## SUBCHAPTER R UTILIZATION REVIEWS FOR HEALTH CARE PROVIDED UNDER A HEALTH BENEFIT PLAN OR HEALTH INSURANCE POLICY 28 TAC §§19.1702, 19.1705, 19.1709, 19.1710, 19.1711, 19.1716, 19.1717, and 19.1718

**INTRODUCTION.** The Texas Department of Insurance proposes to amend 28 TAC §§19.1702, 19.1705, 19.1709, 19.1710, 19.1711, 19.1716, 19.1717, and 19.1718, concerning utilization reviews for health care that is provided under a health benefit plan or a health insurance policy. These amendments implement House Bill 1584, HB 2486, HB 3041, and Articles 2 and 3 of Senate Bill 1742, all enacted by the 86th Legislature, Regular Session (2019).

**EXPLANATION.** Amending §§19.1702, 19.1705, 19.1709, 19.1710, 19.1711, 19.1716, 19.1717, and 19.1718 aligns the rules with statute and with one another, and it implements HB 1584, HB 2486, HB 3041, and SB 1742. All of these bills include statutory changes relating to utilization reviews for health care.

HB 1584 prohibits a health benefit plan that provides coverage for stage-four, advanced metastatic cancer and associated conditions (stage-IV cancer) from requiring the enrollee to fail to successfully respond to a different drug or prove history of failure of a different drug before providing coverage of a prescription drug that is consistent with best practices; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration.

HB 2486 specifies preauthorization requirements for employee benefit plans or health policies that provide dental benefits.

HB 3041 requires health benefit plan issuers that are subject to Insurance Code Chapter 1222 and that require preauthorization as a condition of payment to provide a preauthorization renewal process that allows a provider to request renewal of an existing preauthorization at least 60 days before it expires. It also requires insurers receiving a

request to renew an existing preauthorization to review the request and issue a determination before the existing preauthorization expires, if practicable.

SB 1742 includes provisions requiring the following:

--a shorter response time for a health maintenance organization (HMO) to provide certain information concerning the preauthorization process to a participating physician or provider who requests it,

--a shorter response time for a preferred or exclusive provider health benefit plan issuer to provide certain information concerning the preauthorization process to a preferred provider who requests it,

--requirements for HMOs and preferred or exclusive provider health benefit plan issuers (collectively, health benefit plan issuers) to post certain preauthorization information on their websites, and

--new requirements utilization review agents (URAs) must meet.

The proposed amendments to the sections are described in the following paragraphs.

**Section 19.1702**. **Applicability.** A proposed amendment to §19.1702(b) adds Insurance Code Chapter 1222 and Chapter 1451, Subchapter E to the list of Insurance Code provisions that apply to the rules in 28 TAC Chapter 19, Subchapter R.

In addition, nonsubstantive punctuation and grammatical changes that reflect updates to statutory language are made to §19.1702(a)(1) to change existing rule text to say "the medical necessity, the appropriateness, or the experimental or investigational nature."

**Section 19.1705. General Standards of Utilization Review.** A proposed amendment to §19.1705(a) adds a requirement that the physician who reviews and approves a URA's utilization review plan be licensed to practice medicine in Texas.

The proposed amendments to §19.1705(b) designates the existing text as paragraph (1). Proposed paragraphs (2) and (3) are added to prohibit a health benefit plan that provides coverage for stage-IV cancer from requiring that an enrollee with stage-IV cancer fail to successfully respond to a different drug or prove history of failure of a different drug before the plan provides coverage for certain prescription drugs.

In addition, nonsubstantive punctuation and grammatical changes that reflect updates to statutory language are made to §19.1705(d) to change existing rule text to say "the medical necessity, the appropriateness, or the experimental or investigational nature."

**Section 19.1709. Notice of Determinations Made in Utilization Review.** As proposed to be amended, the section is revised to provide timeframes for requesting renewal of an existing preauthorization and issuing the determination on the request.

The amendments add new subsection (b), which provides that health benefit plan issuers that require preauthorization as a condition for payment must provide a renewal process that allows for the renewal of a preauthorization to be requested at least 60 days before the existing preauthorization expires. The subsections that follow new subsection (b) are redesignated as appropriate to reflect the addition of the new subsection.

The amendments also add new paragraph (4) to redesignated subsection (e). Proposed new §19.1709(e)(4) requires that a URA review a request to renew a preauthorization and make and issue a determination before the existing preauthorization expires, if practicable.

#### Section 19.1710. Requirements Prior to Issuing an Adverse Determination.

The proposed amendments to §19.1710 are nonsubstantive punctuation and grammatical changes that reflect updates to statutory language in the first paragraph of §19.1710 to change existing rule text to say "the medical necessity, the appropriateness, or the experimental or investigational nature."

#### Section 19.1711. Written Procedures for Appeal of Adverse Determinations.

The proposed amendments to §19.1711(a)(6) add text to clarify that the requirements of the paragraph concerning review by a particular type of specialty provider are available to the health care provider either when appealing an adverse determination or after an adverse determination appeal has been denied. The proposed amendments to paragraph (6) also revise text to clarify that the health care provider merely needs to request a particular type of specialty provider review the case and is no longer required to provide good cause in writing for the request.

The proposed amendments to §19.1711(a)(7) revise text to clarify that the requirement to have a method for expedited appeals applies in regard to denial of another service if the requesting health care provider includes a written statement with supporting documentation that the service is necessary to treat a life-threatening condition or prevent serious harm to the patient.

In addition, nonsubstantive punctuation and grammatical changes that reflect updates to statutory language are made to §19.1711(a)(5) to change existing rule text to say "the medical necessity, the appropriateness, or the experimental or investigational nature." Another nonsubstantive grammatical change was made to §19.1711(a)(7) to move the placement of existing rule text "is available" to improve the rule's clarity.

**Section 19.1716. Specialty URA.** The proposed amendments to §19.1716 revise subsections (b) and (d) to specify that utilization review of specialty health care services

must be conducted by a health care provider licensed or authorized in Texas to provide the specialty health care service being reviewed.

In addition, nonsubstantive punctuation and grammatical changes that reflect updates to statutory language are made to §19.1716(f), changing existing rule text to say "the medical necessity, the appropriateness, or the experimental or investigational nature."

**Section 19.1717. Independent Review of Adverse Determinations.** The proposed amendment to §19.1717(a) revises a reference to §19.1709(d)(3), changing it to §19.1709(e)(3) to reflect the proposed redesignation of subsection (d) as (e) in that section. In addition, a nonsubstantive punctuation change is made to §19.1717(c) to reflect TDI's current rule drafting style that "internet" not be capitalized.

Section 19.1718. Preauthorization for Health Maintenance Organizations and Preferred Provider Benefit Plans. The proposed §19.1718(c) revises the deadline for health benefit plan issuers that use a preauthorization process to provide a list of the medical care and health care services that require preauthorization as well as information about the preauthorization process to preferred providers who request this information, changing the deadline from the 10th to the fifth working day after the date a request is made, for consistency with the provisions of SB 1742. In addition, it replaces the "and" in existing text with "or" to reflect a change in statutory language so that the subsection applies to health benefit plan issuers that use a preauthorization process for "medical care or health care services."

The amendments add new subsection (j) to address the posting of preauthorization requirements for medical and health care services. This subsection requires an HMO or a preferred provider benefit plan that uses a preauthorization process for medical care or health care services to make the requirements and information about the preauthorization process readily accessible to enrollees, physicians, health care providers,

and the general public by posting the requirements and information on the HMO's or the preferred provider benefit plan's public internet website. The subsection describes requirements applicable to the preauthorization requirements and information; it addresses how an HMO or preferred provider benefit plan should handle licensed, proprietary, or copyrighted material; it addresses changes to preauthorization requirements; it provides a remedy for noncompliance with the subsection; and it specifies that the provisions of the subsection may not be waived, voided, or nullified by contract.

The amendments add new subsection (k), to address preauthorizations for employee benefit plans or health policies that provide dental benefits. The subsection addresses applicability of relevant definitions to prior authorization for dental care services under an employee benefit plan or health insurance policy. The subsection also addresses what an employee benefit plan or health insurance policy provider or issuer must provide to a dentist in a written prior authorization of benefits for a dental care service. The subsection also addresses what an employee benefit plan or health insurance policy provider or issuer must provide in a denial of a dental care service.

The amendments add new subsection (I), to address preauthorization requests to renew existing preauthorizations. The subsection specifies requirements that apply if preauthorization is required as a condition of payment for a medical or health care service, stating that a preauthorization renewal process must be provided that allows the renewal of an existing preauthorization to be requested by a physician or health care provider at least 60 days before the date the preauthorization expires. The subsection also states that if a request from a physician or health care provider to renew an existing preauthorization is received before an existing preauthorization expires, the request must be reviewed and a determination indicating whether the medical or health care service is preauthorized issued before the existing preauthorization expires, if practicable.

FISCAL NOTE AND LOCAL EMPLOYMENT IMPACT STATEMENT. Debra Diaz-Lara, director of the Managed Care and 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 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.** For each year of the first five years the proposed amendments are in effect, Ms. Diaz-Lara expects that enforcing the proposed amendments will have the public benefits of ensuring that TDI's rules conform with statutory changes regarding preauthorization and utilization reviews adopted by HB 1584, HB 2486, HB 3041 and SB 1742.

Ms. Diaz-Lara expects that the proposed amendments will not increase the cost of compliance with HB 1584, HB 2486, HB 3041 and SB 1742 because they do not impose requirements beyond those explicitly provided for in the statutes and do not include any discretionary decisions or interpretations by TDI.

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. This is because the proposed amendments implement the statutory changes adopted in HB 1584, HB 2486, HB 3041, and SB 1742. Regardless of whether TDI

adopts the proposed amendments, small or micro businesses are required to comply with the statutes. The proposed amendments do not go beyond the explicit statutory requirements and do not include any discretionary decisions or interpretations by TDI. The proposed amendments do not apply to any rural communities. As a result, and in accordance with Government Code §2006.002(c), TDI is not required to prepare a regulatory flexibility analysis.

**EXAMINATION OF COSTS UNDER GOVERNMENT CODE \$2001.0045.** TDI has determined that this proposal does not impose a cost on regulated persons and no additional rule amendments are required under Government Code §2001.0045 because the proposed amendments to §§19.1702, 19.1705, 19.1709, 19.1710, 19.1711, 19.1716, 19.1717, and 19.1718 do not go beyond the requirements provided in the legislation they implement and do not include any discretionary interpretations or decisions. The proposed rule amendments implement the following provisions:

- --Insurance Code §1222.0003 and §1222.0004, as added by HB 3041;
- --Insurance Code §1369.213, as added by HB 1584;
- --Insurance Code §1451.208, as amended by HB 2486; and
- --Insurance Code §§843.348, 843.3481 3483, 1301.135, 1301.1351 1353, 4201.151, 4201.206, 4201.356, 4201.357, and 4201.453, as added or amended by SB 1742.

**GOVERNMENT GROWTH IMPACT STATEMENT.** TDI 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 agency;
  - will not require an increase or decrease in fees paid to the agency;
  - will not create a new regulation;
- will expand an existing regulation, and will not limit or repeal an existing regulation;
- 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.** TDI 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.** TDI will consider any written comments on the proposal that are received by TDI no later than 5 p.m. Central time, on November 23, 2020. Send your comments to ChiefClerk@tdi.texas.gov; or to the Office of the Chief Clerk, MC 112-2A, Texas Department of Insurance, P.O. Box 149104, Austin, Texas 78714-9104.

To request a public hearing on the proposal, submit a request before the end of the comment period, and separate from any comments, to ChiefClerk@tdi.texas.gov; or to the Office of the Chief Clerk, MC 112-2A, Texas Department of Insurance, P.O. Box 149104, Austin, Texas 78714-9104. The request for public hearing must be received by the department no later than 5 p.m. Central time, on November 23, 2020.

If TDI holds a public hearing, TDI will consider written and oral comments presented at the hearing.

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**STATUTORY AUTHORITY.** TDI proposes amendments to §§19.1702, 19.1705, 19.1709, 19.1710, 19.1711, 19.1716, 19.1717, and 19.1718 under Insurance Code §§843.151, 1301.007, 4201.003, and 36.001.

Insurance Code §843.151 allows the Commissioner to adopt reasonable rules as necessary and proper to implement Insurance Chapter 843, addressing HMOs.

Insurance Code §1301.007 provides that the Commissioner adopt rules as necessary to implement Chapter 1301 addressing preferred provider plans.

Insurance Code §4201.003 allows the Commissioner to adopt rules to implement Chapter 4201 addressing URAs.

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

**CROSS-REFERENCE TO STATUTE.** The amendments to §19.1702 implement Insurance Code §§1222.0003, 1222.0004, and 1451.208.

The amendments to §19.1705 implement Insurance Code §4201.151 and §1369.213.

The amendments to §19.1709 implement Insurance Code §1222.0003 and §1222.0004.

The amendments to §19.1710 implement Insurance Code §4201.206.

The amendments to §19.1711 implement Insurance Code §4201.356 and §4201.357.

The amendments to §19.1716 implement Insurance Code §4201.453 and §4201.454.

The amendment to §19.1717 implements Insurance Code §4201.304.

The amendments to §19.1718 implement Insurance Code §§843.348, 843.3481 - 843.3483, 1301.135, 1301.1351 - 1301.1353, 1451.208, 1222.0003, and 1222.0004.

#### TEXT.

#### §19.702. Applicability.

- (a) Limitations on applicability. Except as provided in Insurance Code Chapter 4201, this subchapter applies to utilization review performed under a health benefit plan or a health insurance policy.
- (1) This subchapter does not apply to utilization review performed under workers' compensation insurance coverage.
- (2) This subchapter does not apply to a person who provides information to an enrollee; an individual acting on behalf of an enrollee; or an enrollee's physician, doctor, or other health care provider about scope of coverage or benefits, and does not determine the medical necessity. [or] appropriateness, or the experimental or investigational nature of health care services.
- (b) Applicability of other law. In addition to the requirements of this subchapter, provisions of Insurance Code Chapter 843, concerning Health Maintenance Organizations; Insurance Code Chapter 1222, concerning Preauthorization for Medical or Health Care

Service; Insurance Code Chapter 1301, concerning Preferred Provider Benefit Plans; Insurance Code Chapter 1352, concerning Brain Injury; [and] Insurance Code Chapter 1369, concerning Benefits Related to Prescription Drugs and Devices and Related Services; and Insurance Code Chapter 1451, Subchapter E, concerning Dental Care Benefits in Health Insurance Policies or Employee Benefit Plans, apply to this subchapter.

#### §19.1705. General Standards of Utilization Review.

(a) Review of utilization review plan. The utilization review plan must be reviewed and approved by a physician licensed to practice medicine in Texas and conducted under standards developed and periodically updated with input from both primary and specialty physicians, doctors, and other health care providers, as appropriate.

#### (b) Special circumstances.

(1) A utilization review determination must be made in a manner that takes into account special circumstances of the case [into account] that may require deviation from the norm stated in the screening criteria or relevant guidelines. Special circumstances include, but are not limited to, an individual who has a disability, acute condition, or life-threatening illness.

(2) If coverage is available for stage-four advanced, metastatic cancer and associated conditions, as defined by Insurance Code §1369.211, the URA cannot require, before coverage of a prescription drug, that the enrollee:

- (A) fail to successfully respond to a different drug; or
- (B) prove a history of failure of a different drug.
- (3) Paragraph (2) of this subsection only applies to a drug the use of which

(A) consistent with best practices for the treatment of stage-four advanced, metastatic cancer or an associated condition, as defined by Insurance Code §1369.211;

> (B) supported by peer-reviewed, evidence-based literature; and (C) approved by the United States Food and Drug Administration.

- (c) Screening criteria. Each URA must utilize written screening criteria that are evidence-based, scientifically valid, outcome-focused, and that comply with the requirements in Insurance Code §4201.153. The screening criteria must also recognize that if evidence-based medicine is not available for a particular health care service provided, the URA must utilize generally accepted standards of medical practice recognized in the medical community.
- (d) Referral and determination of adverse determinations. Adverse determinations must be referred to and may only be determined by an appropriate physician, doctor, or other health care provider with appropriate credentials under §19.1706 of this title (relating to Requirements and Prohibitions Relating to Personnel) to determine the medical necessity, the [or] appropriateness, or the experimental or investigational nature[-] of health care services.
- (e) Delegation of review. A URA, including a specialty URA, may delegate the utilization review to qualified personnel in a hospital or other health care facility in which the health care services to be reviewed were, or are, to be provided. The delegation does not relieve the URA of full responsibility for compliance with this subchapter and Insurance Code Chapter 4201, including the conduct of those to whom utilization review has been delegated.
- (f) Complaint system. The URA must develop and implement procedures for the resolution of oral or written complaints initiated by enrollees, individuals acting on behalf of the enrollee, or health care providers concerning the utilization review. The URA must

maintain records of complaints for three years from the date the complaints are filed. The complaints procedure must include a requirement for a written response to the complainant by the agent within 30 calendar days. The written response must include TDI's address, toll-free telephone number, and a statement explaining that a complainant is entitled to file a complaint with TDI.

#### §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) Renewal of existing preauthorizations. If a health benefit plan issuer subject to Insurance Code Chapter 1222 requires preauthorization as a condition of payment for a medical or health care service, the URA must provide a preauthorization renewal process that allows a physician or health care provider to request renewal of an existing preauthorization at least 60 days before the date the preauthorization expires.
- (c) [(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) 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;
  - (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.
- (d)[(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.

(e)[(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 must send written notification within three working days of the telephone or electronic transmission.
- (4) Required timeframe for preauthorization renewal requests. A URA must review a request to renew a preauthorization for a medical or health care service and make and issue a determination before the existing preauthorization expires, if practicable. The determination must indicate whether the medical or health care service is preauthorized.

(f)[(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, [ef] 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.

#### §19.1710. Requirements Prior to Issuing an Adverse Determination.

In any instance in which the URA is questioning the medical necessity, the [or] appropriateness, or the experimental or investigational nature[7] of the health care services prior to the 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 discussion must include, at a minimum, the clinical basis for the URA's decision and a description of documentation or evidence, if any, that can be submitted by the provider of record that, on appeal, might lead to a different utilization review decision.

- (1) The URA must provide the URA's telephone number so that the provider of record may contact the URA to discuss the pending adverse determination.
- (2) The URA must maintain, and submit to TDI on request, documentation that details the discussion opportunity provided to the provider of record, including the date and time the URA offered the opportunity to discuss the adverse determination, the date and time that the discussion, if any, took place, and the discussion outcome.

#### §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 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.

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(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, the [er] appropriateness, or the experimental or investigational nature, of the health care services prior to issuance of 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 <u>requested or</u> denied and, within 10 working days from the <u>request or</u> denial, the health care provider <u>requests</u> [<u>sets forth in writing good cause for having</u>] a particular type of specialty provider review the case, the <u>appeal or the decision denying the appeal [denial</u>] must be reviewed by a health care provider in the same or similar specialty that typically manages the medical, dental, or specialty 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 <u>is available</u> for <u>denials of emergency care, [denials, denials of care for life-threatening conditions, denials of]</u> continued stays for hospitalized enrollees, <u>or [denials of]</u> 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; or a denial of another service if the requesting health care provider includes a written statement with supporting documentation that the service is necessary to treat a life-threatening condition or prevent serious harm to the patient. [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:
- (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;

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- (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 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.

#### §19.1716. Specialty URA.

- (a) Application. To be certified or registered as a specialty URA, an applicant must submit to TDI the application, information, and fee required in §19.1704 of this title (relating to Certification or Registration of URAs).
- (b) Same specialty required. A specialty URA must conduct utilization review under the direction of a health care provider who is of the same specialty as the agent and who is licensed or otherwise authorized to provide the specialty health care service in <u>Texas</u> [by a state licensing agency in the United States]. To conduct utilization review, a specialty URA must be of the same specialty as the health care provider who ordered the service. For example, when conducting utilization review of prescription drugs prescribed by a physician with a specialty in neurological surgery, the specialty URA must be a physician with a specialty in neurological surgery.
- (c) Rule requirements. A specialty URA is subject to the requirements of this subchapter, except for the following provisions:
- (1) Section 19.1705(a) of this title (relating to General Standards of Utilization Review);
- (2) Section 19.1706(a), (c), and (d) of this title (relating to Requirements and Prohibitions Relating to Personnel);

- (3) Section 19.1710 of this title (relating to Requirements Prior to Issuing Adverse Determination); and
- (4) Section 19.1711(a)(4) (6) of this title (relating to Written Procedures for Appeal of Adverse Determination).
- (d) Utilization review plan. A specialty URA must have its utilization review plan, including appeal requirements, reviewed by a health care provider of the appropriate specialty who is licensed or otherwise authorized to provide the specialty health care service in Texas, and the plan must be implemented under standards developed with input from a health care provider of the appropriate specialty who is licensed or otherwise authorized to provide the specialty health care service in Texas. The specialty URA must have written procedures to ensure that these requirements are implemented.
- (e) Requirements of employed or contracted physicians, doctors, other health care providers, and personnel.
- (1) Physicians, doctors, other health care providers, and personnel employed by or under contract with the specialty URA to perform utilization review must be appropriately trained, qualified, and currently licensed.
- (2) Personnel conducting specialty utilization review must hold an unrestricted license, an administrative license issued by a state licensing board, or be otherwise authorized to provide health care services by a licensing agency in the United States.
- (f) Reasonable opportunity for discussion. In any instance in which a specialty URA questions the medical necessity, the [or] appropriateness, or the experimental or investigational nature[-] of the health care services, the health care provider of record must, prior to the issuance of an adverse determination, be afforded a reasonable opportunity to discuss the plan of treatment for the patient and the clinical basis for the decision of the URA with a health care provider of the same specialty as the URA. The

discussion must include, at a minimum, the clinical basis for the specialty URA's decision and a description of documentation or evidence, if any, that can be submitted by the provider of record that, on appeal, might lead to a different utilization review decision.

- (1) The specialty URA's telephone number must be provided to the provider of record so that the provider of record may contact the specialty URA to discuss the pending adverse determination. For a retrospective utilization review, the specialty URA must allow the provider of record five working days to respond orally or in writing.
- (2) The specialty URA must maintain, and submit to TDI on request, documentation that details the discussion opportunity provided to the provider of record, including the date and time the specialty URA offered the opportunity to discuss the adverse determination; the date and time that the discussion, if any, took place; and the discussion outcome.
- (g) Appeal. The decision in any appeal of an adverse determination by a specialty URA must be made by a physician or other health care provider who has not previously reviewed the case and who is of the same specialty as the specialty URA that made the adverse determination.

#### §19.1717. Independent Review of Adverse Determinations.

- (a) Notification for life-threatening conditions. For life-threatening conditions, notification of adverse determination by a URA must be provided within the timeframes specified in  $\S19.1709(e)(3)$  [ $\S19.1709(d)(3)$ ] of this title (relating to Notice of Determinations Made in Utilization Review).
- (1) At the time of notification of the adverse determination, the URA must provide to the enrollee or individual acting on behalf of the enrollee, and to the enrollee's provider of record, the notice of the independent review process and a copy of the request

for a review by an IRO form. The notice must describe how to obtain independent review of the adverse determination.

- (2) The enrollee, individual acting on behalf of the enrollee, or the enrollee's provider of record must determine the existence of a life-threatening condition on the basis that a prudent layperson possessing an average knowledge of medicine and health would believe that the enrollee's disease or condition is a life-threatening condition.
- (b) Appeal of adverse determination involving life-threatening condition. Any party who receives an adverse determination involving a life-threatening condition or whose appeal of an adverse determination is denied by the URA may seek review of that determination or denial by an IRO assigned under Insurance Code Chapter 4202 and Chapter 12 of this title (relating to Independent Review Organizations).
- (c) Independent review involving life-threatening and non life-threatening conditions. A URA, or insurance carrier that made the adverse determination, must notify TDI within one working day from the date the request for an independent review is received. The URA, or insurance carrier that made the adverse determination, must submit the completed request for a review by an IRO form to TDI through TDI's internet [Internet] website.
- (1) Assignment of IRO. TDI will, within one working day of receipt of a complete request for independent review, randomly assign an IRO to conduct an independent review and notify the URA, payor, IRO, the enrollee or individual acting on behalf of the enrollee, enrollee's provider of record, and any other providers listed by the URA as having records relevant to the review of the assignment.
- (2) Payor and URA compliance. The payor and URA must comply with the IRO's determination with respect to the medical necessity, [or] appropriateness, or the experimental or investigational nature[-] of the health care items and services for an enrollee.

(3) Costs of independent review. The URA must pay for the independent review and may recover costs associated with the independent review from the payor.

### §19.1718 Preauthorization for Health Maintenance Organizations and Preferred Provider Benefit Plans.

- (a) The words and terms defined in Insurance Code Chapter 1301 and Chapter 843 have the same meaning when used in this section, except as otherwise provided by this subchapter, unless the context clearly indicates otherwise.
- (b) An HMO or preferred provider benefit plan that requires preauthorization as a condition of payment to a preferred provider must comply with the procedures of this section for determinations of medical necessity, [or] appropriateness, or the experimental or investigational nature[7] of care for those services the HMO or preferred provider benefit plan identifies under subsection (c) of this section.
- (c) An HMO or preferred provider benefit plan that uses a preauthorization process for medical care <u>or</u> [and] health care services must provide to each contracted preferred provider, not later than the <u>fifth</u> [10th] working day after the date a request is made, a list of medical care and health care services that allows a preferred provider to determine which services require preauthorization and information concerning the preauthorization process.
- (d) An HMO or preferred provider benefit plan must issue and transmit a determination indicating whether the proposed medical or health care services are preauthorized. This determination must be issued and transmitted once a preauthorization request for proposed services that require preauthorization is received from a preferred provider. The HMO or preferred provider benefit plan must respond to a request for preauthorization within the following time periods:

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(1) For services not included under paragraphs (2) and (3) of this subsection, a determination must be issued and transmitted not later than the third calendar day after the date the request is received by the HMO or preferred provider benefit plan. If the request is received outside of the period requiring the availability of appropriate personnel as required in subsections (e) and (f) of this section, the determination must be issued and transmitted within three calendar days from the beginning of the next time period requiring appropriate personnel.

- (2) If the proposed medical or health care services are for concurrent hospitalization care, the HMO or preferred provider benefit plan must issue and transmit a determination indicating whether proposed services are preauthorized within 24 hours of receipt of the request, followed within three working days after the transmittal of the determination by a letter notifying the enrollee or the individual acting on behalf of the enrollee and the provider of record of an adverse determination. If the request for medical or health care services for concurrent hospitalization care is received outside of the period requiring the availability of appropriate personnel as required in subsections (e) and (f) of this section, the determination must be issued and transmitted within 24 hours from the beginning of the next time period requiring appropriate personnel.
- (3) If the proposed medical care or health care services involve post-stabilization treatment, or a life-threatening condition as defined in §19.1703 of this title (relating to Definitions), the HMO or preferred provider benefit plan must issue and transmit a determination indicating whether proposed services are preauthorized within the time appropriate to the circumstances relating to the delivery of the services and the condition of the enrollee, but in no case to exceed one hour from receipt of the request. If the request is received outside of the period requiring the availability of appropriate personnel as required in subsections (e) and (f) of this section, the determination must be issued and transmitted within one hour from the beginning of the next time period

requiring appropriate personnel. The determination must be provided to the provider of record. If the HMO or preferred provider benefit plan issues an adverse determination in response to a request for post-stabilization treatment or a request for treatment involving a life-threatening condition, the HMO or preferred provider benefit plan must provide to the enrollee or individual acting on behalf of the enrollee, and the enrollee's provider of record, the notification required by §19.1717(a) and (b) of this title (relating to Independent Review of Adverse Determinations).

- (e) A preferred provider may request a preauthorization determination via telephone from the HMO or preferred provider benefit plan. An HMO or preferred provider benefit plan must have appropriate personnel as described in §19.1706 of this title (relating to Requirements and Prohibitions Relating to Personnel) reasonably available at a toll-free telephone number to provide the determination between 6:00 a.m. and 6:00 p.m., Central Time, Monday through Friday on each day that is not a legal holiday and between 9:00 a.m. and noon, Central Time, on Saturday, Sunday, and legal holidays. An HMO or preferred provider benefit plan must have a telephone system capable of accepting or recording incoming requests after 6:00 p.m., Central Time, Monday through Friday and after noon, Central Time, on Saturday, Sunday, and legal holidays and must acknowledge each of those calls not later than 24 hours after the call is received. An HMO or preferred provider benefit plan providing a preauthorization determination under subsection (d) of this section must, within three calendar days of receipt of the request, provide a written notification to the preferred provider.
- (f) An HMO providing routine vision services or dental health care services as a single health care service plan is not required to comply with subsection (e) of this section with respect to those services. An HMO providing routine vision services or dental health care services as a single health care service plan must:

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(1) have appropriate personnel as described in §19.1706 of this title reasonably available at a toll-free telephone number to provide the preauthorization determination between 8:00 a.m. and 5:00 p.m., Central Time, Monday through Friday on each day that is not a legal holiday;

- (2) have a telephone system capable of accepting or recording incoming requests after 5:00 p.m., Central Time, Monday through Friday and all day on Saturday, Sunday, and legal holidays, and must acknowledge each of those calls not later than the next working day after the call is received; and
- (3) when providing a preauthorization determination under subsection (d) of this section, within three calendar days of receipt of the request, provide a written notification to the preferred provider.
- (g) If an HMO or preferred provider benefit plan has preauthorized medical care or health care services, the HMO or preferred provider benefit plan may not deny or reduce payment to the physician or provider for those services based on medical necessity, [er] appropriateness, or the experimental or investigational nature[7] of care unless the physician or provider has materially misrepresented the proposed medical or health care services or has substantially failed to perform the preauthorized medical or health care services.
- (h) If an HMO or preferred provider benefit plan issues an adverse determination in response to a request made under subsection (d) of this section, a notice consistent with the provisions of §19.1709 of this title (relating to Notice of Determinations Made in Utilization Review) and §19.1710 of this title (relating to Requirements Prior to Issuing Adverse Determination) must be provided to the enrollee or an individual acting on behalf of the enrollee, and the enrollee's provider of record. An enrollee, an individual acting on behalf of the enrollee, or the enrollee's provider of record may appeal any adverse

determination under §19.1711 of this title (relating to Written Procedures for Appeal of Adverse Determination).

- (i) This section applies to an agent or other person with whom an HMO or preferred provider benefit plan contracts to perform utilization review, or to whom the HMO or preferred provider benefit plan delegates the performance of preauthorization of proposed medical or health care services. Delegation of preauthorization services does not limit in any way the HMO or preferred provider benefit plan's responsibility to comply with all statutory and regulatory requirements.
- (j) The provisions in this subsection apply to an HMO or a preferred provider benefit plan that uses a preauthorization process for medical or health care services.
- (1) An HMO or a preferred provider benefit plan must make the requirements and information about the preauthorization process readily accessible to enrollees, physicians, health care providers, and the general public by posting the requirements and information on the HMO's or the preferred provider benefit plan's public internet website.
- (2) The preauthorization requirements and information described by paragraph (1) of this section must:

#### (A) be posted:

(i) conspicuously in a location on the public internet website that does not require the user to login or input personal information to view the information; except as provided by paragraph (3) or (4) of this subsection;

(ii) in a format that is easily searchable; and

(iii) in a format that uses design and accessibility standards defined in Section 508 of the U.S. Rehabilitation Act;

(B) except for the screening criteria under subparagraph (D)(iii) of this paragraph, be written:

(i) using plain language standards, such as the Federal Plain Language Guidelines found on www.PlainLanguage.gov; and

(ii) in language that aims to reach a 6th to 8th grade reading level, if the information is for enrollees and the public;

(C) include a detailed description of the preauthorization process and procedure; and

(D) include an accurate and current list of medical or health care services for which the HMO or the preferred provider benefit plan requires preauthorization that includes the following information specific to each service:

(i) the effective date of the preauthorization requirement;

(ii) a list or description of any supporting documentation that the HMO or preferred provider benefit plan requires from the physician or health care provider ordering or requesting the service to approve a request for that service;

(iii) the applicable screening criteria, which may include Current Procedural Terminology codes and International Classification of Diseases codes; and

(iv) statistics regarding the HMO's or the preferred provider benefit plan's preauthorization approval and denial rates for the service in the preceding calendar year, including statistics in the following categories:

(I) physician or health care provider type and specialty,

if any;

(II) indication offered;

(III) reasons for request denial;

(IV) denials overturned on internal appeal;

(V) denials overturned by an independent review

organization; and

(VI) total annual preauthorization requests, approvals,

and denials for the service.

(3) This subsection may not be construed to require an HMO or a preferred provider benefit plan to provide specific information that would violate any applicable copyright law or licensing agreement. To comply with a posting requirement described by paragraph (2) of this subsection, an HMO or a preferred provider benefit plan may, instead of making that information publicly available on the HMO's or the preferred provider benefit plan's public internet website, supply a summary of the withheld information sufficient to allow a licensed physician or other health care provider, as applicable for the specific service, who has sufficient training and experience related to the service to understand the basis for the HMO's or the preferred provider benefit plan's medical necessity or appropriateness determinations.

(4) If a requirement or information described by paragraph (1) of this subsection is licensed, proprietary, or copyrighted material that the HMO or the preferred provider benefit plan has received from a third party with which the HMO or the preferred provider benefit plan has contracted, to comply with a posting requirement described by paragraph (2) of this subsection, the HMO or the preferred provider benefit plan may, instead of making that information publicly available on the HMO's or the preferred provider benefit plan's public internet website, provide the material to a physician or health care provider who submits a preauthorization request using a nonpublic secured internet website link or other protected, nonpublic electronic means.

(5) The provisions in this paragraph apply when an HMO or a preferred provider benefit plan makes changes to preauthorization requirements.

(A) Except as provided by subparagraph (B) of this paragraph, not later than the 60th day before the date a new or amended preauthorization requirement takes effect, an HMO or a preferred provider benefit plan must provide notice of the new

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or amended preauthorization requirement and disclose the new or amended requirement in the HMO's or the preferred provider benefit plan's newsletter or network bulletin, if any, and on the HMO's or the preferred provider benefit plan's public internet website.

(B) For a change in a preauthorization requirement or process that removes a service from the list of medical and health care services requiring preauthorization or amends a preauthorization requirement in a way that is less burdensome to enrollees or participating physicians or health care providers, an HMO or a preferred provider benefit plan must provide notice of the change in the preauthorization requirement and disclose the change in the HMO's or the preferred provider benefit plan's newsletter or network bulletin, if any, and on the HMO's or the preferred provider benefit plan's public internet website not later than the fifth day before the date the change takes effect.

(C) Not later than the fifth day before the date a new or amended preauthorization requirement takes effect, an HMO or a preferred provider benefit plan must update its public internet website to disclose the change to the HMO's or the preferred provider benefit plan's preauthorization requirements or process and the date and time the change is effective.

(6) In addition to any other penalty or remedy provided by law, an HMO or a preferred provider benefit plan that uses a preauthorization process for medical or health care services that violates this subsection with respect to a required publication, notice, or response regarding its preauthorization requirements, including by failing to comply with any applicable deadline for the publication, notice, or response, must provide an expedited appeal under Insurance Code §4201.357 for any health care service affected by the violation.

(7) The provisions of this subsection may not be waived, voided, or nullified by contract.

- (k) The provisions of this subsection apply to dental care services under an employee benefit plan or health insurance policy that require prior authorization.
- (1) In this subsection, the definitions in Texas Insurance Code §1451.201 for "dental care service," "employee benefit plan," and "health insurance policy" apply.
- (2) In this subsection, "prior authorization" means a written and verifiable determination that one or more specific dental care services are covered under the patient's employee benefit plan or health insurance policy and are payable and reimbursable in a specific stated amount, subject to applicable coinsurance and deductible amounts. The term includes preauthorization and similar authorization. The term does not include "predetermination" as that term is defined by Insurance Code §1451.207(c).
- (3) For services for which a prior authorization is required, on request of a patient or treating dentist, an employee benefit plan or health insurance policy provider or issuer must provide to the dentist a written prior authorization of benefits for a dental care service for the patient. The prior authorization must include a specific benefit payment or reimbursement amount. Except as provided by paragraph (4) of this subsection, the plan or policy provider or issuer may not pay or reimburse the dentist in an amount that is less than the amount stated in the prior authorization.
- (4) An employee benefit plan or health insurance policy provider or issuer that preauthorizes a dental care service under paragraph (3) of this subsection may deny a claim for the dental care service or reduce payment or reimbursement to the dentist for the service only if:
- (A) the denial or reduction is in accordance with the patient's employee benefit plan or health insurance policy benefit limitations, including an annual maximum or frequency of treatment limitation, and the patient met the benefit limitation after the date the prior authorization was issued;

(B) the documentation for the claim fails to reasonably support the claim as preauthorized;

(C) the preauthorized dental service was not medically necessary based on the prevailing standard of care on the date of the service, or is subject to denial under the conditions for coverage under the patient's plan or policy in effect at the time the service was preauthorized, because of a change in the patient's condition or because the patient received additional dental care after the date the prior authorization was issued;

(D) a payor other than the employee benefit plan or health insurance policy provider or issuer is responsible for payment of the claim;

(E) the dentist received full payment for the preauthorized dental care service on which the claim is based;

(F) the claim is fraudulent;

(G) the prior authorization was based wholly or partly on a material error in information provided to the employee benefit plan or health insurance policy provider or issuer by any person not related to the provider or the issuer; or

(H) the patient was otherwise ineligible for the dental care service under the patient's employee benefit plan or health insurance policy and the plan or policy issuer did not know, and could not reasonably have known, that the patient was ineligible for the dental care service on the date the prior authorization was issued.

(l) If a health benefit plan issuer subject to Insurance Code Chapter 1222 requires preauthorization as a condition of payment for a medical or health care service, the heath benefit plan issuer must provide a preauthorization renewal process that allows a physician or health care provider to request renewal of an existing preauthorization at least 60 days before the date the preauthorization expires. When practicable, a URA must review and issue a determination on a renewal request before the existing

preauthorization expires if the URA receives the request before the existing preauthorization expires. The determination must indicate whether the medical or health care service is preauthorized.

**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 October 6, 2020.

DocuSigned by:

James Person

James Person, General Counsel Texas Department of Insurance