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SUBCHAPTER A. GENERAL PROVISIONS 28 TAC §12.4

SUBCHAPTER G. INDEPENDENT REVIEW OF PREAUTHORIZATION EXEMPTIONS 28 TAC §12.601

INTRODUCTION. The Commissioner of Insurance adopts amended 28 TAC §12.4, concerning applicability, and new 28 TAC Subchapter G, §12.601, concerning review of preauthorization exemptions by independent review organizations (IROs). These amended and new sections implement House Bill 3459, 87th Legislature, 2021. The amended and new sections were published in the April 8, 2022, issue of the *Texas Register* (47 TexReg 1854). The Commissioner adopts amended §12.4 with a nonsubstantive change to the proposed text. The Commissioner adopts new §12.601 with changes to the proposed text in response to public comments and other nonsubstantive changes.

REASONED JUSTIFICATION. Amended §12.4 and new §12.601, are necessary to conform the Texas Department of Insurance's (TDI) utilization review rules with HB 3459, which allows a health maintenance organization or insurer to rescind an exemption from preauthorization requirements under certain conditions. A physician or provider may appeal an adverse determination regarding a preauthorization to an IRO to review the appropriateness of the rescission determination by the health maintenance organization or insurer.

The amended and new sections are described in the following paragraphs.

Section 12.4. The amendments to §12.4(a) replace the phrase "of this subchapter" with "of this title" and add a reference to the section heading for consistency with current

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agency language preferences and drafting practices. TDI makes a grammatical change to the text of subsection (a) as proposed to remove the comma that follows "managed care entities."

The amendments to §12.4(b) remove obsolete applicability language. New language states that independent reviews of adverse determinations regarding preauthorization exemptions made under Texas Insurance Code Chapter 4201, Subchapter N, must comply with new §12.601.

Subchapter G. Independent Review of Preauthorization Exemptions. TDI adds new Subchapter G, which consists of new §12.601. TDI modifies the proposed title of the new subchapter to more clearly describe the contents of the subchapter.

Section 12.601. New §12.601 outlines requirements and procedures for appeals of adverse determinations regarding a preauthorization exemption.

New §12.601(a) defines "adverse determination regarding a preauthorization exemption," "issuer," "physician," "preauthorization exemption," and "provider" to clarify these terms, which may have different meanings in other contexts in 28 TAC Chapter 12, and to refer to the preauthorization exemption process in 28 TAC Chapter 19.

New §12.601(b) states that the independent review of an adverse determination regarding a preauthorization exemption, the IRO that performs the review, and the appropriate issuer are subject to Insurance Code Chapter 4201, Subchapter N, and 28 TAC Chapter 12, except as otherwise specified in §12.601.

New §12.601(c) states that for the purposes of §12.601, a physician or provider should be identified using the National Provider Identifier under which a physician or provider makes preauthorization requests.

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New §12.601(d) states that an issuer must submit a request for independent review of an adverse determination regarding a preauthorization exemption to TDI on behalf of a physician or provider.

In response to comment, TDI modifies the text of new §12.601(e) as proposed to clarify that the IRO must base its decision on whether to uphold an exemption recission on the total number of claims in the initial random sample and a second random sample, if one was requested under Insurance Code §4201.656(d) and available as provided in 28 TAC §19.1733(e). New §12.601(e) provides that, if a second random sample is requested and available, the IRO must identify the new sample of at least five and no more than 20 claims from the list of eligible claims provided by the issuer. The IRO must review each claim that the issuer retrospectively reviewed and determined did not meet the applicable criteria and, if applicable, each claim included in the second random sample identified by the IRO. The IRO may request any medical records needed to evaluate the claims subject to review and must provide at least three business days for receipt of records.

New §12.601(f) states that appeals for an adverse determination regarding a preauthorization exemption follow TDI's process for assigning IROs under 28 TAC §12.502, except that TDI will only provide notice of the appeal to the IRO, the issuer, and the physician or provider.

New §12.601(g) states that 28 TAC §12.206 does not apply to an IRO's independent review of an adverse determination regarding a preauthorization exemption. In response to comment, TDI modifies §12.601(g) to clarify that an IRO must provide timely notice to an issuer regarding its determination consistent with the timeframe provided under Insurance Code §4201.656(c).

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SUMMARY OF COMMENTS AND AGENCY RESPONSE.

Commenters: TDI received written comments from 23 commenters, and two commenters spoke at a public hearing on the proposal held on May 12, 2022.

Commenters in support of the proposal were: Texas Healthcare and Bioscience Institute.

Commenters in support of the proposal with changes were: eviCore Healthcare, Pharmaceutical Care Management Association, Quest Diagnostics, Texas Academy of Family Physicians, Texas Association of Health Plans, Texas Chapter of the American College of Cardiology, Texas Chapter of the American College of Physicians Services, Texas College of Emergency Physicians, Texas Medical Association, Texas Neurological Society, Texas Orthopaedic Association, Texas Pain Society, Texas Pediatric Society, Texas Public Policy Foundation, Texas Society for Gastroenterology and Endoscopy, Texas Society of Pathologists, Texas Society of Plastic Surgeons, Texas Urological Society, one individual, two state representatives, and two state senators.

Comments on Chapter 12 Generally

Comment. One commenter expresses broad support for the proposal.

Agency Response. TDI appreciates the support.

Comment. One commenter suggests that TDI require providers to be responsible for IRO fees if the IRO upholds an issuer's rescission determination.

Agency Response. TDI declines to make the requested change. Insurance Code §4201.656(b) requires the issuer to pay for any appeal or independent review.

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Comments on §12.601

Comment. One commenter requests TDI provide clarification on how a random sample is compiled and the number of claims required to be included in the sample. Another commenter requests TDI make an amendment to confirm that (1) the only reason a physician or provider may request a new sample for the IRO is if the issuer based the rescission on cases that were outside the random sample, and (2) that the physician or provider cannot request review of a second random sample without reason.

Another commenter objects to an IRO reviewing only the claims in a second random sample, arguing that Insurance Code §4201.656(d) requires that if another random sample is requested, the IRO must base its determination on both the original random sample and the second random sample.

Several commenters jointly state that they oppose the language in proposed §12.601(e) that references the issuer reviewing claims outside of the original random sample because of concerns with lack of alignment with the statutory language. They recommend that TDI implement the language of Insurance Code §4201.656(d) according to its express terms. The commenters suggest that when a provider requests review of "another random sample," as permitted under Insurance Code §4201.656(d), the IRO should perform a first-time review and not a re-review of claims reviewed by the issuer. Alternatively, the commenters suggest that the plan review additional claims upon the provider's request.

Agency Response. In response to the request for clarification, TDI affirms that an evaluation of a physician's or provider's continued eligibility for an exemption is based on a random sample of five to 20 payable claims that were submitted during the most recent evaluation period.

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TDI agrees that an issuer may conduct a retrospective review of a health care service subject to an exemption only as provided in §4201.659(b)(1) and (2) and has modified the text of §12.601 as adopted to permit a provider to request that an IRO review another random sample of claims as long as the notice of rescission identified that at least five additional claims were eligible for review but not included in the original random sample. As adopted, §12.601(e) states that the IRO must identify the second random sample of at least five and no more than 20 claims from the list of eligible claims provided by the issuer. In the case that the issuer did not identify that at least five additional claims were eligible but not included in the original random sample, the IRO would be unable to select an additional random sample that differed from the original sample.

The revisions to §12.601(e) require the IRO to review each claim that the issuer retrospectively reviewed and determined did not meet the applicable medical necessity criteria and, if applicable, each claim included in the second random sample identified by the IRO. The IRO's evaluation of a physician's or provider's continued eligibility for an exemption is based on the total number of claims in the initial random sample and, if applicable, the second random sample, consistent with Insurance Code §4201.656(d).

TDI declines to make the requested amendment to limit the circumstances under which the physician or provider may request a second random sample because such an amendment would be inconsistent with Insurance Code §4201.656.

Comment. Several commenters jointly recommend that an IRO be required to make an independent decision regarding whether there was truly a failure to provide medical records necessary for the issuer to make a determination.

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Agency Response. TDI declines to make a change. If a rescission is based on one or more claims in which the issuer determined that the physician or provider failed to provide sufficient records to demonstrate medical necessity, the physician or provider must include the applicable records with the request for an independent review. If an IRO believes additional information is needed, the IRO can request any medical records needed to make a determination.

Comment. Two commenters request clarification on the length of time an IRO has to process a review and return the determination to the issuer. The commenters note that there is no clarification for how long the IRO has to perform and complete the review before returning a verdict to the issuer, and that under §12.601(g), the general IRO notice requirements within §12.206 do not apply. One commenter recommends a requirement for a timely IRO notice to the issuer. The other commenter recommends adding a 30-day limitation on the length of time an IRO has to process an appeal. The commenter says this would ensure that a physician denied an exemption experiences no delay in his or her appeal process.

Agency Response. Insurance Code §4201.656(c) clearly states that an IRO must complete its review not later than the 30th day after a physician or provider files the request for a review. TDI modifies the text of §12.601(g) as proposed to clarify that an IRO must provide timely notice to an issuer regarding its determination consistent with the timeframe provided under Insurance Code §4201.656(c).

Comment. One commenter asks that TDI provide clarity on when rescissions become effective.

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Agency Response. Consistent with Insurance Code §4201.654, a rescission becomes effective either on the 30th day after the issuer notifies the physician or provider of the rescission determination (as indicated on the notice issued under §19.1732(d)), or, if the physician or provider appeals the determination, on the fifth day after the date the IRO affirms the issuer's determination to rescind the exemption.

SUBCHAPTER A. GENERAL PROVISIONS 28 TAC §12.4

STATUTORY AUTHORITY. The Commissioner adopts the amendments to §12.4 under Insurance Code §4201.003 and §36.001.

Insurance Code §4201.003 authorizes the Commissioner to 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 TDI under the Insurance Code and other laws of this state.

TEXT.

§12.4. Applicability.

(a) All independent review organizations (IROs) performing independent reviews of adverse determinations made by utilization review agents, health insurance carriers, health maintenance organizations, and managed care entities must comply with this chapter. IROs performing independent reviews of adverse determinations made by certified workers' compensation health care networks and workers' compensation insurance carriers must comply with this chapter, subject to §12.6 of this title (relating to

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Independent Review of Adverse Determinations of Health Care Provided Under Labor Code Title 5 or Insurance Code Chapter 1305).

(b) All IROs performing independent reviews of adverse determinations regarding preauthorization exemptions made under Insurance Code Chapter 4201, Subchapter N, concerning Exemption From Preauthorization Requirements for Physicians and Providers Providing Certain Health Care Services, must comply with §12.601 of this title (relating to Preauthorization Exemptions).

SUBCHAPTER G. INDEPENDENT REVIEW OF PREAUTHORIZATION EXEMPTIONS 28 TAC §12.601

STATUTORY AUTHORITY. The Commissioner adopts the new §12.601 under Insurance Code §4201.003 and §36.001.

Insurance Code §4201.003 authorizes the Commissioner to 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 TDI under the Insurance Code and other laws of this state.

TEXT.

§12.601. Preauthorization Exemptions.

(a) In this section, the following words and terms have the following meanings unless context clearly indicates otherwise.

(1) Adverse determination regarding a preauthorization exemption--Has the same meaning as defined in §19.1730 of this title (relating to Definitions).

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(2) Issuer--Has the same meaning as defined in §19.1730 of this title.

(3) Physician--Has the same meaning as defined by Insurance Code §843.002, concerning Definitions.

(4) Preauthorization exemption--Has the same meaning as defined in §19.1730 of this title.

(5) Provider--Has the same meaning as defined in Insurance Code §843.002.

(b) An independent review of an adverse determination regarding a preauthorization exemption, the independent review organization (IRO) that performs the review, and the appropriate issuer are subject to Insurance Code Chapter 4201, Subchapter N, concerning Exemption from Preauthorization Requirements for Physicians and Providers Providing Certain Health Care Services, and the associated standards and requirements in this chapter, except as otherwise specified in this section.

(c) For purposes of this section, a physician or provider should be identified using the National Provider Identifier under which a physician or provider makes preauthorization requests.

(d) Notwithstanding §12.501 of this title (relating to Requests for Independent Review), an issuer must submit a request for independent review of an adverse determination regarding a preauthorization exemption to the department on behalf of a physician or provider.

(e) If a second random sample is requested under Insurance Code §4201.656(d), concerning Independent Review of Exemption Determination, and available as provided in §19.1733(e) of this title (relating to Retrospective Reviews and Appeals of Preauthorization Exemption Rescissions), the IRO must identify, from the list of eligible claims provided by the issuer, a second random sample of at least five and no more than

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20 claims. The IRO must review each claim that the issuer retrospectively reviewed and determined did not meet the applicable medical necessity criteria and, if applicable, each claim included in the second random sample identified by the IRO. Consistent with Insurance Code §4201.656(b), the IRO may request any medical records needed to evaluate the claims subject to review and must provide at least three business days for receipt of records. Based on the total number of claims in the initial random sample and, if applicable, the second random sample, the IRO must determine whether to affirm or overturn the issuer's determination that less than 90 percent of the claims met the applicable medical necessity criteria.

(f) Appeals for an adverse determination regarding a preauthorization exemption to an IRO follow the department's process for assigning IROs under §12.502 of this title (relating to Random Assignment), except that notification under §12.502(a) will only be made to the IRO, the issuer, and the physician or provider.

(g) Section 12.206 of this title (relating to Notice of Determinations Made by Independent Review Organizations) does not apply to a review by an IRO under this section. An IRO must complete its review and provide timely notice to an issuer regarding its determination, consistent with the timeframe provided under Insurance Code §4201.656(c).

CERTIFICATION. This agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Issued at Austin, Texas, on August 12, 2022.

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James Person, General Counsel Texas Department of Insurance

The Commissioner adopts amended 28 TAC §12.4 and new §12.601.

—DocuSigned by:

Gbrown Cassie Brown Commissioner of Insurance

Commissioner's Order No. 2022-7435