

**SUBCHAPTER R. UTILIZATION REVIEWS FOR HEALTH CARE PROVIDED UNDER A
HEALTH BENEFIT PLAN OR HEALTH INSURANCE POLICY
DIVISION 1. UTILIZATION REVIEWS
28 TAC §19.1710**

**DIVISION 2. PREAUTHORIZATION EXEMPTIONS
28 TAC §§19.1730 - 19.1733**

INTRODUCTION. The Commissioner of Insurance adopts amended 28 TAC §19.1710 and new 28 TAC Chapter 19, Subchapter R, Division 2, §§19.1730 - 19.1733, concerning requirements prior to issuing an adverse determination and preauthorization exemptions. These amended and new sections implement House Bill 3459, 87th Legislature, 2021. The Commissioner adopts §19.1710 without changes to the proposed text published in the April 8, 2022, issue of the *Texas Register* (47 TexReg 1856). The Commissioner adopts §§19.1730 - 19.1733 with revisions made in response to public comments.

REASONED JUSTIFICATION. Amended §19.1710 and new Division 2, §§19.1730 - 19.1733 are necessary to conform the Texas Department of Insurance's (TDI) utilization review rules with HB 3459, which allows an issuer such as a health maintenance organization or insurer to grant, deny, or rescind an exemption from preauthorization requirements under certain conditions. Under the adopted rules, an issuer must provide notice of an initial exemption or denial of an exemption not later than October 1, 2022, based on an evaluation period of January 1, 2022, through June 30, 2022.

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

Section 19.1710. Amended §19.1710 clarifies that a utilization review agent must afford the provider of record a reasonable opportunity to discuss the plan of treatment for the enrollee with a physician licensed to practice in Texas. This section follows Insurance Code §4201.206, as amended by HB 3459, in which new language specifies that an agent must provide to a health care provider an opportunity to discuss the health care service in question with a physician licensed to practice medicine "in this state." The section is also amended to add a sentence stating, in accordance with Insurance Code §4201.206, that if the health care service was ordered, requested, or provided by a physician, the opportunity to discuss the health care service in question must be with a physician licensed to practice medicine in Texas and who has the same or similar specialty as the requesting physician. Physicians holding Texas Administrative Medicine Licenses under the Medical Practice Act and Texas Medical Board rule, 22 TAC §172.17, can meet this standard. TDI has historically interpreted §4201.206 to include Texas Administrative Medicine Licenses, and TDI believes that recent changes to Insurance Code §4201.206 do not indicate that this long-standing position should change.

Division 2. Preauthorization Exemptions. TDI adds new Division 2, titled "Preauthorization Exemptions," to distinguish §§19.1730 - 19.1733 from existing rules in Subchapter R, which relate to utilization review and preauthorization procedures generally. A new Division 1 with the heading "Utilization Reviews" and consisting of §§19.1701 - 19.1719 has been administratively designated in Chapter 19, Subchapter R to distinguish between the sections that address utilization review and those that address preauthorization exemptions.

Section 19.1730. New §19.1730 defines terms used in the new division: "adverse determination regarding a preauthorization exemption," "denial of preauthorization

exemption," "eligible preauthorization request," "evaluation," "evaluation period," "issuer," "particular health care service," "physician," "preauthorization," "preauthorization exemption," "provider," "random sample," "rescission of preauthorization exemption," and "treating physician or provider." The definitions clarify:

- the nature of an adverse determination regarding a preauthorization exemption, as compared with the meaning of adverse determination under §19.1703;
- the number of eligible preauthorization requests needed for granting or denying a preauthorization exemption;
- the threshold percentage of accepted claims needed for an issuer to grant, deny, or rescind a preauthorization exemption;
- the nature of an evaluation depending on whether the physician or provider currently has a preauthorization exemption in place;
- the time allowed for evaluation periods; and
- the scope of "particular health care service" to include prescription drugs.

TDI changes the definition of "adverse determination regarding a preauthorization exemption" as proposed to add the word "retrospectively" and include a reference to paragraph (4)(B) of the section, where the applicable evaluation is defined, to add clarity and consistency with other changes made in response to comments.

TDI changes the definition of "denial of preauthorization exemption" as proposed in response to comment to add clarity by inserting a reference to paragraph (4)(A) of the section and adding references to the newly defined term, "eligible preauthorization request."

Along with the proposed defined terms, TDI adopts a new defined term "eligible preauthorization request" in response to comments to clarify which preauthorization requests may be counted as approved or denied for the purposes of an evaluation.

TDI changes the definition of "evaluation" as proposed in response to comments to specify that the evaluation for a continuation or rescission analysis is based on a retrospective review of a random sample of claims. The definition is changed to add references to "eligible" preauthorization requests, "retrospective" review, and "payable" claims. TDI also clarifies that claims submitted "in connection with" a physician or provider are subject to an evaluation of the physician's or provider's continued eligibility for an exemption. TDI adds the word "meeting" to clarify that a determination the claims would have been approved is based on meeting the issuer's applicable medical necessity criteria. TDI makes a grammatical change at the end of the definition of "evaluation," to replace the semicolon with a period.

TDI changes the definition of "provider" as proposed by removing unnecessary text after citing to Insurance Code §843.002.

TDI changes the definition of "rescission of preauthorization exemption" as proposed in response to comments to add a reference to paragraph (4)(B) of the section, where the applicable evaluation is defined, and replace language regarding the physician licensure requirement with a reference to Insurance Code §4201.655(b).

TDI changes the definition of "treating physician or provider" as proposed to reference "health and medical care" in place of "health care for an illness or injury," and add "or ordering" to add clarification and avoid the appearance of unintentionally narrowing the scope of the definition. TDI also replaces "includes" with "can include" to improve the grammatical structure in the second sentence of the definition.

TDI renumbers the paragraphs of the defined terms that follow the new defined "eligible preauthorization request."

Section 19.1731. New §19.1731 describes the initial preauthorization exemption process. Subsection (a) clarifies that for purposes of Division 2, a "physician" or "provider" should be identified using the National Provider Identifier (NPI) under which a physician or provider makes preauthorization requests. TDI changes subsection (a) as proposed to add a reference to the abbreviation "NPI."

Subsection (b) states that an issuer must review the outcomes of no fewer than five eligible preauthorization requests for a particular health care service in a given evaluation period and determine whether the physician or provider qualifies for an exemption. TDI specifically sought comments on this minimum threshold for review and in response to comments changes the proposed text to reduce it from 20 preauthorization requests to five eligible preauthorization requests.

Subsection (c) provides the requirements for an issuer to rescind a preauthorization exemption that has already been granted to a physician or provider, which must be rescinded consistent with Insurance Code §4201.655. TDI changes subsection (c) as proposed to add a reference to the definition of evaluation in §19.1730(4)(B).

Subsection (d) clarifies that if a treating physician or provider without a preauthorization exemption relies on another physician's or provider's preauthorization exemption in violation of subsection (d), the physician or provider who has qualified for an exemption may be considered by the issuer as failing to substantially perform the health care service. In that situation, the issuer may reduce or deny payment for that service under Insurance Code §4201.659. In response to comments, TDI changes subsection (d) as proposed to consistently reference a physician "or provider" and clarifies

that it is the exempt physician or provider that would be considered to have failed to provide a service if the treating physician or provider inappropriately relied on the exempt physician's or provider's exemption. In response to comments and questions, TDI adds a sentence to subsection (d) that clarifies that supervised providers, such as nurses and physician's assistants, may rely on the supervising physician's exemption in certain circumstances.

Finally, TDI adds new subsection (e) to the text of §19.1731 as proposed to address concerns that issuers would be unable to operationalize exemptions for ordering or referring physicians and providers, unless the rendering and billing provider includes the exempt provider's NPI on the claim form.

Section 19.1732. New §19.1732(a) states that an issuer must provide notice to the physician or provider when granting a preauthorization exemption, and it requires that an exemption be in place for at least six months before it can be rescinded. In response to comments, TDI changes subsection (a) as proposed to require the exemption notice to include a plain language explanation of the effect of the preauthorization exemption and any claim coding guidance needed to document the exemption, consistent with §19.1731(e). If an issuer subsequently receives a preauthorization request from the physician or provider for a service for which the physician or provider has been granted an exemption, the issuer must provide notice in accordance with Insurance Code §4201.659(e).

For denials of preauthorization exemptions, new §19.1732(b) states that an issuer must provide notice of the denial to the physician or provider and list the reasons for a denial in accordance with Insurance Code §4201.655(c)(2). In response to comments, TDI changes subsection (b) as proposed to also require a denial notice to include a description

of how to appeal the denial using the issuer's complaints and appeals processes and information on how to file a complaint with TDI.

New §19.1732(c) provides a required timeframe for issuing notices of exemption or denial following the initial and subsequent evaluation periods and clarifies that such notices are required with respect to a particular health care service only if the physician or provider had submitted at least five eligible preauthorization requests during the evaluation period. TDI specifically sought comments on this minimum duration for exemptions and the timeframe for issuing notices, and whether either should be modified. In response to comments, TDI changes subsection (c) as proposed to clarify that an issuer must provide notice within five days of completing an evaluation, as required by Insurance Code §4201.659(d). Consistent with the change to §19.1731(b) as proposed, TDI also changes the minimum threshold from 20 to five eligible preauthorization requests. To conform with agency style, TDI removes the parenthetical reference following §19.1731(b), since the reference is added as part of the change to subsection (a).

New §19.1732(d) describes the requirements of the notice that must be delivered to a physician or provider when rescinding a preauthorization exemption, the requirements for a physician or provider to appeal a rescission of preauthorization exemption, and notes an example form (LHL011) available on TDI's website. In response to comments, TDI changes the text of subsection (d) as proposed to clarify that rescission notices must be provided during the months specified in Insurance Code §4201.655(a)(1). TDI changes subsection (d)(1) as proposed to specify that the rescission notice must include the date the notice is issued and changes subsection (d)(2) as proposed to clarify that issuers must allow providers to return appeal forms by mail or electronic means. TDI changes subsection (d)(3) as proposed to provide that the notice must state the total

number of eligible claims with respect to the health care service subject to rescission and the number of claims included in the random sample. TDI changes subsection (d)(3)(A) as proposed to remove the reference to retrospective review of additional claims that were not included in the random sample. In response to comment, TDI changes subsection (d)(3)(C)(i) to clarify that the rescission notice must state if the principal reason for a determination is based on a failure to submit specified medical records. TDI makes a grammatical change in subsection (d)(3)(C)(iv) as proposed by replacing "that" with "who," when referencing the physician, doctor, or other health care provider. TDI changes subsection (d)(5) as proposed in response to comment to require the rescission notice to include an instruction for the physician or provider to include applicable medical records with the request for independent review for any determination that was based on a failure to provide medical records.

TDI also adds new subsection (e) to the text of §19.1732 as proposed to require issuers to offer physicians and providers an option to request appeals and receive communications regarding preauthorization exemptions by mail or electronically and a method for physicians and providers to indicate their preferred contact information for these communications.

Section 19.1733. New §19.1733(a) clarifies that Insurance Code §4201.305 does not apply to retrospective reviews conducted under Insurance Code §4201.659(b)(1).

New §19.1733(b) provides that a physician or provider has at least 30 days to provide medical records or other documents for the issuer to conduct an evaluation. Medical records can be requested only during an evaluation period or within 90 days following the end of an evaluation period. If the physician or provider does not provide the necessary records for an issuer to make a determination, the issuer may determine

that the claim would not have met the screening criteria. In response to comment, TDI changes the text as proposed to add a reference to the applicable definition of evaluation in §19.1730(4)(B). TDI makes a nonsubstantive formatting change to the proposed text to capitalize "Contact" in the reference to "URA Contact." TDI also changes language in subsection (b) as proposed to clarify that medical records requested "in connection with a retrospective review of a random sample of claims as authorized under Insurance Code §4201.659(b)(1) should be limited to no more than 20 claims. . ."

New §19.1733(c) states that a physician or provider may request an independent review of the retrospective review that resulted in the rescission of preauthorization exemption at any time before the rescission is effective. In response to comment, TDI changes the proposed text to clarify that the date of the request must be documented on the form and the form must be sent electronically or postmarked before the date the rescission becomes effective.

New §19.1733(d) provides that a physician or provider must submit to the issuer the form provided by the issuer under §19.1732(c) in order to request an independent review. Upon receipt, the issuer must submit the request for independent review to TDI, consistent with adopted new 28 TAC §12.601 (included in a separate adoption) and 28 TAC §19.1717. In response to comment, TDI changes subsection (d) as proposed to require that a physician or provider include applicable records with any request for independent review where one or more determinations subject to review were based on a failure to provide specified medical records. In the last sentence of subsection (d), TDI clarifies that the requirement for the issuer to submit the request for independent review applies only if the issuer seeks to proceed with the proposed rescission. TDI adds a reference to

Insurance Code §4201.402 to clarify the obligation of the issuer to provide information concerning the appeal to the independent review organization (IRO) in a timely manner.

TDI changes new §19.1733(e) as proposed in response to comments. The subsection now states that a physician or provider may request that the IRO review another random sample of claims, as authorized under Insurance Code §4201.656(d), if the notice of rescission of preauthorization exemption identified that at least five additional claims were eligible for review but not included in the original random sample. If the request for a new random sample is made, the issuer must provide a listing of all eligible claims that were not included in the original random sample when submitting the request for independent review to TDI. The listing must be sufficiently detailed to allow the IRO to identify each payable claim to be used in an additional random sample, as provided in conforming changes to §12.601(e), which are discussed in a separate adoption.

New §19.1733(f) states that an issuer must communicate the determination of a review by the IRO to the physician or provider within five days.

New §19.1733(g) states that physicians and providers must continue to maintain medical records adequate to demonstrate that the exempted services they provide meet medical guidelines, in order to retain a preauthorization exemption. Most, if not all, physicians and providers subject to this adopted rule already maintain records for a sufficient amount of time. *See, e.g.*, 22 TAC §76.4(a) (Texas Board of Chiropractic Examiners rule imposing a six-year records retention requirement); 22 TAC §165.1(b)(1) (Texas Medical Board rule imposing a six-year records retention requirement); and 22 TAC §§291.34(a), 291.75(a), and 291.94(a) (Texas State Pharmacy Board rules imposing a two-

year records retention requirement). If there are no adequate records for an issuer to use during an evaluation, an exemption may be rescinded.

SUMMARY OF COMMENTS AND AGENCY RESPONSE.

Commenters: TDI received written comments from 32 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: America's Health Insurance Plans; eviCore Healthcare; Harris Health System; National Infusion Center Association; Oncology Consultants, P.A.; Pharmaceutical Care Management Association; Quest Diagnostics, Sendero Health Plans, Inc.; Texas Academy of Family Physicians; Texas Association of Community Health Plans; 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 Oncology; 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; TSAOG Orthopaedics & Spine; one individual; two state representatives; and two state senators.

Comments on Chapter 19 Generally

Comment. One commenter expresses support for the amendments.

Agency Response. TDI appreciates the support.

Comment. One commenter strongly encourages TDI to allow preauthorization requests to be made by clinical laboratories for laboratory services, and permit clinical laboratory claims to be measured to grant or deny preauthorization exemption requests. The commenter suggests that these modifications would ensure that clinical laboratories are evaluated fairly and able to obtain the exemption stated in the law.

Agency Response. TDI disagrees that a change is needed. Preauthorization exemptions are available to any physician or provider who makes preauthorization requests with respect to a particular health care service. The definitions of "provider" and "health care services" in Insurance Code §843.002 are generally broad enough to encapsulate clinical laboratories and laboratory services, respectively.

Comment. One commenter suggests that insurance companies and pharmacy benefit managers may have initiated more denials in anticipation of the rule, so that physicians would be denied access to a prior authorization exemption.

Agency Response. TDI recognizes that the statute may have unavoidable incentives with respect to approvals and denials as implementation became imminent, but TDI is unable to address that issue through rulemaking. TDI will monitor issuers' compliance with the law and rules and take appropriate action as necessary.

Comments on §19.1710

Comment. Two commenters support allowing physicians holding administrative medical licenses to discuss the plan of treatment for the enrollee with a physician licensed to practice medicine in Texas. Another commenter expresses support for the proposed

amendments and states the language is critical in ensuring justified discussions during utilization review. One commenter states that the amendments may have the unintended consequence of preventing a plan from providing a specialty expert who has a higher level of specialty knowledge than the ordering physician.

Several commenters jointly disagree with TDI's assertion that a full medical license is not needed to act as a utilization review peer. They state that the limitations placed on an administrative medical license make the licensee ill-suited for the functions performed by the Texas-licensed physician who conducts the peer-to-peer call. They further state that the use of a limited license for the practice of administrative medicine is inconsistent with both the statutory intent and public policy goals of HB 3459. They recommend adding a new subsection (b) to §19.1710 that provides that a "physician licensed to practice medicine in Texas" means an individual with a full, unrestricted license to practice medicine in Texas issued by the Texas Medical Board (TMB).

Agency Response. TDI disagrees that a change is needed. In 2005, the Legislature enacted Occupations Code §155.009, which directs TMB to adopt rules on licensure for administrative medicine. In 2010, TMB adopted 22 TAC §172.17, establishing criteria for obtaining a limited license for the practice of administrative medicine. The rules define "administrative medicine" to mean "administration or management utilizing the medical and clinical knowledge, skill, and judgment of a licensed physician, and capable of affecting the health and safety of the public or any person." The rules make clear that a physician who holds an administrative medicine license is subject to the Medical Practice Act and the same rules of the board as a person holding a full Texas medical license. In 2013, TDI updated utilization review rules and added a requirement in 28 TAC §19.1706(a), implementing Insurance Code §4201.153(d) and §4201.252(a) and providing that all health

care providers that perform utilization review be appropriately trained, qualified, and currently licensed (including via an administrative license).

In 2019, the Legislature enacted Senate Bill 1742, 86th Legislature, which amended Insurance Code Chapter 4201 in several places to require utilization review to be conducted under the direction of a "physician licensed to practice medicine in this state." In implementing SB 1742, TDI has accepted Texas administrative licenses for those physicians. HB 3459 amended Insurance Code §4201.206 to require that a peer-to-peer discussion (which must be offered before an adverse determination may be issued) must be with "a physician licensed to practice medicine in this state and who has the same or similar specialty as the physician" who ordered, requested, or is to provide the health care service. This change did not alter utilization review more broadly or otherwise exclude administrative medical licensees from participating in the peer-to-peer discussions.

From a practical perspective, TMB rules generally require physicians to be engaged in the active practice of medicine on a "full-time basis" in order to obtain a full medical license. *See* 22 TAC §163.11 ("full-time basis" means "at least 20 hours per week for 40 weeks' duration during a given year). Physicians employed by health plans generally do not meet this standard. Therefore, requiring physicians who perform utilization review and conduct peer-to-peer reviews under Insurance Code §4201.206 to hold a full medical license, rather than an administrative license, would significantly limit the ability of health plans to hire full-time physicians to perform utilization review.

Comments on §19.1730

Comment. One commenter suggests a modification to §19.1730(2) to specifically reference the evaluation in the definition of "denial of preauthorization exemption." The

suggested change would read "A determination that a physician or provider does not qualify for a preauthorization exemption based on the issuer conducting an evaluation, as defined in [§19.1730(4)(A),] of preauthorization requests and demonstrating that the physician or provider received full and final approval for fewer than 90% of the preauthorization requests made for a particular health care service during the most recent evaluation period."

Agency Response. TDI agrees and has made the suggested change.

Comment. A commenter states that the proposed definition of "denial of preauthorization exemption" in §19.1730(2) may encourage delay as a result of including "full and final approval" as part of the term. The commenter suggests that insurers often include modifications to prior authorization approvals, and that this language may encourage the addition of modifications. The commenter states that these modifications could delay or prevent exemptions, and ultimately delay access to care or pose unnecessary risk if modifications are routine.

Several commenters express concern about what TDI may mean by "full" approval and request clarification. Many prior authorizations are reviewed on the basis of Current Procedural Terminology (CPT) codes, either for a specific CPT code or for a group of codes. In addition, the commenters state that for a three-drug regimen, each drug should be considered a separate service. They ask whether the language concerning "full" approval is intended to apply so that a denial of any part of a three-drug regimen results in the service not being approved for granting a preauthorization exemption.

Agency Response. TDI agrees that if a preauthorization request is modified with agreement of the provider and approval of the issuer, it should be counted as an approved

preauthorization request for the purposes of calculating eligibility for a preauthorization exemption with respect to the service that is approved. TDI modifies the definition of "denial of preauthorization exemption" to remove the words "full and final" and add the term "eligible" before the references to "preauthorization requests." For consistency, TDI modifies the definition of "evaluation" in §19.1730(4)(A) to add the word "eligible" before "preauthorization requests." TDI also adds a definition of "eligible preauthorization request" to clarify that a preauthorization request is eligible for the purposes of an evaluation if the request is submitted by the physician or provider and finalized by the health plan during the evaluation period, is not pending appeal, and has an outcome of either approving the request or issuing an adverse determination. If a preauthorization request includes more than one particular health care service, the outcome for each service must be counted separately for the purposes of an evaluation.

Comment. Several commenters jointly suggest that the definition of "evaluation" in proposed §19.1730(3) (redesignated as §19.1730(4)) be clarified to specify that the retrospective review for a continuation or rescission analysis is based on a retrospective review of a random sample of claims. The commenters express concern that the rule language as proposed could be construed as permitting additional claims selected by the issuer to be reviewed as part of the retrospective review to assess continuation or rescission of a preauthorization exemption. Specifically, they suggest that §19.1730(3)(B) read "with respect to a particular health care service for which a physician or provider has a preauthorization exemption, a retrospective review of a random sample of claims submitted by the physician or provider during the most recent evaluation period to determine the percentage of claims that would have been approved, based on meeting

the issuer's applicable medical necessity criteria at the time the service was provided, which is conducted for the purpose of evaluating whether to continue or rescind a preauthorization exemption and consistent with Insurance Code §4201.655, concerning Denial or Rescission of Preauthorization Exemption."

Agency Response. TDI agrees that the suggested language better aligns with Insurance Code §4201.655(a)(2) and has made the change.

Comment. One commenter suggests that plans may not have the ability to evaluate exempt providers with fewer than five claims in an evaluation period. The commenter states that this would be a barrier to health plans evaluating quality of care.

Agency Response. TDI understands the commenter's concern but declines to make a change. Insurance Code §4201.655(a) permits an issuer to rescind an exemption "only . . . on the basis of a retrospective review of a random sample of not fewer than five and no more than 20 claims. . . ." TDI also believes that the minimum threshold for receiving an initial preauthorization exemption provides an adequate method to ensure that preauthorization exemptions are granted to physicians and providers who have demonstrated appropriate clinical judgment.

Comment. One commenter states that, based on the definition of "evaluation" in §19.1730(3)(B) (redesignated as §19.1730(4)(B)), it is possible that a provider who is not the treating provider could become perpetually exempt. Since many referring providers do not perform the treatments and will never submit a claim for the service, there would be no way to pull a sample of claims for exempt referring providers. The commenter also suggests that in situations where the referring and treating providers differ--because of

the absence of an existing authorization--health plans cannot approve the claim for a non-exempt treating provider if there is no reference on the claim to the exempt ordering (referring) provider. The commenter recommends that TDI require all claims to include ordering provider information on the claim form - HCFA Box 17 (name) and Box 17B (NPI).

Another commenter states that the term "claims submitted" is broad and could be interpreted to include complete claims, rejected claims, claims denied due to bundling/coding errors, etc. The commenter recommends the language be revised to read "payable claims submitted."

Another commenter asks whether pharmacy benefit managers are expected to determine a provider's rate for each prescription drug, for all requests, for particular drug classes, or for some other grouping of medications.

Agency Response. TDI agrees that to take advantage of a preauthorization exemption, the claim must include information that identifies the physician or provider with the exemption. In response to this comment, TDI adds subsection (e) to §19.1731 to require the treating physician or provider to include the name and NPI of the ordering physician or provider on the claim in fields 17 and 17B of CMS Form 1500, or in fields 76 - 79, or another appropriate field in Form UB-04 or in the corresponding fields for electronic claims using the ASC X12N 837 format. The issuer may provide coding guidance to physicians and providers to ensure this information is appropriately captured on the claim.

Absent this information, an issuer may treat the claim as subject to an otherwise applicable preauthorization requirement. TDI also modifies the definition of "evaluation" in §19.1730(4)(B) by replacing the phrase "claims submitted by the physician or provider during the most recent evaluation period," with "*payable* claims submitted by *or in connection with* the physician or provider during the most recent evaluation period." This

change removes the implication that an evaluation of a preauthorization exemption is possible only for claims submitted by the treating provider. All claims that rely on a physician's or provider's exemption are subject to an evaluation to determine continued eligibility for an exemption, whether the claim is submitted by the exempt provider or the claim references the exempt provider's information on the claim as required by §19.1731(e).

With respect to the question of how evaluations must be conducted for prescription drugs, this will depend on the issuer's listing that identifies the particular health care services that are subject to preauthorization. Refer to the definition of "particular health care service" in §19.1730(6).

Comment. Several commenters jointly state they would strongly object to any further delay in defining the initial evaluation period. In addition, the commenters state that it is unclear how TDI intends to implement proposed §19.1730(4)(C) (which TDI redesignates as §19.1730(5)(C)). The commenters state that the rule would permit plan-determined six-month evaluation periods for the rescissions, provided that notice of rescission (in either January or June of the year) is no more than two months after the evaluation period ends. The commenters have concerns about plan-determined evaluation periods, as this could promote issuer manipulation of the preauthorization exemption results and lead to shorter preauthorization exemption durations. The commenters ask that TDI (1) make it clear that a plan cannot duplicate any months from an evaluation period that was already reviewed, and (2) adopt language similar to that in proposed §19.1732.

Another commenter states that the timeframe of auditing denials may require additional attention by TDI. The commenter states concern that the timing of denials does

not appear to line up with the six-month look-back period, as denials are only allowed in January and June.

Another commenter states that it appears that the rule gives issuers flexibility to determine a six-month period that could be used for the rescission evaluation period, but that the language is confusing. The commenter requests that TDI clarify the language.

Agency Response. TDI declines to make a change to the evaluation periods. While there are rare circumstances when an evaluation period for a rescission could overlap with a previous evaluation period in which an exemption was granted, this is a result of the statutory requirement that rescissions occur only in January or June of each year. Section 19.1732(a) requires that an exemption be in place for at least six months before it may be rescinded. TDI clarifies that the requirement in Insurance Code §4201.655(a)(1) that rescissions occur only in January or June does not apply to denials. If an exemption is not in place, the issuer must adhere to the evaluation period specified in §19.1730(5)(B). TDI also clarifies that issuers do have some flexibility to determine the six-month evaluation period on which a notice of rescission is based. The phrase "or the subsequent six-month periods that follow" would be relevant if a rescission is not finalized.

Comment. Two commenters specifically assert that TDI has the authority to include drug benefits and prescription drugs in the proposed §19.1730(6) definition of "particular health care service," which TDI redesignates as §19.1730(7). The commenters note that Insurance Code §4201.651 states that terms defined by Insurance Code §843.002, including "health care services," "physician," and "provider," have the meanings assigned by that section. Further, the commenters state that the definition of "health care services" in Insurance Code §843.002 specifically includes pharmaceutical services. Another

commenter states that preauthorization exemption provisions of HB 3459 must apply to health care services, including prescriptions.

On the other hand, another commenter states that there are no references to prescription drugs in HB 3459, and a plain language reading of the bill shows the exemption requirements apply only to health care services provided, and not for products such as prescription drugs or devices.

Another commenter also opposes the inclusion of prescription drugs under the definition of a "particular health care service." The commenter suggests that the provisions of HB 3459 contain no language that would expand the purview of these preauthorization exemptions to prescription drugs. Specifically, HB 3459 provides no statutory authority to apply the preauthorization exemption and payment requirements to products like prescription drugs. Under the plain language of the law, the requirements apply only to "health care services." While pharmacy "services" would likely be included, prescription drugs by plain definition are not included within health care "services" or pharmacy "services"--they are supplies and products. So HB 3459's requirements simply do not apply. In the commenter's view, pharmaceutical "services" are not the same thing as prescription drugs. The commenter notes that there are CPT codes specific to pharmaceutical services and procedures, while prescription drugs are billed using different coding systems. The commenter also notes that lawmakers have recognized "pharmacy procedures," such as in Insurance Code §1451.1261, and argues that "services" and "procedures" are different from drugs.

In addition, two commenters state that applying preauthorization exemption requirements to prescription drugs would create a very dangerous and expensive new mandate to cover and pay for prescription drugs, including opioids and other dangerous

narcotics, with no ability to check for dangerous drug interactions or to confirm that risky drugs are appropriate for certain patients. One commenter raises further concerns, including that health plans often suggest more appropriate drugs, whether certain high-risk medications ought to be exempted from the program, whether there are allowances for considerations such as clinical appropriateness and patient safety, and how it would work when claims are for opioid drugs. The commenter also asks whether application of the exception would be permitted at the generic-product-identifier level. The commenter asks, too, whether management of formulary exceptions by pharmacy benefit managers should be included in preauthorization exemption evaluations.

Agency Response. TDI declines to make a change. Insurance Code §843.002(13) defines "health care services" as "services provided to an individual to prevent, alleviate, cure, or heal human illness or injury," including pharmaceutical services and medical care, and care or services incidental to pharmaceutical services and medical care. TDI recognizes that in certain circumstances, the term "services" is distinguishable from products or commodities. But in the context of HB 3459, TDI believes the Legislature intended that "pharmaceutical services," as defined in §843.002, includes prescription drugs. See Webster's Ninth New Collegiate Dictionary 881 (1987) (the adjective "pharmaceutical" means "of, relating to, or engaged in pharmacy," which in turn means "the art or practice of preparing, preserving, compounding, and dispensing drugs[.]"). This position is consistent with TDI rules implementing SB 1742 (adopted at 46 TexReg 1647).

TDI is also mindful of the real safety concerns that could arise from improper prescribing or unintentional drug interactions and encourages providers and plans to remain vigilant on this issue. However, as noted in the preceding paragraph, TDI believes it was the Legislature's intent that HB 3459 cover prescription drugs. But TDI encourages

stakeholders to maintain and provide, as needed, additional information as exemptions are implemented to help policymakers monitor this issue.

Comment. One commenter states that HB 3459's preauthorization exemption provisions must apply to health care services, including prescriptions, supplies, products, and procedures. The commenter recommends that proposed §19.1370(6) (which TDI redesignates as §19.1730(7)) be changed to read "A health care service, as defined by §4201.651(2), Insurance Code, including a prescription drug, lab, x-ray, medical equipment, product, or supply, that is subject to preauthorization as listed on the issuer's website under §19.1718(j) of this title (relating to Preauthorization for Health Maintenance Organizations and Preferred Provider Benefit Plans)." The commenter suggests that anything less than an expansive application of the term "health care services" would thwart the Legislature's goal of removing unnecessary barriers to patient access to care.

Agency Response. TDI agrees with the commenter's suggestion that the term "health care services" is broad but declines to make a change. The definition of "health care services" in Insurance Code §843.002(13) includes medical care and care or services incidental to medical care. By extension, the definitions of "medical care" in Insurance Code §843.002(19) and "practicing medicine" under Occupations Code §151.002(13) provide additional specificity regarding the meaning of the term "health care services." Collectively, these definitions provide sufficient clarity that the term would include drugs, labs, imaging, and medical equipment and supplies ordered by a physician to diagnose, prevent, and "treat a mental or physical disease or disorder or a physical deformity or injury by any system or method."

Comment. One commenter has concerns that §19.1730(6) as proposed (which TDI redesignates as §19.1730(7)) ties the definition of "particular health care service" to what is posted on the plan's website. The commenter has concerns about transparency and how this affects the implementation of HB 3459's requirements. The commenter notes that various plan websites do not approach preauthorization in a consistent format. The commenter suggests that TDI set clearer parameters on the definition of "particular health care service." The commenter does not necessarily oppose tying the definition of a "particular health care service" to the website posting in theory, but states that TDI needs to adopt clearer regulatory parameters for a "particular health care service" posting to avoid any potential gamesmanship and to promote transparency. The commenter suggests that TDI conduct additional monitoring of plan websites for compliance with statutory and regulatory requirements on the posting of preauthorization requirements to ensure that the goals of HB 3459 would be addressed through this definition.

Another commenter states that the proposed definition of "particular health care service" in §19.1730(6) removes critical patient protections because reasons for requesting a particular health care service can vary. For example, services ordered as a combination of service codes performed at the same time are different clinical services than each code ordered individually. The commenter recommends amending the definition of "particular health care service" to mean "a specific individual or combination of health care services, including prescription drugs, that is subject to preauthorization as listed on the issuer's website, used for a specific clinical indication."

Agency Response. TDI recognizes these concerns related to preauthorization procedures and acknowledges that different plans may have different preauthorization procedures. However, TDI does not agree that changes to the rule text are necessary and declines to

amend the rule. TDI is not proposing specific additional regulations that would directly prescribe a singular method or format for preauthorization review. Existing §19.1718(j) provides detailed preauthorization requirements, including (1) information about how the preauthorization requirements must be posted; (2) that the posting must specify a detailed description of the process and procedure; and (3) that it must include an accurate list of the services for which the plan requires preauthorization, as well as specific information on each service subject to preauthorization.

TDI will monitor compliance with the provisions of HB 3459 and other insurance laws and take further regulatory action as necessary, including amendments to the sections included in this adoption order. TDI wishes to balance the efficacy of these rules while remaining mindful of the potential unforeseen consequences of prescribing overly detailed and inflexible procedures. TDI will use market conduct examinations, complaint information, and targeted data collections where necessary to follow implementation of HB 3459 and these rules. In addition, TDI will closely observe implementation and be ready to provide additional guidance as needed.

Comment. One commenter expresses concern about the overall lack of specificity of definitions in §19.1730. The commenter encourages TDI to specifically include clinical laboratories as part of the definition of "provider" and laboratory and pathology services as part of the definition of "particular health care service."

Agency Response. TDI declines to amend the proposed rule to include clinical laboratories as part of the definition of "provider" and laboratory and pathology services as part of the definition of "particular health care service." The definitions are clearly

defined under Insurance Code §843.002 and are intended to be as broad as the statute allows.

Comment. A commenter states support for the definition of "preauthorization" in proposed §19.1730(8), which TDI redesignates as §19.1730(9). The commenter approves of not including concurrent utilization review within the scope of preauthorization, consistent with the definition in Insurance Code §4201.651.

Agency Response. TDI appreciates the support.

Comment. One commenter requests that TDI replace the word "privilege" in the proposed definition of "preauthorization exemption" under §19.1730(9), which TDI redesignates as §19.1730(10). The commenter states that there are rights and payment protections associated with a preauthorization exemption granted under the law. The commenter is concerned that the word "privilege" fails to accurately reflect the legal status of an exemption.

Agency Response. TDI declines to make a change, as the wording does not interfere with any of the rights and protections granted under the law.

Comment. Several commenters jointly suggest a change to the definition of "random sample" in proposed §19.1730(11), which TDI redesignates as §19.1730(12). The commenters are concerned that this proposed definition of "random sample" does not sufficiently (1) reflect what a true "random sample" is; (2) set parameters to avoid gamesmanship or cherry-picking in issuer selection of random samples; and (3) address TDI's prior questions regarding what happens when there are fewer than five total claims

for a particular health care service during the relevant evaluation period. The commenters suggest TDI modify the language to reflect that the sample must be selected through a method that gives each claim an equal probability of being chosen for the sample.

The commenters suggest the definition be "A collection of at least five but no more than 20 claims for a particular health care service, selected through a method that gives each claim an equal chance of being chosen for the sample, for the purpose of conducting an evaluation, as defined by [§19.1730(4)(B)], of physician's or provider's continued eligibility for or rescission of a preauthorization exemption. The random samples must be selected as follows: (A) If only five to 20 claims were submitted by the physician or provider during the most recent evaluation period, all of the claims submitted by the physician or provider during the most recent evaluation period will constitute the random sample; (B) If more than 20 claims were submitted by the physician or provider during the most recent evaluation period, 20 of those claims will constitute the random sample but those claims must be selected through simple random sampling, which requires using randomly generated numbers to choose a sample. Specific metrics may not be applied by the issuer in selecting a random sample, such as specific patient cohorts or site of service, which may favor the issuer's decision-making. An issuer must maintain records demonstrating the simple random sampling used for each sample under this paragraph. If an issuer does not maintain records and the physician or provider files a complaint with the department or the department performs an audit or review regarding the sample selection, the department shall presume that the sampling was not random and automatically continue any preauthorization exemption that was being reviewed using a non-random sample."

Agency Response. TDI understands the commenters' concerns but declines to make a change. Insurance Code §4201.655(a)(2) gives issuers discretion regarding the size of the

random sample, as long as it includes at least five and no more than 20 claims. The definition of "random sample" as proposed requires that the claims be selected "without method or conscious decision," which is consistent with the meaning of "random."

Comment. Several commenters jointly express concerns with the language in the definition of "rescission of preauthorization exemption" as proposed in §19.1730(12), which TDI redesignates as §19.1730(13). The commenters state that the language as proposed fails to clarify that a rescission must be based on a random sample of claims under Insurance Code §4201.655 and reflect other limitations or conditions imposed on rescissions under the law and the proposed rules. They state that it omits statutory language specifying that if the determination is in regard to an exemption for a physician, then the decision must be made by an individual licensed to practice medicine in this state who has the same or similar specialty as that physician.

The commenters suggest the definition read "An adverse determination regarding a preauthorization exemption's continuation based on an evaluation, as defined in [paragraph (4)(B)] of this section, of a random sample of claims and determination made by an individual licensed to practice medicine in this state in which the issuer would have approved fewer than 90% of claims for a particular health care service. For a determination under this paragraph with respect to a preauthorization exemption held by a physician, the determination must be made by an individual licensed to practice medicine in this state who has the same or similar specialty as the physician."

Agency Response. TDI agrees with the comment and has modified the definition of a "rescission of preauthorization exemption" to reference the applicable definition of an evaluation related to a rescission determination and to replace the physician licensure

language with a reference to Insurance Code §4201.655(b), in order to fully capture the statutory requirements without restating them unnecessarily. TDI also agrees that a rescission evaluation must be based on a random sample, but in the interest of brevity declines to repeat that in this definition, since it is already clearly stated in §19.1731(c) and Insurance Code §4201.655(a)(2), and incorporated into the referenced definition of "evaluation."

Comment. Several commenters jointly suggest new language for the definition of "treating physician or provider" as proposed in §19.1730(13), which TDI redesignates as §19.1730(14). They state the proposed definition is too restrictive, and that the "primarily responsible" and the "illness" or "injury" language could inappropriately narrow the scope of the law's application. They suggest the definition read "A physician or other provider who is treating or responsible for a patient's health care for an illness, physical or mental condition, disease, or disorder, injury, physical deformity, or providing preventative care. A 'treating physician or provider' includes a rendering physician or provider or a referring or ordering physician or provider."

Another commenter encourages TDI to limit the definition to the referring physician or provider, as the rendering provider generally does not evaluate the patient or determine the course of treatment. The commenter says that precertification exemption must be tied to the primary care physician who evaluated the patient and made the decision to request the service, not the physician who conducted the MRI and did not participate in the clinical decision-making to order the service for the patient.

Another commenter supports the proposed rules, stating that the rule successfully encourages claims payment by defining a treating physician or provider as including "a rendering physician or provider."

Agency Response. TDI agrees to modify the definition of "treating physician or provider" to clarify that care may be broader than in relation to an illness or injury. TDI also modifies the definition by replacing "health care for an illness or injury" with "health and medical care," and expanding the definition to include an "ordering" physician or provider. TDI disagrees with suggestions for further modifying the definition. TDI believes it is unnecessary to exclude a rendering physician or provider from the definition since a preauthorization exemption can be obtained only on the basis of a history of approved preauthorization requests. Also, a treating provider may both order and render the care.

Comments on §19.1731

Comment. One commenter suggests that §19.1731(a) be modified to require a physical location, in addition to an NPI, as a means of identifying a facility. The commenter argues that HB 3459 seeks to reduce burdens for providers that are considered exemplary in determining what care is medically necessary and appropriate; since this could vary by hospital location, the exemption should be determined for each location separately.

Agency Response. TDI declines to make a change. Applying the exemption analysis at a more granular level as the commenter suggests would create additional complexity and reduce the amount of data available to inform each exemption.

Comment. TDI specifically sought comment on the minimum number of preauthorization requests needed to qualify for an exemption. Many commenters provided valuable input.

Several commenters support the proposed provision requiring a minimum of 20 preauthorization requests for an exemption. One states that the requirement is sufficiently stringent and is aligned with the principles of HB 3459. Another commenter states the threshold provides guardrails for low-volume providers, who are most likely to benefit from utilization management under the preauthorization process. One of these commenters recommends that the number of the threshold be raised to 30, stating that 30 is considered by statisticians to be the minimum number to have an appropriate confidence interval.

Several commenters disagree with the proposed minimum threshold of 20 claims. One commenter states that the threshold is too high and would prevent far too many capable physicians from receiving exempt preauthorization status.

Other commenters state that HB 3459, as written and passed, does not contain a minimum number of claims for a particular health care service that must be met for the initial granting of a preauthorization exemption. They say that imposing such a requirement at all, but certainly one that requires a minimum of 20 claims, would undercut the goal of the legislation by reducing the intended scope of its application. The commenters argue that applying a minimum of 20 preauthorization requests would inappropriately limit the number of exemptions. One commenter recommends lowering the minimum threshold for review to five claims. Other commenters recommend removing the language "The evaluation must be based on no fewer than 20 preauthorization requests." The commenters state that TDI's creation of the threshold lacks statutory authority and is contrary to the intended meaning of the statute. The commenters also disagree that the request must be both submitted and finalized during the relevant six-month period.

One commenter states that the proposed threshold would create unintended consequences if each particular health care service required no fewer than 20 preauthorization requests to be reviewed within a six-month period to determine whether the physician or provider qualifies for an exemption. The commenter notes that many providers will not have the minimum number of preauthorization requests of a particular health care service for each insurance carrier. The commenter also requests clarification on services that required preauthorization under the parent insurance carrier.

Several commenters jointly oppose §19.1731(c) as proposed. They state it effectively creates a minimum preauthorization submission threshold of 20 requests for reviewing, granting, or denying, and notifying of a grant or denial of a preauthorization exemption, which is in clear conflict with the plain language of the law and the intent of HB 3459.

Agency Response. TDI agrees to reduce the proposed minimum threshold of 20 preauthorization requests for a particular health care service because it may unintentionally limit the number of exemptions that are granted. As adopted, the rule sets a minimum threshold of five eligible preauthorization requests. TDI also adds a definition of "eligible preauthorization request" to clarify which preauthorization requests are counted in an evaluation. TDI declines to change the requirement that the minimum threshold be based on preauthorization requests submitted and finalized during the six-month evaluation period because this aligns with the basis for an evaluation provided in Insurance Code §4201.653(a).

While the statute does not expressly set a minimum number of preauthorization requests needed to qualify for an exemption, TDI does not believe that deprives the agency of authority to set a reasonable threshold by rule or that such a threshold is

inconsistent with the statute. *See Tex. State Bd. of Exam'rs of Marriage & Family Therapists v. Tex. Med. Ass'n*, 511 S.W.3d 28, 33 (Tex. 2017) (A state agency "can adopt only such rules as are authorized by and consistent with its statutory authority.") (internal citations and quotations omitted). A primary purpose of HB 3459 is to reduce the burden of preauthorization requirements for providers who have demonstrated high approval rates and adherence to medical necessity guidelines. When there are fewer than five preauthorization requests, there may be insufficient evidence to warrant an exemption and the continued preauthorization requirement creates only a limited burden. Furthermore, without such a threshold, it could allow for abuse of the system (especially since issuers can only rescind a provider's exemption for a particular health care service if the provider has at least five claims for that service during an evaluation period). Ultimately, TDI believes this rule is in harmony with HB 3459's general objectives. *See id.* (a rule must be "in harmony with the general objectives of the act involved").

Comment. One commenter recommends modifying the rule to prevent exemptions from continuing in perpetuity, even if the provider retires, or if the standard of care evolves. The commenter suggests either requiring a minimum number of services to be provided for an exemption to be retained, or allowing an issuer to rescind an exemption with fewer than five claims after a reasonable length of time has passed without any new claims for the particular health care service.

Agency Response. TDI declines to make a change. Insurance Code §4201.655 provides a process and standards for issuers to rescind an exemption. Furthermore, if a provider is not actively practicing, the exemption would not be in use.

Comment. One commenter notes that some carriers have different preauthorization requirements for each of their plans. The commenter suggests that each provider be reviewed on the basis of all requests in total of all health care provided under a parent insurance company - not by each particular health care service.

Another commenter asks for clarification on whether exemptions are assessed separately for each health plan.

Another commenter asks whether reviews for provider exemption for medical benefit drugs and pharmacy benefit drugs are to be conducted separately if the preauthorization requirements are different and preauthorization determinations are made by a different entity.

Agency Response. TDI agrees that the minimum threshold should apply across each issuer and clarifies that an issuer may not conduct evaluations and grant exemptions separately for different plans offered by the issuer. Affiliated issuers are encouraged to perform a combined exemption analysis, to the extent practical. Likewise, to the extent that an issuer uses similar networks and utilization review processes to administer self-funded plans, TDI encourages issuers to use all applicable data when evaluating a physician's or provider's exemption with respect to a particular health care service.

Reviews for different health care services may occur separately, but a review with respect to a particular health care service must include all applicable data and may not be segmented, even if the issuer uses multiple administrators. TDI disagrees that an exemption review can occur across all health care services, because Insurance Code §4201.653(a) provides for an exemption "for a particular health care service."

Comment. One commenter asks whether the data included in the review to determine exemption eligibility would include claims data and actual preauthorization submissions. The commenter notes that not all payor preauthorization web portals include both the ordering physician NPI and the facility NPI. The commenter also asks for clarification in a situation where a facility requests preauthorization for the facility charges but the facility is not actually ordering the service. The commenter asks whether facilities will be awarded an exemption status of their own, and if not, how an affiliated facility will know of exemption status awarded to physicians. Relatedly, if facilities will be awarded their own exemptions status, the commenter wants to know how those determinations would be made.

Agency Response. Evaluations for an initial exemption are based on the preauthorization requests submitted by a physician or provider for a particular health care service. The initial review does not include claims data. The exemption would be granted to the physician or provider who makes the preauthorization request. There is nothing in the statutes or rules that prevents a facility from qualifying for a preauthorization exemption. Evaluations for continued eligibility for an exemption are based on claims submitted by, *or in connection with*, a physician or provider for the particular health care service. If the preauthorization exemption is held by a physician or provider who orders but does not render a particular health care service, then the billing provider must obtain information about the exemption and include the ordering physician's or provider's NPI on the claim. Such claims would be evaluated to determine whether to continue or rescind an exemption held by the ordering physician or provider. TDI adds new subsection (e) to §19.1731 to clarify the information that must be included on a claim. Issuers must ensure

that their systems enable providers to include all information required to identify exempt providers where needed to operationalize the exemptions.

Comment. Several commenters jointly recommend that TDI change the provision regarding rescissions to underscore that an issuer may, but is not required to, conduct an evaluation to determine whether to rescind an exemption. They also suggest the language clarify what the effect is when there is an insufficient number of claims to constitute a "random sample" of claims and suggest the language cross-reference the definition of "evaluation" to make clear that a rescission is based on a retrospective review of a random sample of claims. They suggest specific language to amend §19.1731(c).

Agency Response. TDI modifies §19.1731(c) to include a reference to the definition of the applicable evaluation under §19.1730(4)(B). TDI declines to make other changes, as Insurance Code §4201.653(c) makes clear that issuers may continue an exemption without performing an evaluation. Likewise, Insurance Code §4201.655(a)(2) makes clear that a rescission is not permitted if the issuer does not evaluate at least five claims. This standard is restated in the definition of "random sample" in §19.1730(12) and in §19.1731(c).

Comment. One commenter supports the provision in proposed §19.1731(d) under which a treating physician or provider who inappropriately relies on another physician's or provider's exemption in violation of the rule may be considered by the issuer as failing to substantially perform the health care service. The commenter also states opposition to the provision allowing a "rendering" provider who does not qualify for an exemption to take advantage of an exemption held by the ordering physician or provider.

Another commenter supports preventing a treating physician or provider who does not have a preauthorization exemption from relying on another physician's or provider's exemption. The commenter expresses strong concern with the proposed rules that allow a non-exempt rendering provider to use the ordering or referring provider's preauthorization exemption. The commenter recommends that a preauthorization exemption should be available only when the ordering provider is the same as the provider providing the direct care of the patient.

One commenter asks whether a referring physician without a preauthorization exemption can rely on the rendering physician's exemption. The commenter asks for additional clarification from TDI on how this would be tracked. Another commenter asks whether the exemption extends to anyone that may submit an authorization under the provider's authority.

Several commenters jointly recommend that §19.1731(d) be modified to also apply to treating providers. The commenters also recommend that TDI strike the last sentence of subsection (d), as providing a service in erroneous reliance on another physician's or provider's exemption is not the same as failure to substantially perform a service from a plain language standpoint. The commenters state that Insurance Code §4201.659, referenced in the proposed section, would imply that a preauthorization exemption is not in effect for--and could not be used by--the physician or provider to whom the issuer attempts to reduce or deny payment. The commenters provide alternate language for §19.1731(d). The commenters state that if TDI does not adopt their suggested language, they strongly recommend the inclusion of additional language, which they offer, to limit the ability of the issuer to utilize Insurance Code §4201.659. In addition, the commenters

ask TDI to clarify the intent of the provision and include illustrative examples to aid understanding of the provision's application and impact.

Agency Response. TDI believes that limiting the application of a preauthorization exemption to care ordered and performed by a physician or provider would unintentionally limit the scope of the statute and inappropriately shift the responsibilities for obtaining preauthorization to other physicians and providers rather than reducing the burden of preauthorization when an exemption has been granted. With respect to evaluations and tracking exemptions generally, §19.1731(a) indicates that physicians and providers are identified using the NPI under which they make preauthorization requests. TDI adds new subsection (e) to §19.1731 to clarify how an exempt physician or provider would be identified on a claim for care that they order but do not perform or bill for.

TDI modifies §19.1731(d) in response to comments to consistently reference both physicians and providers, and TDI replaces the phrase "that treating physician" with "the physician or provider who has qualified for the preauthorization exemption." This change more accurately reflects that the exemption and its protections do not extend to care that is not ordered, referred, or provided by the physician or provider who qualifies for the exemption. TDI also adds a sentence to the end of subsection (d) to clarify that it is not a violation for a provider, such as a nurse or physician's assistant who practices under the supervision of a physician, to rely on the supervising physician's exemption if the provider appropriately orders care and requests preauthorization under the supervising physician's NPI.

To clarify this provision, TDI offers the following examples:

1. A nurse and physician's assistant work under the supervision of a physician and submit preauthorization requests under the physician's NPI. The physician

qualifies for an exemption. In this case, the nurse and physician's assistant are permitted to rely on the physician's exemption because the physician is supervising the care and is considered to be a treating physician.

2. A physician works in a group practice with other physicians. Each physician in the group practice submits preauthorization requests under their individual NPIs. One physician qualifies for an exemption. In this case, the other physicians are not permitted to rely on their partner's exemption; they must continue submitting preauthorization requests for their own patients. The physician with the exemption is not considered to be a treating physician with respect to the patients of his or her partners.

Comment. One commenter asks whether there will be a data repository that identifies all physicians and providers who have been awarded a preauthorization exemption.

Agency Response. Neither the statute nor the rules require issuers to publish data regarding preauthorization exemptions. However, TDI encourages issuers to consider how best to maintain and share this information with providers, in addition to the notices required under §19.1732.

Comment. One commenter asks if, in a situation where an exempted service is provided and the service transitions into a more complicated service, additional services, or surgery, whether all associated services will also be exempt.

Agency Response. Exemptions apply only with respect to particular health care services. If a service is performed that is not eligible for an exemption, then it could be subject to a retrospective review to evaluate whether it is medically necessary and would not have the protections that are provided in Insurance Code §4201.659.

Comments on §19.1732

Comment. One commenter disagrees with the requirement in §19.1732(a) that an exemption must be in place for at least six months before it may be rescinded. The commenter states that it would be cumbersome for both the health plan and provider. The commenter notes that industry standards already issue authorizations for cancer patients and other chronic disease treatments for one year, and the commenter suggests that the preauthorization exemption period be extended to an annual basis. The commenter states this would result in savings both toward patients' benefits premium dollars and the costly work involved in the process for both health plans and providers.

Another commenter also encourages a one-year exemption duration. This cycle would allow predictability around the staffing levels required to perform the administrative functions of preauthorization. The commenter states that having to adjust to a six-month basis and have the appropriate number of staff to support this will be nearly impossible. Another commenter states that the exemption should be determined by an annual evaluation period. The commenter states that, because of the seasonal nature of health care, a physician may perform a procedure or prescribe a treatment that requires preauthorization far more often in one six-month period than another.

Several commenters jointly state that they strongly support requiring the exemption to be in place for at least six months before it can be rescinded and strongly contend that any shorter period would be contrary to both the express language and spirit of the law.

Agency Response. TDI declines to make a change. Since the statute provides that a health plan may rescind a preauthorization exemption only in January or June, TDI does not believe the Legislature anticipated an exemption to have a minimum duration of one year.

TDI believes the minimum duration of six months is more consistent with the language and intent of the statute.

Comment. Several commenters jointly ask TDI to expand on the list of statutory elements for the notification letters described in §19.1732. They note that Insurance Code §4201.659(d) requires this notice to "include" certain elements, and that "includes" is a word of enlargement under the Code Construction Act. They suggest that the exemption notice under §19.1732(a) should be required to include (1) a plain language explanation of the impact and meaning of the exemption, and (2) contact information for both TDI and the issuer. In addition, they recommend that TDI standardize these notices and require the use of the form so that the notices are more uniform, easier to identify, and easier to read. They state that the notification of a denial under §19.1732(b) should include notice of the physician's or provider's appeal rights; require the form to state that the issuer is required to pay for any IRO review; and include the email address, fax, and any other electronic method the physician or provider prefers to use to return the form.

The commenters provide some specific recommendations to modify the wording on Form LHL011, and to clarify the rule text regarding the dates that exemption notices are issued, effective, and appealed.

The commenters also ask that TDI clarify that the date the appeal is being requested in the context of Form LHL011 is the same thing as the signature date of the physician completing the appeal form, even if the provider returns the form to the issuer before the date the rescission becomes effective.

Another commenter expresses concern with the level of detail required in the rescission notices, specifically citing the requirement to include the principal reason for

the determination, the clinical basis for the determination, a description of the sources of screening criteria used as guidelines, and the specialty of the determining provider. The commentor argues that the rule goes well beyond what is required by the statute.

Another commenter suggests that the notice of the initial exemption be required only for physicians or providers who receive an exemption, and that notification not be required for denial of preauthorization exemption for services that the physician or provider did not expressly request an exemption for.

One commenter states support for the rule that an issuer must provide notice when exemptions are both granted or denied. This protects physicians or providers from mistakenly thinking they are exempt, ordering tests, and not requesting preauthorization.

Agency Response. TDI agrees to modify the notice requirement for exemptions issued under §19.1732 and require notices to include a plain language explanation of the effect of the preauthorization exemption and any claim-coding guidance needed to document the exemption. TDI declines to create standardized forms for exemption and denial notices, or to require the use of TDI's example form for rescission notice. Such requirements would limit the flexibility that issuers have and would be difficult to establish at this early phase of implementation. TDI will instead monitor issuers' implementation of these notices and take future action to improve clarity and uniformity if necessary.

TDI also agrees that a denial notification should include a description of how to appeal the denial using an issuer's complaints and appeals processes and information on how to file a complaint with TDI. Section 19.1732(b) has been modified accordingly.

TDI disagrees that the contents of the rescission notice required under §19.1732(d) are too burdensome or inconsistent with statute. Insurance Code §4201.655(a)(3) requires an issuer to include on a rescission notice "the sample information used to make the

determination" that less than 90% of the claims met the medical necessity criteria. Insurance Code §4201.655(b) requires a rescission determination to be made by a Texas-licensed physician, and for a rescission of a physician's exemption, the physician must have the same or similar specialty. The contents of the rescission notice required under §19.1732(d) are simply designed to inform the provider why the exemption is being rescinded, who made that decision, and what the provider can do about it.

TDI declines to remove the requirement that issuers provide denial notices. Insurance Code §4201.653 broadly requires issuers to conduct exemption evaluations without the physician's or provider's request, and Insurance Code §4201.655(c) requires denial notices. However, consistent with changes to the initial threshold under §19.1731(b), TDI modifies §19.1732(c) to clarify that notice is provided only when at least five eligible preauthorization requests are available for an initial evaluation.

With respect to the date a rescission notice is provided and the date it is effective, TDI declines to make a change; Insurance Code §4201.654 makes clear that an exemption remains in effect until the 30th day after the date the issuer notifies the physician or provider of the issuer's determination to rescind the exemption. TDI agrees to clarify the language in the Form LHL011 notice by adding "Unless you request an appeal to an independent dispute resolution organization as set forth below," before the statement of the effective date of the rescission. TDI expects issuers to use timely methods to transmit notices so providers receive the notices on the same day they are sent electronically, or typically within five calendar days of mailing.

TDI also modifies Form LHL011 to add the clarifying text "at no cost to you" within the explanation of the right to appeal the rescission and clarifies that the appeal request form may be sent electronically. TDI modifies §19.1732(d)(1) to clarify that the rescission

notice must include the date the notice is issued, consistent with the example form LHL011 as proposed. TDI modifies §19.1732(d)(2) to clarify that the issuer must provide contact information for returning the appeal form "by paper or electronic means."

Comment. Several commenters jointly recommend the addition of a new subsection requiring issuers to solicit from physicians and providers their preferred contact method and preferred contact information, and to use the preferred method and information to provide required notices. A separate commenter also recommends that physicians and providers should be permitted to designate their notification address. The joint commenters suggest that TDI add language that if an issuer notifies a physician or provider via any other method, any rescission notice would be defective, and the exemption would continue. The commenters also suggest that TDI require issuers to retain records to show they provided timely and effective notice through the preferred method and contact information, and that failure to retain records would make rescission ineffective. In addition, the commenters recommend that TDI modify the rule to provide that if an issuer fails to retain a record of notice of granting a preauthorization exemption, then the six-month period before an exemption may be rescinded is extended to be counted from the date the issuer provides effective notice.

Agency Response. TDI agrees that physicians and providers should be able to designate their preferred contact information and has added new subsection (e) to §19.1732 to clarify that issuers must allow physicians and providers to choose whether to receive communications regarding preauthorization exemptions electronically or by mail and provide a method for updating contact information. New §19.1732(e) also requires issuers to include instructions for updating contact preferences on the website required under

§19.1718(j) and in all communications issued under §19.1732. TDI disagrees that additional requirements are necessary; it will monitor this issue through complaints, but expects issuers and providers to work in good faith to establish practical and effective communication methods. TDI declines to modify the rule to add extensive record retention requirements for issuers. The statute and rule provide sufficient clarity regarding the notification requirements, minimum period for an exemption, and requirements for rescissions. Consistent with Insurance Code §4201.654, a rescission is not effective until at least 30 days after notice is issued.

Comment. One commenter recommends modifying the threshold percentage and timeframe to require providers to submit proof to a health plan 30 days before the end of an exemption period that they have maintained an 80% compliance rate with evidence-based guidelines for a particular medical service.

Agency Response. TDI declines to make a change. The statutory criteria for exemptions require a provider to meet the medical guidelines in 90% of cases. With respect to the timeframe, the statute requires a six-month evaluation period. This could not be achieved if the exemption determination is made before the end of the six-month period. While the 90-day period following the initial evaluation period does delay the effective date of exemptions, TDI believes this is necessary for the health plans to operationalize the rules. Once an exemption is granted, it will be in effect until it is rescinded.

Comment. One commenter states that the October 1 deadline for initial notification of preauthorizing exemptions is too delayed. The commenter states that if the data

necessary to evaluate is readily available, then there should be no reason that this excessive amount of time is necessary.

Several commenters jointly state they oppose the October 1 deadline. They state that Insurance Code §4201.659(d) suggests that the law would technically require issuers to provide initial notices granting or denying exemptions no later than five days after the physician or provider qualifies for the exemption. They also recognize that the timing of the rule adoption may inhibit compliance with this timeframe for the initial grant or denial of a preauthorization exemption. They recommend that if TDI intends to move forward with a longer period for the initial notice granting or denying a preauthorization exemption to account for the adoption of final rules, then TDI should require the notice of the initial granting or denial to be provided no later than August 1, 2022. The commenters also state that for subsequent evaluation periods during which a physician or provider does not have a preauthorization exemption, an issuer must provide notice to the physician or provider granting or denying a preauthorization exemption no later than five days following the day after the end of the evaluation period, rather than the two-month period in proposed §19.1730(4)(C), redesignated as §19.1730(5)(C).

Noting the initial exemption notification date, another commenter asks whether providers can count on all aspects of this law to be operationalized by October 1, 2022, or whether there is another date for implementation.

Agency Response. TDI understands the commenters' concerns regarding the five-day notice following the end of the evaluation period and modifies §19.1732(c) to clarify that, consistent with Insurance Code §4201.659(d), an issuer must provide a notice granting or denying a preauthorization exemption within five days of completing an evaluation. This clarifies that issuers should issue notices timely, following the completion of an evaluation,

rather than waiting until the specified deadline. However, TDI declines to modify the proposed deadlines for issuing notices. Issuers must make substantial operational changes to implement the requirements of the statute and rule, and the flexibility provided in the timeframes should support issuers' ability to implement the statute as intended, with minimal impact on the physicians and providers who qualify for exemptions. TDI expects that as time goes on, issuers will develop systems that allow evaluations to be completed and communicated faster than the maximum amount of time provided by the rules. TDI will monitor the issue to determine whether future changes are needed.

This rule takes effect 20 days after the date it is submitted to the *Texas Register*. October 1, 2022, represents the deadline for issuers to provide initial notifications of preauthorizing exemptions.

Comment. One commenter states that a provider should be notified by May 15 or December 15 of the notice to rescind an exemption. The commenter states that providers need notification early enough to make sure they have the processes in place before rescission.

Agency Response. TDI disagrees that providers should be notified by May 15 or December 15 of the notice to rescind an exemption. Insurance Code §4201.654(a) requires notice 30 days before a rescission is effective. Insurance Code §4201.655 permits rescissions to occur only during January or June of each year. Given that an appeal would likely modify the actual effective date of a rescission, for consistency, TDI modifies §19.1732(d) to clarify that the January and June dates specified by statute apply with

respect to the timing of the notice, rather than with respect to the timing of the rescission effective date.

Comments on §19.1733

Comment. One commenter notes that the proposed rules contain no mechanism to challenge the initial denial of a preauthorization exemption. The commenter recommends that an appeal process should include the initial evaluation period.

One commenter supports limiting the IRO review to the rescission evaluation.

Other commenters request clarification that the right to appeal to an IRO exists for initial exemptions. They state that the legislative intent was to allow physicians and providers the opportunity to appeal in the event they do not receive an exemption for a particular health care service as expected.

Agency Response. TDI declines to make a change to §19.1733 but does modify §19.1732(b) to require denial notices to describe how to appeal using the issuer's complaints and appeals processes and how to file a complaint with TDI. An initial denial of a preauthorization exemption is issued on the basis of the total rate of approvals and adverse determinations of preauthorization requests during the evaluation period, and under Insurance Code Chapter 4201, providers have the right to appeal each adverse determination of a preauthorization request on which an exemption denial is based. The calculation of the approval rate that determines whether an exemption is granted or denied does not involve the use of medical judgment.

Insurance Code §4201.656 provides for an independent review of an adverse determination regarding a preauthorization exemption. The term "adverse determination regarding a preauthorization exemption" is not defined in the Insurance Code, but TDI

interprets it in §19.1730(1) as "a decision by an issuer that one or more claims retrospectively reviewed as part of an evaluation as defined in §19.1730(4)(B) . . . , with respect to a particular health care service for which the physician or provider has a preauthorization exemption, did not meet the issuer's screening criteria[.]" This interpretation is informed by the definition of "independent review" in 28 TAC §12.5 ("Independent review" means a "system for final administrative review by a designated IRO of an adverse determination regarding the *medical necessity and appropriateness or the experimental or investigational nature of health care services.*") (emphasis added); the definition of "adverse determination" in Insurance Code §4201.002 ("Adverse determination" means "a determination by a utilization review agent that health care services provided or proposed to be provided to a patient *are not medically necessary or are experimental or investigational.*") (emphasis added); and the references to a "rescission review" in Insurance Code §4201.656(b)(2), "claims" in Insurance Code §4201.656(d), and "determination . . . to rescind" in Insurance Code §4201.657.

Comment. One commenter states that §19.1733(b) requires that up to 20 medical records requests per particular health care service, per individual plan per provider, would need to be submitted to the insurance carrier during the evaluation period. The commenter states that this could effectively require the provider to submit almost all patient medical record files to each insurance carrier during the review period. This would cause an extreme burden on the practice, increasing--not reducing--the administrative burden this legislation intended to relieve responsible providers of.

Several commenters jointly suggest alternate language for proposed §19.1733(b). They suggest language that would, (1) add a reference to proposed §19.1730(3)(B)

(redesignated as §19.1730(4)(B)), (2) specify that the request for documents be "as minimally necessary," and (3) clarify that medical records may not be requested and a retrospective review may not be conducted for any claims that are outside the original random sample of five to 20 claims, unless a provider agrees. The commenters also recommend that the rules require the issuer to provide a physician or provider with a reminder request for any outstanding records needed for the assessment at least 15 days before the end of the deadline; require the issuer's notice to have enough specificity that a reasonable physician could identify the needed records; require the issuer to inform the physician or provider of the effect of a failure to provide records in the reminder request; and expressly make it a violation to request more information than is needed, fail to provide a request with sufficient specificity, or fail to provide the follow-up request.

Agency Response. TDI declines to restrict an issuer's ability to determine the size of the random sample (and by extension, the number of medical records requested for each particular health care service) beyond the statutory constraint. The statute requires a rescission to be based on a review of at least five and no more than 20 claims.

TDI recognizes these concerns related to potential additional specificity and clarification of the review procedures. However, TDI does not agree that substantive changes to the rule text are necessary. TDI declines to add language that medical record requests must be "as minimally necessary" and include sufficient specificity, because §19.1707, as referenced, already provides standards for requesting medical records. To add clarity, TDI modifies §19.1733(b) to add a reference to the definition of an applicable evaluation under §19.1730(4)(B). TDI also clarifies that medical records requested in connection with a retrospective review of a random sample of claims as authorized under Insurance Code §4201.659(b)(1) should be limited to no more than 20 claims.

TDI declines to add a new requirement for issuers to provide a reminder request or warn physicians or providers of the consequences of failing to respond to a request for medical records because physicians and providers should already have systems in place to be responsive to such requests. However, issuers are not precluded from providing such reminders or warnings.

TDI will monitor compliance with the provisions of HB 3459 and other insurance laws and may take further regulatory action as necessary, including amendments to these rules. TDI wishes to balance the efficacy of the rules while remaining mindful of the potential unforeseen consequences of prescribing overly detailed and inflexible procedures. TDI will use market conduct examinations, complaint information, and targeted data collections where necessary to follow implementation of HB 3459 and these rules. In addition, TDI will closely observe implementation and be ready to provide additional guidance as needed.

Comment. One commenter recommends changing the time limit for providers to submit medical records from 30 to 15 days. The commenter argues that there is a built-in incentive for providers to appeal every rescission determination and it could give providers months of additional time under an exemption that should be rescinded. In addition, the commenter suggests that an independent review should not be available for a rescission that is based on a provider's failure to provide medical records. The commenter argues that allowing a provider to submit supporting records for the first time as part of an independent review would add substantial additional costs.

Another commenter states support for the need for a time limit for providers to submit requested records in proposed §19.1733(b), but states the language is not

sufficiently clear as to require submission of records in a timely manner. The commenter recommends that a physician's or provider's timeframe to submit records be capped at 30 days to ensure that the reviewing organization has adequate time to conduct the evaluation.

Agency Response. TDI declines to change the time limit for providers to submit medical records from 30 to 15 days because the definition of evaluation periods under §19.1730(5)(C) provides sufficient time and flexibility for issuers to complete evaluations, taking into account the 30-day period. TDI disagrees that the language is not sufficiently clear. Under §19.1733(b), issuers must provide at least 30 days for medical records to be provided and specifies the consequence if medical records are not provided.

TDI agrees that issuers may face costs in the form of IRO fees if providers habitually fail to submit medical records and then appeal rescissions to IROs. If issuers are unable to review the medical records, this could lead to more proposed rescissions and more appeals, when the issuer would not have proposed to rescind the exemption had they been able to review the medical records. Nevertheless, Insurance Code §4201.656(a) provides a clear right to providers to have a rescission reviewed by an IRO, and the statute does not limit that right based on the issuer's reason for a rescission. But because of the potential costs to issuers noted above, TDI will monitor the issue to determine whether future changes are needed.

TDI also agrees that it would be impractical for an IRO to request medical records for the first time in cases where the provider has failed to provide them during the issuer's initial review. Insurance Code §4201.656(c) requires an IRO to complete its review not later than the 30th day after the physician or provider requests a review and does not provide for this timeframe to be extended while records are being requested. Therefore, to

address this concern, TDI does modify §19.1733(d) to clarify that in order to request an appeal for a determination that was based on a failure to provide medical records, the physician or provider must include the applicable records in conjunction with their request for an independent review. Conforming changes are made to §19.1732(d)(3)(C)(i) and §19.1732(d)(5) to ensure that issuers specify when a determination is based on lack of medical records and instruct providers to include the records with the request for an independent review.

TDI also changes the last sentence in §19.1733(d) to clarify that the requirement for the issuer to submit the request for independent review applies only if the issuer seeks to proceed with the proposed rescission. This should mitigate the risk of unnecessary IRO appeals when the issuer is able to review records and determine that the provider continues to qualify for an exemption.

Comment. One commenter states that proposed §19.1733(b) should require issuers to send a medical records request via certified mail and that the request be made within 30 days following the end of the evaluation period, rather than 90 days as proposed. The commenter expresses concern that issuers could receive a negative determination due to lack of medical records where the request was not received because it was not sent via certified mail.

Agency Response. TDI declines to require issuers to send requests via certified mail because this would significantly increase costs. This should not be necessary since issuers will allow providers to designate their preferred contact method and address. Issuers will need to make timely requests for medical records, either during or shortly after an evaluation period, in order to meet the timeframe for rescissions specified in §19.1732(c).

TDI declines to change the 90-day timeframe for medical record requests because an issuer or IRO may need to request additional records during an evaluation or appeal.

Comment. A commenter requests clarification of §19.1733(b) to avoid ambiguity or interpretation by the carriers that would cause claims already submitted and paid during the exemption period to be retrospectively denied if the provider fails to submit medical records.

Agency Response. TDI declines to make a change. In response to the commenter's clarification request, an issuer would not be allowed to request repayment of claims paid while an exemption was in effect, even if the exemption was subsequently rescinded. Insurance Code §4201.657(b) makes clear that an issuer is not permitted to retroactively deny a claim.

Comment. Several commenters jointly express concern with the reference to "additional claims that were not included in the random sample." They contend that the statute does not give issuers authority to choose to review claims that are not part of the operative sample. 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.

One commenter states that proposed §19.1733(e) introduces ambiguity that can be read as allowing the provider to request a second random sample. The commenter requests that TDI change the provision to confirm that 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 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.

Agency Response. TDI agrees that an issuer may conduct a retrospective review of a health care service subject to an exemption only as provided in Insurance Code §4201.659(b)(1) and (2) and modifies §19.1733(d)(3)(A) to remove the reference to retrospective review of additional claims that were not included in the random sample.

TDI agrees that Insurance Code §4201.656(d) permits an IRO to review claims for the first time that were not first reviewed by the issuer and modifies §19.1733(e), as proposed, to permit a provider to request that an IRO review another random sample of claims if the issuer identifies on the rescission form that at least five additional claims were eligible for review but not included in the original random sample. In the case that fewer than five additional claims were eligible for review, it would not be possible to select another random sample that did not duplicate claims from the original sample. If a second random sample is requested, the issuer must, when submitting the request for independent review to the department, provide a listing of all payable claims that were eligible to be evaluated but that were not included in the original random sample. The listing must be sufficiently detailed to allow the IRO to identify each claim when selecting an additional random sample. Conforming changes were made to §12.601(e), which are discussed in a separate adoption.

To support the changes made in §19.1733(e), TDI modifies §19.1732(d)(3) to require issuers to include on the rescission notice the total number of payable claims that were eligible to be evaluated with respect to the health care service subject to rescission and the number of claims included in the random sample. This makes clear whether the physician or provider may request another random sample.

Comment. A commenter suggests clarifying that the response time for an insurer to communicate the determination of a review by the IRO to the physician or provider under §19.1733(f) is five business days.

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 proposed §19.1733(f) states that the issuer has five days to give an IRO determination to a physician. The commenters also 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 the general IRO notice requirements within 28 TAC §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. TDI declines to change §19.1733(f) in response to comment. The five-day requirement is based on the provision in Insurance Code §4201.654(a)(2) that a preauthorization exemption remains in effect until the fifth day after the date the IRO affirms the issuer's determination to rescind the exemption. The five days provided is consistent with Government Code §311.014, which requires that if the last day occurs on

a Saturday, Sunday, or legal holiday, the period is extended to include the next business day. TDI also declines to amend §19.1733(f) to specify how long the IRO has to complete its review because Insurance Code §4201.656(c) clearly states that an IRO must complete its review not later than the 30th day after the physician or provider files the request for a review.

Comment. Several commenters jointly recommend that TDI clarify proposed §19.1733(g) to be limited to requiring the maintenance of medical records only with respect to claims eligible to be evaluated under the rules. Since the independent review is limited to claims that the issuer determined did not meet the screening criteria, the commenters ask TDI to clarify that the other reviewed claims be deemed to have met screening criteria and not be subsequently challenged on the basis of a lack of medical necessity or a failure to maintain medical records.

Agency Response. TDI disagrees that clarification is needed and declines to make a change. The requirement to maintain medical records clearly applies only in the context of the retention of a preauthorization exemption and the obligation of a physician or provider to cooperate with an evaluation and an appeal, which can be conducted and result in a favorable outcome only if the physician or provider provides the necessary records.

**SUBCHAPTER R. UTILIZATION REVIEWS FOR HEALTH CARE PROVIDED UNDER A
HEALTH BENEFIT PLAN OR HEALTH INSURANCE POLICY
DIVISION 1. UTILIZATION REVIEWS
28 TAC §19.1710**

STATUTORY AUTHORITY. The Commissioner adopts amended §19.1710 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.

§19.1710. Requirements Prior to Issuing an Adverse Determination.

In any instance in which the URA is questioning the medical necessity, the appropriateness, or the experimental or investigational nature 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 licensed to practice medicine in Texas. 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. If the health care service was ordered, requested, or provided, or is to be provided, by a physician, then the opportunity must be with a physician licensed to practice medicine in Texas and who has the same or similar specialty as the physician.

(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.

DIVISION 2. PREAUTHORIZATION EXEMPTIONS
28 TAC §§19.1730 - 19.1733

STATUTORY AUTHORITY. The Commissioner adopts new Division 2, §§19.1730 - 19.1733, 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.

§19.1730. Definitions.

The following words and terms have the following meanings when used in this subchapter unless the context clearly indicates otherwise.

(1) Adverse determination regarding a preauthorization exemption--A decision by an issuer that one or more claims retrospectively reviewed as part of an evaluation as defined in paragraph (4)(B) of this section, with respect to a particular health care service for which the physician or provider has a preauthorization exemption, did not meet the issuer's screening criteria, and leads to an issuer's decision to rescind a

preauthorization exemption. An adverse determination regarding a preauthorization exemption is not an adverse determination as defined under §19.1703 of this title (relating to Definitions).

(2) Denial of preauthorization exemption--A determination that a physician or provider does not qualify for a preauthorization exemption based on the issuer conducting an evaluation, as defined in paragraph (4)(A) of this section, of eligible preauthorization requests and demonstrating that the physician or provider received approval for fewer than 90% of the eligible preauthorization requests made for a particular health care service during the most recent evaluation period.

(3) Eligible preauthorization request--A preauthorization request for a particular health care service is eligible for the purposes of an evaluation under paragraph (4)(A) of this section if it is submitted by the physician or provider and finalized by the health plan during the evaluation period, is not pending appeal, and has an outcome of either approving the particular health care service or issuing an adverse determination for the particular health care service. A preauthorization request that is modified with the acceptance of the physician or provider and approved by the plan as modified is an eligible preauthorization request for the purpose of conducting an evaluation under this section, with respect to the particular health care service that was approved. If a preauthorization request includes more than one particular health care service, the outcome for each service must be counted separately for the purposes of an evaluation.

(4) Evaluation--

(A) with respect to a particular health care service for which a physician or provider does not have a preauthorization exemption, a review of the outcomes of eligible preauthorization requests submitted by the physician or provider

during the most recent evaluation period to determine the percentage of requests that were approved, which is conducted for the purpose of evaluating whether to grant or deny a preauthorization exemption; or

(B) with respect to a particular health care service for which a physician or provider has a preauthorization exemption, a retrospective review of a random sample of payable claims submitted by or in connection with the physician or provider during the most recent evaluation period to determine the percentage of claims that would have been approved, based on meeting the issuer's applicable medical necessity criteria at the time the service was provided, which is conducted for the purpose of evaluating whether to continue or rescind a preauthorization exemption and consistent with Insurance Code §4201.655, concerning Denial or Rescission of Preauthorization Exemption.

(5) Evaluation period--The six-month period preceding an evaluation. The evaluation periods are as follows:

(A) for an initial determination of a preauthorization exemption grant or denial, the evaluation period is the six-month period that begins on January 1, 2022, or the subsequent six-month periods of July 1 - December 31 and January 1 - June 30 that follow each year;

(B) after a denial or rescission of a preauthorization exemption for a particular health care service, the subsequent six-month evaluation period begins on the first day following the end of the evaluation period that formed the basis of the denial or rescission; and

(C) for a notification of a preauthorization exemption rescission as provided in Insurance Code §4201.655(a), the evaluation period is the six-month period

an issuer determines or the subsequent six-month periods that follow, but there may not be more than two months between an evaluation period ending and the provision of notice under §19.1732 of this title (relating to Notice of Preauthorization Exemption Grants, Denials, or Rescissions).

(6) Issuer--A health maintenance organization or insurer that is subject to Insurance Code Chapter 4201, Subchapter N, including a URA or a person who contracts with an issuer to issue a preauthorization determination, or performs the functions described in this division.

(7) Particular health care service--A health care service, including a prescription drug, that is subject to preauthorization as listed on the issuer's website under §19.1718(j) of this title (relating to Preauthorization for Health Maintenance Organizations and Preferred Provider Benefit Plans).

(8) Physician--Has the meaning assigned by Insurance Code §843.002, concerning Definitions.

(9) Preauthorization--Has the meaning assigned in Insurance Code §4201.651, concerning Definitions. "Preauthorization" under this division does not include concurrent utilization review.

(10) Preauthorization exemption--A privilege obtained under this division in which a physician or provider is not subject to a preauthorization requirement that otherwise applies with respect to a particular health care service. The preauthorization exemption applies both to care rendered by a treating physician or provider and to care ordered by a physician or provider who is acting in his or her capacity as a treating physician or provider.

(11) Provider--Has the meaning assigned by Insurance Code §843.002.

(12) Random sample--A collection of at least five but no more than 20 claims for a particular health care service, selected without method or conscious decision, for the purpose of evaluating a physician's or provider's continued eligibility for a preauthorization exemption.

(13) Rescission of preauthorization exemption--An adverse determination regarding a preauthorization exemption based on an evaluation, as defined in paragraph (4)(B) of this section and consistent with Insurance Code §4201.655(b), in which the issuer would have fully approved fewer than 90% of claims for a particular health care service.

(14) Treating physician or provider--The physician or other provider who is primarily responsible for a patient's health and medical care. A "treating physician or provider" can include a rendering physician or provider or a referring or ordering physician or provider.

§19.1731. Preauthorization Exemption.

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

(b) With respect to a particular health care service for which a physician or provider does not have a preauthorization exemption, an issuer must conduct an evaluation of all preauthorization requests submitted by the physician or provider during the most recent evaluation period that were finalized prior to the evaluation and may not include a request that is pending appeal at the time the data is analyzed. The evaluation must be based on no fewer than five eligible preauthorization requests.

(c) With respect to a particular health care service for which a physician or provider has a preauthorization exemption, an issuer may conduct an evaluation, as defined in §19.1730(4)(B) of this title (relating to Definitions), to determine whether to rescind a preauthorization exemption consistent with Insurance Code §4201.655, concerning Denial or Rescission of Preauthorization Exemption. In order to determine whether to rescind an exemption, the issuer must conduct a retrospective review of a random sample of at least five and no more than 20 claims submitted during the most recent evaluation period.

(d) Other than care ordered by a treating physician or provider that has a preauthorization exemption that is then rendered by a physician or provider that does not have an exemption, a treating physician or provider may not rely on another physician's or provider's preauthorization exemption. If a treating physician or provider does not have a preauthorization exemption and relies on another physician's or provider's preauthorization exemption in violation of this subsection, an issuer may consider the physician or provider who has qualified for the preauthorization exemption as failing to substantially perform the health care service under Insurance Code §4201.659, concerning Effect of Preauthorization Exemption, and may reduce or deny payment for that service on that basis. It is not a violation of this subsection for a provider, such as a nurse or physician's assistant, who practices under the supervision of a physician, to rely on the supervising physician's exemption, if the provider appropriately orders care and requests preauthorization under the supervising physician's NPI.

(e) For care ordered by a treating physician or provider that has a preauthorization exemption that is then rendered by a physician or provider that does not have an exemption, the treating physician or provider must include the name and NPI of the ordering physician or provider on the claim in fields 17 and 17B of CMS Form 1500, in

fields 76 - 79 or another appropriate field in Form UB-04, or in the corresponding fields for electronic claims using the ASC X12N 837 format. The issuer may provide coding guidance to physicians and providers to ensure that this information is appropriately captured on the claim. If this information is not included, the issuer may treat the claim as subject to an otherwise applicable preauthorization requirement.

§19.1732. Notice of Preauthorization Exemption Grants, Denials, or Rescissions.

(a) When granting a preauthorization exemption, an issuer must provide notice to the physician or provider, consistent with Insurance Code §4201.659(d), concerning Effect of Preauthorization Exemption. The notice must include a plain language explanation of the effect of the preauthorization exemption and any claim coding guidance needed to document the preauthorization exemption, consistent with §19.1731(e) of this title (relating to Preauthorization Exemption). The exemption begins on the date the notice is issued and must be in place for at least six months before it may be rescinded. If an issuer subsequently receives a preauthorization request from the physician or provider for a particular health care service for which an exemption has been granted, the issuer must provide a notice consistent with Insurance Code §4201.659(e).

(b) When denying a preauthorization exemption, an issuer must provide notice to the physician or provider that demonstrates that the physician or provider does not meet the criteria for a preauthorization exemption, consistent with Insurance Code §4201.655(c)(2), concerning Denial or Rescission of Preauthorization Exemption; a description of how to appeal the denial using the issuer's complaints and appeals processes; and information on how to file a complaint with the department.

(c) After completing an evaluation as defined under §19.1730(4)(A) of this title (relating to Definitions), an issuer must provide a notice granting or denying a preauthorization exemption within five days. For the initial evaluation period of January 1 through June 30, 2022, an issuer must provide notice granting or denying a preauthorization exemption no later than October 1, 2022. For subsequent evaluation periods during which a physician or provider does not have a preauthorization exemption, an issuer must provide notice to the physician or provider granting or denying a preauthorization exemption no later than two months following the day after the end of the evaluation period. Notice need only be provided for a particular health care service if the issuer was able to complete an evaluation of at least five eligible preauthorization requests, as provided in §19.1731(b) of this title.

(d) When rescinding a preauthorization exemption, an issuer must provide notice to the physician or provider, consistent with Insurance Code §4201.655(a)(3). Notice of the rescission must be provided during the months specified in Insurance Code §4201.655(a)(1). The notice must include the following (a sample form LHL011 is available on TDI's website):

(1) an identification of the health care service for which a preauthorization exemption is being rescinded, the date the notice is issued, and the date the rescission is effective, consistent with Insurance Code §4201.654, concerning Duration of Preauthorization Exemption;

(2) a plain language explanation of how the physician or provider may appeal and seek an independent review of the determination, the date the notice is issued, and the company's address and contact information for returning the form by mail or electronic means to request an appeal;

(3) a statement of the total number of payable claims submitted by or in connection with the physician or provider during the most recent evaluation period that were eligible to be evaluated with respect to the health care service subject to rescission, the number of claims included in the random sample, and the sample information used to make the determination, including:

(A) identification of each claim included in the random sample;

(B) the issuer's determination of whether each claim met the issuer's screening criteria; and

(C) for any claim determined to not have met the issuer's screening criteria:

(i) the principal reasons for the determination that the claim did not meet the issuer's screening criteria, including, if applicable, a statement that the determination was based on a failure to submit specified medical records;

(ii) the clinical basis for the determination that the claim did not meet the issuer's screening criteria;

(iii) a description of the sources of the screening criteria that were used as guidelines in making the determination; and

(iv) the professional specialty of the physician, doctor, or other health care provider who made the determination;

(4) a space to be filled out by the physician or provider that includes:

(A) the name, address, contact information, and identification number of the physician or provider requesting an independent review;

(B) an indication of whether the physician or provider is requesting that the independent review organization review the same random sample or a different random sample of claims, if available; and

(C) the date the appeal is being requested; and

(5) an instruction for the physician or provider to return the form to the issuer before the date the rescission becomes effective and to include applicable medical records for any determination that was based on a failure to provide medical records.

(e) An issuer must allow physicians and providers to designate an email address or a mailing address for communications regarding preauthorization exemptions, denials, and rescissions. An issuer must provide an option for physicians and providers to submit a request for appeal by mail or by email or other electronic method. Issuers must include an explanation of how the physician or provider may update their preferred contact information and delivery method on all communications issued under this section and on the website required under §19.1718(j) of this title (relating to Preauthorization for Health Maintenance Organizations and Preferred Provider Benefit Plans).

§19.1733. Retrospective Reviews and Appeals of Preauthorization Exemption Rescissions.

(a) For a retrospective review that is conducted under Insurance Code §4201.659(b)(1), concerning Effect of Preauthorization Exemption, to determine whether the physician or provider still qualifies for an exemption, Insurance Code §4201.305, concerning Notice of Adverse Determination for Retrospective Utilization Review, does not apply.

(b) An issuer that is conducting an evaluation as defined in §19.1730(4)(B) of this title (relating to Definitions) to determine whether a physician or provider still qualifies for a preauthorization exemption may request medical records or other documents, consistent with §19.1707 of this title (relating to URA Contact with and Receipt of Information from Health Care Providers), and must provide at least 30 days for a physician or provider to provide the records. Medical records requested in connection with a retrospective review of a random sample of claims as authorized under Insurance Code §4201.659(b)(1) should be limited to no more than 20 claims for a particular health care service and may be requested only during an evaluation period or within 90 days following the end of an evaluation period. If the physician or provider fails to provide the records necessary for the issuer to make a determination, the issuer may determine that the claim would not have met the screening criteria.

(c) After receiving a notice of rescission, a physician or provider may request an independent review of the adverse determination regarding a preauthorization exemption at any time before the rescission becomes effective. The date of the request must be documented on the form, and the form must be sent electronically or postmarked before the date the rescission becomes effective.

(d) In order to request an independent review of a rescission of a preauthorization exemption, a physician or provider must submit the form provided by the issuer under §19.1732(c) of this title (relating to Notice of Preauthorization Exemption Grants, Denials, or Rescissions). If one or more determinations subject to review were based on a failure to provide specified medical records, the physician or provider must include the applicable records with the request for an independent review. Upon receipt, if the issuer seeks to proceed with the proposed rescission, the issuer must submit the request for

independent review to the department, consistent with §12.601 of this title (relating to Preauthorization Exemptions), and §19.1717(c) of this title (relating to Independent Review of Adverse Determinations), and provide information to the IRO consistent with Insurance Code §4201.402.

(e) If the notice of rescission of preauthorization exemption identified that at least five additional claims were eligible for review but not included in the original random sample, the physician or provider may request review of another random sample of claims, as authorized under Insurance Code §4201.656(d). If this request is made, the issuer must, when submitting the request for independent review to the department, provide a listing of all payable claims for the same health care service submitted by or in connection with the physician or provider during the most recent evaluation period that were eligible to be evaluated but that were not included in the original random sample. The listing must be sufficiently detailed to allow the IRO to identify each payable claim to be used in an additional random sample, as provided by §12.601(e) of this title.

(f) An issuer must communicate the determination of a review by an independent review organization under §12.601 of this title to the physician or provider within five days.

(g) In order to retain a preauthorization exemption, a physician or provider must continue to maintain medical records adequate to demonstrate that health care services meet medical guidelines. In the absence of adequate records during an evaluation or appeal, an exemption may be rescinded.

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.

2022-7434

TITLE 28. INSURANCE
Part I. Texas Department of Insurance
Chapter 19. Licensing and Regulation of Insurance Professionals

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

DocuSigned by:

75578E954EFC48A...
James Person, General Counsel
Texas Department of Insurance

The Commissioner adopts amended 28 TAC §19.1710 and new §§19.1730 - 19.1733.

DocuSigned by:

FC5D7EDDFFBB4F8...
Cassie Brown
Commissioner of Insurance

Commissioner's Order No. **2022-7434**