change their existing processes. Instead, the proposal leaves the decision to continue sending the information to the discretion of the URA. If a URA changes its process, this is a business decision and not a requirement under this proposal.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS. The

department has determined that the proposed amendments will not have an adverse economic effect or a disproportionate economic impact on small or micro businesses, or on rural communities. As discussed in the Public Benefit and Cost Note section, the rule requirements result from statute and do not result from the enforcement or administration of the proposed amendments. As a result, and in accordance with Government Code §2006.002(c), the department is not required to prepare a regulatory flexibility analysis.

EXAMINATION OF COSTS UNDER GOVERNMENT CODE §2001.0045. The department has determined that the proposed amendments do not impose a cost on regulated

persons, so no additional rule amendments or repeals are required under Government Code §2001.0045. Additionally, even if the proposed amendments were to impose additional costs, Government Code §2001.0045 does not apply to the proposed amendments because the changes are necessary to implement HB 1621 and SB 680. The proposed amendment to §19.1711(a)(8) reduces the amount of information that a URA must provide to an enrollee if an appeal of an adverse determination results in a favorable outcome for the enrollee. It does not prohibit sending the information or require any changes in existing systems for URAs. Any cost increase for a URA would be the result of a business decision by the URA.

GOVERNMENT GROWTH IMPACT STATEMENT. The department has determined that for each year of the first five years that the proposed amendments are in effect the proposed rule:

- will not create or eliminate a government program;

- will not require the creation of new employee positions or the elimination of existing employee positions;

- will not require an increase or decrease in future legislative appropriations to the department;

- will not require an increase or decrease in fees paid to the department;

- will expand regulation in §§19.1709, 19.1711(b)(9), and 19.1711(a)(10) to include notices and procedures related to appeals of adverse determinations that URAs must provide to enrollees under Insurance Code §§4201.303, 4201.357, and 4201.3601 as amended by HB 1621 and SB 680;

- will limit regulation under §19.1711(a)(8) by reducing the information URAs must provide when appeals of adverse determinations are resolved with a favorable outcome for the enrollee; - will not increase or decrease the number of individuals subject to the rule's applicability; and

- will not positively or adversely affect the Texas economy.

TAKINGS IMPACT ASSESSMENT. The department has determined that no private real property interests are affected by this proposal and that this proposal does not restrict or limit an owner's right to property that would otherwise exist in the absence of government action. As a result, this proposal does not constitute a taking or require a takings impact assessment under Government Code §2007.043.

REQUEST FOR PUBLIC COMMENT. The department will consider any written comments on the proposal received by the department no later than 5:00 p.m., Central time, on February 25, 2019. Send your comments to ChiefClerk@tdi.texas.gov; or to the Office of the Chief Clerk, Mail Code 113-2A, Texas Department of Insurance, P.O. Box 149104, Austin, Texas 78714-9104. To request a public hearing, submit a written request before the end of the comment period to ChiefClerk@tdi.texas.gov or to the Office of the Chief Clerk, Mail Code 113-2A, Texas Department of Insurance, P.O. Box 149104, Austin, Texas 78714-9104. The request for public hearing must be separate from any comments and received by the department no later than 5:00 p.m., Central time, on February 25, 2019. If the department holds a public hearing, the department will consider written and oral comments presented at the hearing.

SUBCHAPTER R

28 TAC §19.1709 and §19.1711

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.

CROSS-REFERENCE TO STATUTE. Amendments to §19.1709 and §19.1711 affect Insurance Code §§1369.0546, 4201.303, 4201.357, 4201.359, and 4201.3601.

TEXT.

§19.1709. Notice of Determinations Made in Utilization Review.

(a) (No change.)

(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:

(1) - (8) (No change.)

(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 <u>or who is denied the provision of prescription drugs or intravenous infusions</u> for which the patient is receiving benefits under the health insurance policy.

(c) (No change.)

(d) Prospective and concurrent review.

(1) - (2) (No change.)

(3) Required <u>time frames</u> [timeframes]. Except as otherwise provided by the Insurance Code, the <u>time frames</u> [timeframes] 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 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 <u>time</u> <u>frames</u> [timeframes] for the notice of adverse determination, that comply with Insurance Code §4201.305 and this section.

(2) (No change.)

§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:

(1) time frames [timeframes] 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) - (6) (No change.)

(7) In addition to the written appeal, a method for expedited appeals for emergency care denials, denials of care for life-threatening conditions, [-and] 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 <u>Code §1369.0546</u> is available. The provision must state that:

(A) - (C) (No change.)

(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 [The provision must state that the] letter must include:

(A) - (H) (No change.)

(9) (No change.)

(10) In a circumstance involving an enrollee's life-threatening condition <u>or</u> <u>the denial of prescription drugs or intravenous infusions for which the enrollee is receiving</u> <u>benefits under the health insurance policy</u>, 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) - (c) (No change.)

CERTIFICATION. This agency certifies that legal counsel has reviewed the proposal and

found it to be within the agency's authority to adopt.

Issued in Austin, Texas, on January 11, 2019.

<u>/s/ Norma Garcia</u>

Norma Garcia General Counsel Texas Department of Insurance