SUBCHAPTER S. FORMS TO REQUEST PRIOR AUTHORIZATION

DIVISION 1. TEXAS STANDARD PRIOR AUTHORIZATION REQUEST FORMS 28 TAC §19.1803

DIVISION 3. TEXAS STANDARD PRIOR AUTHORIZATION REQUEST FORM FOR PRESCRIPTION DRUG BENEFITS 28 TAC §19.1820

INTRODUCTION. The Commissioner of Insurance adopts amendments to 28 TAC §19.1803, concerning Texas standard prior authorization request forms, and §19.1820, concerning the Texas standard prior authorization request form for prescription drug benefits. The Commissioner adopts §19.1803 and §19.1820 with changes to the proposed text published in the February 25, 2022, issue of the *Texas Register* (47 TexReg 884).

REASONED JUSTIFICATION. Insurance Code §1369.304(a) requires the Commissioner by rule to prescribe a single standard form for requesting prior authorization of prescription drug benefits. Insurance Code §1369.305(c) authorizes the Commissioner to consult with the Advisory Committee for the Standard Request Form for Prior Authorization of Prescription Drug Benefits (Advisory Committee) as needed on a subsequent amendment of an adopted rule described by §1369.304. Health benefit plan issuers are required by statute to accept the form the Texas Department of Insurance (TDI) adopts for any prior authorization of prescription drug benefits required by the plan.

Insurance Code §1369.305(d) provides that the Advisory Committee must meet every two years to review the form, examine the form's effectiveness and impact on patient safety, and determine whether changes are needed. The Advisory Committee met on December 17, 2020, and recommended substantive revisions to the form and rule. It also recommended that an informal draft of the form and rule be posted for public

comment. An informal draft was posted on June 16, 2021, with comments due July 1, 2021. The Advisory Committee reconvened on September 8, 2021, in a public meeting to review the comments received and make recommendations in response. Staff considered Advisory Committee recommendations in drafting the proposal.

Section 19.1803. Definitions. Amended §19.1803 deletes the defined terms "BIN" (processor identification number) and "PCN" (processor control number), and the paragraphs in the section are renumbered to reflect deletion of the two defined terms. These amendments remove extraneous pharmacy-related data-collection terms from the section, for consistency with removal of the terms from §19.1820(a)(4). These terms, as previously used in §19.1820(a)(4), required the prescribing provider or the prescribing provider's designee to provide, if available, the BIN and PCN. Corresponding deletions of the fields referring to "BIN # (if available)" and "PCN (if available)" are adopted in Section III of the request form without change from the proposed version.

As adopted, §19.1803(1) is changed to correct an error in the proposed text by deleting the term "technology."

Section 19.1820. Prior Authorization Request Form for Prescription Drug Benefits, Required Acceptance, and Use.

In addition to making a number of changes in §19.1820(a) to conform to current TDI language preferences and drafting practices, amended §19.1820(a) changes the name of the request form in both the rule and the form adopted by reference in the rule to "Texas Standard Prior Authorization Request Form for Prescription Drug Benefits." The revisions conform the rule and the request form heading to the name used in the definition of "form" in §19.1803(4) and on page 1 of the request form. Also, amended §19.1820(a) deletes a redundant use of the word "form." Amended §19.1820(a) also removes a mailing address for requesting the form and its instruction sheet because TDI no longer mails the request form but instead provides access via the TDI website.

To reflect that changes are made to the form in response to comments, adopted §19.1820(a) is changed to update the form revision date from the date included in the proposed text.

In response to comments, TDI does not adopt the proposed changes to §19.1820(a)(3) and the corresponding proposed changes to Section II of the request form. The proposed changes would have added a provision for a non-expedited/non-urgent prior authorization review request, including a certification by the prescribing provider or the prescribing provider's designee that applying the standard review time frame is medically appropriate.

Amendments to §19.1820(a)(4) delete the requirement that the request form contain a space for the BIN, PCN, and pharmacy ID numbers (referred to as "Rx ID #" in the request form).

An amendment removes an extraneous "its" from §19.1820(a)(6). Amendments to §19.1820(a)(6)(A) clarify that the form will contain space for the name of the prescription drug.

In response to comment, the text of adopted §19.1820(a)(6)(G) and §19.1820(a)(6)(G)(ii) is changed from the proposed text to add the phrase "to the best of the prescribing provider's knowledge" to address concerns that a prescribing provider does not have any guarantee that a patient is actually taking the prescribed medication.

Section 19.1820(a)(6)(G)(ii) is amended to add a requirement that the prescribing provider state, in the case of a request for continuation of therapy, whether the patient is adhering to the drug therapy regimen and whether the regimen is effective. In response to comment, the proposed phrase “complying with” in §19.1820(a)(6)(G)(ii)(II) is changed to “adhering to.”

To correct typographical errors in the existing rule text that were identified after proposal, TDI changes the text as proposed to delete the word "and" from the end of §19.1820(a)(11) and substitutes "; and" for the period at the end of paragraph (12).

TDI changes §19.1820(a)(13) as proposed by moving the proposed text of the paragraph to subsection (a). The word "also" is not included in the text as inserted in subsection (a), and the phrase "to the form" is added, so that the paragraph items solely describe information entered into the form as indicated in the paragraph list's lead-in sentence. In response to comment and for clarification, TDI also changes §19.1820(a)(13) by adding text that provides for the incorporation of a directive to the prescribing provider into the request form. The directive states that, for a request for prior authorization of continuation of therapy, it is not necessary to complete the sections of the request form regarding patient clinical information and justification for the therapy (i.e., Sections VIII and IX of the request form) unless there has been a material change in the information previously provided. This addition correlates the rule with the change (as was proposed) to Section V of the request form. New subparagraph (A) clarifies that this directive does not apply to a request for a step-therapy exception. In the case of a request for a step-therapy exception, a prescribing provider should instead complete the section of the request form regarding the justification for the step-therapy exception (i.e., Section IX), as described in new subparagraph (B). Corresponding language also has been added to Section V of the request form. For additional clarification, TDI adds a reference and a link to Insurance Code §1369.0546(c) in the instruction sheet, under the heading "Section IX - Justification," in the fourth bullet regarding step therapy.

Amendments to §19.1820(c) require that an issuer accept a request for prior authorization made by a prescribing provider using the form on or after the effective date of the section, and they require that an issuer accept a request for prior authorization

using the form that was in place prior to the effective date of the section for 90 days after the effective date.

Texas Standard Prior Authorization Request Form for Prescription Drug Benefits

Revisions to the Texas Standard Prior Authorization Request Form for Prescription Drug Benefits, adopted by reference in §19.1820(a), update the instruction sheet by deleting a reference to a specific effective date and replacing it with a reference to the rule itself and by removing a reference to a specific version of the ICD manual. The revisions also include deletion of the TDI mailing address located at the bottom of the sheet and an updated revision date.

In response to comment, the paragraph of the instruction sheet entitled "Section IX - Justification" is changed from what was included with the proposed rule by adding a citation to Insurance Code §1369.0546(c).

As is addressed in the discussion regarding revisions to §19.1820(a), the revisions to the request form revise its heading on page 2 to correlate with the heading on the instruction sheet and revise a corresponding reference to the form in the instruction sheet.

In response to comments, the proposed language in Section II of the request form that would have added a provision to certify non-expedited/non-urgent review requests is removed, as is the "OR" in Section II that separated the two types of review. The proposed addition of a heading in Section II indicating a directive for checking an appropriate box for certification and a directive for signing and dating the form is also removed. The revisions add a date line and the proposed deletion of the phrase "By checking this box and signing below" is changed to add the statement "By checking this box and signing and dating below."

In Section III of the request form, the revisions delete extraneous pharmacy-related data-collection fields. These fields required the prescribing provider or the prescribing

provider's designee to provide, if available, the BIN, PCN, and pharmacy ID number (referred to in Section III of the previously adopted version of the request form as "Rx ID #").

In the case of a request for continuation of therapy, added fields provide opportunity to include statements in Section V of the request form for the prescribing provider or the prescribing provider's designee to state, to the best of their knowledge, whether the patient is adhering to the drug therapy regimen and whether the drug therapy regimen is effective. In response to comment, the proposed phrase "Patient is complying with the drug therapy regimen" is replaced in Section V of the adopted version of the request form with the phrase "Patient is adhering to the drug therapy regimen." In response to comment, TDI changes the phrase in Section V "For continuation of therapy, complete the following" (as was proposed) to read instead "For continuation of therapy, complete the following to the best of your knowledge." These statement fields are followed by a note in Section V indicating that it is not necessary for the prescribing provider or the prescribing provider's designee to complete Sections VIII or IX of the request form unless there has been a material change in the information previously provided; this note is adopted with changes from the sentence as proposed. In response to comments requesting clarification, the sentence is changed to distinguish between the information requirements for a request for continuation of therapy versus those for a request for a step-therapy exception. As referenced previously in the discussion regarding §19.1820(a)(13)(A) and (B), the note in Section V of the request form is also changed to add a directive to the prescribing provider stating that, for a request for a step-therapy exception, Section IX of the request form must be completed.

SUMMARY OF COMMENTS AND AGENCY RESPONSE.

Commenters: TDI received comments from four commenters. Commenters in support of the proposal with changes were Pharmaceutical Care Management Association, the Texas Association of Health Plans, the Texas Medical Association, and the Texas Healthcare and Bioscience Institute.

Comments on the rules generally

Comment. A commenter states that the cost statements in the rule proposal are incorrect and speculative and the cost statements inappropriately discount prior comments of health plans and pharmacy benefit managers (PBMs), as well as the statutory provisions of Texas step-therapy laws. The commenter states that health plan issuers do not agree that including partial information and incorrect instructions on the form will eliminate the need to obtain additional information to support step-therapy exception requests. The commenter also states that the reference to issuers having their own form is misleading because issuers are required by law to accept the promulgated form. The commenter strongly disagrees that the overall cost of complying with the amendments will be the same as, or lower than, the cost of complying with the current rule.

On the other hand, another commenter applauds TDI's intent to fast-track the process for prior authorizations for continuation of therapy and supports the recommended changes to Section V of the request form as proposed. The commenter states that these changes will appropriately decrease the administrative burden and the amount of information submitted by providers for a prior authorization for continuation of therapy that has previously been reviewed and approved by the issuer. This process simplification will help ensure that providers are not required to spend valuable time conducting duplicative administrative processes and can spend more time focused on patient care.

A commenter states that the proposal creates uncertainty as to whether and how to proceed in instances where a conflict is identified between the provider's certification of patient compliance with the therapy regimen and evidence to the contrary. This could cause medication delays, as well as the potential for prescriptions to be dispensed when not appropriate, creating patient safety concerns and the potential for fraud, waste, and abuse (especially for high-cost specialty drugs).

Agency Response. In response to the comment regarding the cost impact on issuers, TDI revises the rule and the form, including the instruction sheet, with regard to requests for an exception to a health plan step-therapy protocol. TDI believes that, in the case of a request for a step-therapy exception, the added language (*see* the added statutory reference and link in Section IX of the instruction sheet, the note in Section V of the request form, and §19.1820(a)(13) as adopted) will clarify the application of the form regarding such requests and will lessen the potential for confusion in its use. The added language will support issuers' ability to obtain the necessary information in order to respond to the step-therapy exception request.

TDI disagrees that the proposal's reference to issuers having their own form is misleading. While issuers are required by law to accept the promulgated form, nothing prohibits an issuer from developing and using an alternative form.

TDI also disagrees that the proposal will lead to uncertainty in cases of conflict between the prescribing provider's certification of patient compliance and evidence to the contrary. In the event of such a conflict, TDI believes that the issuer has sufficient access to information concerning patient adherence (for example, dispensing history) to identify cases of potential fraud or patient noncompliance. Nevertheless, TDI will monitor issuers' implementation of the rules and new request form and take future action to improve clarity if necessary.

Comments on §19.1820

Comment. A commenter recommends retaining the current TDI mailing address information in §19.1820(a) of the rule for ease of access, particularly for any physician who may encounter technical issues in downloading or otherwise accessing the request form online. The commenter states that, given the numerous prior authorization requests currently imposed by health plan issuers, it is important for TDI to facilitate access to the standard form through as many methods as possible.

Agency Response. TDI declines to make the change. TDI no longer mails the request form but instead relies on access via the agency's website, which TDI believes is sufficient. Furthermore, having TDI's mailing address in the rule and form has led to confusion in the past, with providers mailing the form to TDI instead of the appropriate carrier. In many instances this has resulted in a delay of care for patients. Therefore, to alleviate this confusion, TDI believes it appropriate to remove its mailing address from the rule and form.

Comment. Three commenters express opposition to the proposed language in §19.1820(a)(3) (and the corresponding proposed changes to the request form) regarding certification of a non-expedited/non-urgent request for review of a prior authorization. They recommend that TDI not adopt the proposed language in §19.1820(a)(3) that would add a provision for a non-expedited/non-urgent prior authorization review request, including a certification by the prescribing provider or the prescribing provider's designee that applying the standard review time frame is medically appropriate. Two commenters state that TDI lacks statutory authority for the additional certification. A commenter argues that the requirement is unnecessary, creates additional administrative burden, and

could be seen as improperly shifting responsibility regarding delays in the prior authorization review from health plans to physicians.

Agency Response. TDI disagrees that it lacks statutory authority for the provision, but, on the basis of the commenters' concerns, agrees to remove the proposed language from the rule and from Section II of the request form.

Comment. Several commenters express concern that the proposed rule would eliminate the current practice by some health plans, PBMs, and utilization review agents of not requiring the requesting provider's signature on a prior authorization request. They oppose this disallowance, and recommend the rules recognize that health plans, PBMs, and utilization review agents have the option to not require signatures on all prior authorization requests, as this would expedite the approval process.

Agency Response. TDI declines to make a change to the request form or rules. The rules do not specifically address the use and acceptance of the request form in situations where there is no signature of the requesting provider or designee. It is anticipated that health plans, PBMs, and utilization review agents have processes in place that address the authority of the prescribing provider and the manner in which the prescribing provider is to complete and submit the request form. TDI believes that the proposed changes strike the appropriate balance between promoting efficiency in the prior authorization process while recognizing patient safety standards in current practice.

Comment. Several commenters express concerns about the impact of the proposed revisions to §19.1820 and the request form on a request for a step-therapy exception. They state that the revisions would create a conflict in the use of the form with regard to a request for a step-therapy exception because the standard for requesting such an exception is in conflict with the standard in the rule and the request form. They note that

Insurance Code §1369.0546(b) requires the prescribing provider to use the request form and that Insurance Code §1369.0546(c) sets forth specific requirements that the request must meet in order for a health plan issuer to grant the request for a step-therapy exception. One commenter states that this lack of clarity could leave a plan without proper recourse in how to proceed, and due to a conflict and lack of clarity, could lead to a delay in a patient's therapy.

One commenter states that Senate Bill 680, 85th Legislature, 2017, requires supporting documentation and imposes requirements for an exception to a health plan step-therapy protocol. The commenter recommends that the rule and proposed request form require the requesting provider to submit supporting documents and state that "the change in the patient's prescription drug regimen required by the step-therapy protocol is expected to be ineffective or cause harm to the patient based on the known clinical characteristics of the patient and the known characteristics of the required prescription drug therapy regimen."

Two commenters object to the changes to Section V of the request form directing the prescribing provider to not complete Sections VIII or IX of the form unless there has been a material change in the information previously provided. They state that this change would conflict with the documentation requirements for a step-therapy exception request in Insurance Code §1369.0546(c).

Two commenters express concerns that the proposed changes to §19.1820(a)(6)(G) and the corresponding changes to Section V of the request form would conflict with the documentation requirements for requesting a step-therapy exception under Insurance Code §1369.0546(c). One of the commenters recommends that TDI revise the rule and request form to track the documentation requirements spelled out in Insurance Code §1369.0546(c)(4), since the step-therapy exception requirement clearly does not apply unless these conditions are met.

Agency Response. TDI disagrees that the proposed rule conflicts with Insurance Code §1369.0546(c) because a request for an exception to a health plan step-therapy protocol is distinct from a request for a continuation of therapy. However, to avoid any confusion regarding the documentation required for a request for a step-therapy exception, TDI modifies the note in Section V of the request form and makes corresponding changes to §19.1820(a) by adding new text to paragraph (13). These modifications clarify that the reduced information required for a request for continuation of therapy does not extend to a request for a step-therapy exception. The instructions for the current request form, in the section entitled "Section IX - Justification," specify that Section IX of the request form is to be used by the prescribing provider to "provide pertinent information about any step-therapy exception, if applicable." TDI believes that Section IX is the appropriate place for a prescribing provider to provide documentation of a request for a step-therapy exception as set forth in Insurance Code §1369.0546(c). Hence, no change to §19.1820(a)(6)(G) or to Section IX of the request form is necessary.

With regard to the recommendation that §19.1820 and the request form be revised to include language from Insurance Code §1369.0546(c), TDI declines to make the requested change. The change to the adopted rule and the request form clarify that the standard for requesting a continuation of therapy differs from the standard for requesting an exception to a health plan step-therapy protocol, so no change is necessary.

With regard to commenters' objections to the changes to Section V of the request form directing the prescribing provider to not complete Sections VIII or IX of the request form unless there has been a material change in the information previously provided, TDI declines to make the requested change to the request form. TDI notes that the parenthetical note in Section V does not prohibit a prescribing provider from completing Sections VIII and IX. The language in Section V prohibiting completion of Sections VIII or IX (unless there was a material change in information) was contained in the informal

markup of the request form, but was revised in the proposed rulemaking in response to the recommendation of the Advisory Committee. Instead, Section V provides, with regard to continuation of therapy, that "it is not necessary" to complete Sections VIII or IX unless there has been a material change in the information previously provided. This change has been carried over into the adopted version of the form.

With regard to a request for a step-therapy exception made under Insurance Code §1369.0546(c), it is expected that the prescribing provider would address the documentation requirements specified in Insurance Code §1369.0546(c) by including this documentation in Section IX of the request form. Since the request is for an exception to a health plan step-therapy protocol (and not a request for continuation of therapy), the prescribing provider would not be expected to complete the parts of Section V of the request form that address patient adherence to a drug therapy regimen and the drug therapy regimen's effectiveness.

The instructions for the request form, in the section entitled "Section IX - Justification," specify that Section IX of the request form is to be used by the prescribing provider to "provide pertinent information about any step-therapy exception, if applicable." TDI believes that Section IX is the appropriate place for a prescribing provider to document a step-therapy exception request as set forth in Insurance Code §1369.0546(c). So no change to §19.1820(a)(6)(G) is necessary.

For clarification, TDI adds a reference and a link to Insurance Code §1369.0546(c) in the instruction sheet of the request form, under the heading "Section IX - Justification," in the fourth bullet regarding step therapy. Also, TDI adds new text to §19.1820(a)(13) to clarify that the reduced information required for a request for continuation of therapy does not extend to a request for a step-therapy exception. In addition, TDI adds a corresponding directive to Section V of the request form.

Comment. Regarding §19.1820(a)(6)(G), in the context of a step-therapy exception request, a commenter recommends including a note or instruction that if the submitted documentation does not address the specific required drug alternatives, then additional information may be required.

Agency Response. TDI recognizes that for an exception to a health plan step-therapy protocol, documentation must be provided as specified in Insurance Code §1369.0546(c)(1), (2), (3), or (4). To ensure providers understand the supporting documentation that must accompany a request for a step-therapy exception, TDI modifies the instruction sheet by adding a reference and a link to Insurance Code §1369.0546(c) under the heading "Section IX - Justification." Also, TDI adds new text to §19.1820(a)(13) to clarify that the reduced information required for a request for continuation of therapy does not extend to a request for a step-therapy exception. In addition, TDI adds a corresponding directive to Section V of the request form.

Comment. Three commenters recommend that the transition period in §19.1820(c) (during which the requesting provider could use either the old or the revised request form) be changed from 90 days after the rule's effective date, as was proposed, to a different time period. Two commenters recommend that the rule provide for an unspecified, shorter time frame. Another commenter recommends that TDI provide 120 days, rather than 90 days, as an appropriate transition period.

Agency Response. TDI declines to make a change. TDI believes that 90 days is a reasonable transition period for issuers to discontinue use of the former request form and instructions.

Comment. A commenter strongly supports a reduction in the required completion of certain fields (Sections VIII and IX) in the request form related to continuation of therapy,

stating that any streamlining in the prior authorization process likely will have a dramatic impact on physician practices.

Agency Response. TDI appreciates the support.

Comments on the request form

Comment. Two commenters state that the standard for expedited review ("may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function") in Section II of the request form conflicts with the description in Insurance Code §4201.357 regarding utilization review and the expedited appeal of a denial of emergency care, continued hospitalization, or another service. Insurance Code §4201.357(a) requires that the requesting health care provider include "a written statement with supporting documentation that the service is necessary to treat a life-threatening condition or prevent serious harm to the patient" for an expedited appeal of the denial. One of the two commenters requests a resolution to the conflict of definitions for expedited appeal standards. The other commenter opposes the addition of a new standard for non-expedited/non-urgent review and recommends that TDI use the correct statutory language ("necessary to treat") in the revised rule, request form, and instructions.

Agency Response. TDI declines to make a change. Insurance Code §4201.357 applies to expedited appeals of certain adverse determinations (after the patient requested and was denied a service or a prescription drug). It is inapplicable to the sections being amended, which address the initial request for a prescription drug or the continuation of that prescription drug. TDI acknowledges that the two standards ("necessary to treat" in the case of an expedited appeal of a denial under Insurance Code §4201.357 vs. "may seriously jeopardize" in the case of a request for expedited or urgent review of a prior authorization request in §19.1820(a)(3) and Section II of the request form) are different; however, they are not in conflict in this case. Each standard applies to a different setting.

Comment. A commenter recommends that Section V of the request form include the dosing frequency. The commenter states that this can be very helpful, especially on appeal requests, when health plans are handling prior authorization requests for medications that include both a loading and maintenance dose.

Agency Response. TDI declines to make a change. The dosing frequency should already be part of the prescription, not an extra step in the request form.

Comment. A commenter states that if there is no material change in the information previously provided in Sections VIII or IX of the request form, then those sections should not be completed. The commenter does not believe that TDI needs to add the two new proposed requirements regarding drug effectiveness and patient compliance to Section V of the request form to justify the removal of the requirements to complete Sections VIII and IX for continuing therapies when there has been no material change in the information previously provided. The commenter recommends in that case that TDI not adopt the two new required statements (regarding drug effectiveness and patient compliance). The commenter recommends that if TDI adds the two new components to §19.1820(a)(6)(G)(ii)(II) and (III), then it also should make certain changes to the rule and the form. Specifically, the commenter recommends that the rule be modified to include qualifiers that the prescribing provider is attesting only to the best of his or her knowledge.

Agency Response. TDI disagrees with the commenter's recommendation to not include the two new proposed requirements (concerning patient compliance and drug therapy regimen effectiveness) in Section V of the request form and §19.1820(a)(6)(G)(ii)(II) and (III). Inclusion of these two new requirements will provide an added layer of assurance regarding the use and effectiveness of the fast-track therapy-continuation process. TDI

does, however, agree to add a corresponding knowledge qualifier to the provision in Section V relating to continuation of therapy. TDI also has made similar changes to §19.1820(a)(6)(G) and §19.1820(a)(6)(G)(ii).

Comment. A commenter states strong opposition to the two additional requirements in §19.1820(a)(6)(G)(ii)(II) and (III) (even with the modification discussed previously) if they were stand-alone new additions without any corresponding benefit in relief from completing the fields in Sections VIII and IX of the request form adopted at the same time as the requirements in §19.1820(a)(6)(G)(ii)(II) and (III). The commenter states further that, on their own, these requirements would increase, rather than decrease, the administrative burdens of physicians completing the standard prior authorization form; depart from the typical required elements included on prior authorization forms; and not appropriately recognize that it may be medically necessary and appropriate to provide a drug therapy regimen to a patient who is not fully compliant.

Agency Response. TDI declines to make a change. The two additional requirements contained in §19.1820(a)(6)(G)(ii)(II) and (III) (concerning patient compliance and drug therapy effectiveness) and in Section V of the request form are intended to apply only in the context of a request for prior authorization for a continuation of therapy. They are not intended as stand-alone provisions.

Comment. A commenter strongly recommends that TDI adopt the following proposed language in Section V of the request form: "NOTE: For a request for prior authorization of continuation of therapy, it is not necessary to complete Sections VIII or IX of the request form unless there has been a material change in the information previously provided."

Agency Response. TDI agrees to make the requested change, but has made modifications to the suggested text to clarify the application of Section V of the request

form with regard to a request for a step-therapy exception in response to a separate comment.

Comment. A commenter encourages TDI to provide additional guidance to address two key points so that the fast-track process works as intended by the Advisory Committee. The first point is a request to clarify that the notation on the form that the drug therapy regimen is effective indicates that the provider supports continued treatment with the designated therapy. The second point is a request to include instructions that limit the ability of an issuer to add administrative requirements beyond what is asked for in the standard form simply because the provider has taken advantage of the fast-track process. The commenter states that this guidance is necessary to ensure that this fast-track process has the full impact intended and does not become a trigger for an issuer to mandate additional processes that bypass the use of the standard form required by law.

Agency Response. TDI declines to make the requested change to the request form. Section V of the request form requires, in the case of a request for prior authorization of continuation of therapy, that a prescribing provider check the boxes regarding patient adherence to the drug therapy regimen and the drug therapy regimen's effectiveness. Completion of this portion of the request form indicates that the request is for continuation of therapy and that it is for the drug named in Section V.

Regarding the second point--inclusion of instructions that limit an issuer's ability to add administrative requirements beyond what is in the standard form--TDI declines to make a change to the form or the rule. However, it should be emphasized that the main purpose of the fast-track continuation of therapy process in Section V of the request form (and corresponding §19.1820(a)(6)(G)(ii)(II) and (III)) is to reduce the administrative burden of the prior authorization process on prescribing providers. The addition of the fast-track provision was a key recommendation of the Advisory Committee. TDI plans to monitor

the rollout of this provision and, if warranted, will consider whether future rulemaking is appropriate to address obstacles to its implementation.

Comment. In discussing the instruction sheet to the request form, a commenter notes that it states that an "issuer may also provide an electronic version of this form on its website." The commenter also notes that the Insurance Code contains a specific provision requiring plan issuers and agents to exchange prior authorization requests electronically with a prescribing provider who has e-prescribing capability and who initiates a request electronically. Citing standards for electronic prior authorizations (ePAs) adopted by the National Council for Prescription Drug Programs, the commenter encourages TDI to revisit these standards and, in compliance with the law, update the request form as soon as possible to facilitate the expanded use of ePAs. The commenter states that doing so will simplify and decrease administrative burdens and decrease delays for patients.

Agency Response. TDI declines to make the change. The Centers for Medicare & Medicaid Services adopted rules that address certain transactions with regard to submission of ePAs under Medicare Part D. *See* 42 CFR §423.160. The federal regulation applies to Medicare Part D sponsors. The state rules that are the subject of this adoption order apply to a "health benefit plan issuer or the agent of the health benefit plan issuer that manages or administers prescription drug benefits." *See* Insurance Code §1369.304(a)(2). Therefore, the federal e-prescribing rules are inapplicable to non-Medicare plan sponsors. Nevertheless, the department did review the federal e-prescribing rules in developing this rulemaking.

Comment. A commenter recommends that in Section V of the request form, the term "compliant" be replaced with the more updated term "adherence." The commenter states

that, in recent years, the use of the term "compliant" has raised concerns in the patient advocate and health care community.

Agency Response. TDI agrees to make the suggested change. TDI deletes the phrase "complying with" in Section V of the request form and replaces it with the phrase "adhering to." TDI makes a corresponding change in §19.1820(a)(6)(G)(ii)(II).

SUBCHAPTER S. FORMS TO REQUEST PRIOR AUTHORIZATION
DIVISION 1. TEXAS STANDARD PRIOR AUTHORIZATION REQUEST FORMS
28 TAC §19.1803

STATUTORY AUTHORITY. The Commissioner adopts amendments to §19.1803 under Insurance Code §1369.304 and §36.001.

Insurance Code §1369.304 requires that the Commissioner by rule prescribe a single standard form for requesting prior authorization of prescription drug benefits.

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.

§19.1803. Definitions.

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

(1) CDT--Current Dental Terminology code set maintained by the American Dental Association.

(2) CPT--Current Procedural Terminology code set maintained by the American Medical Association.

(3) Department or TDI--Texas Department of Insurance.

(4) Form--In Division 2 of this subchapter, the Texas Standard Prior Authorization Request Form for Health Care Services. In Division 3 of this subchapter, the Texas Standard Prior Authorization Request Form for Prescription Drug Benefits.

(5) HCPCS--Healthcare Common Procedure Coding System.

(6) Health benefit plan--

(A) a plan that provides benefits for medical or surgical expenses incurred as a result of a health condition, accident, or sickness, including an individual, group, blanket, or franchise insurance policy or insurance agreement, a group hospital service contract, or a small or large employer group contract or similar coverage document offered by a health benefit plan issuer.

(B) Health benefit plan also includes:

(i) group health coverage made available by a school district in accord with Education Code §22.004;

(ii) coverage under the child health program in Health and Safety Code Chapter 62, or the health benefits plan for children in Health and Safety Code Chapter 63;

(iii) a Medicaid managed care program operated under Government Code Chapter 533, or a Medicaid program operated under Human Resources Code Chapter 32;

(iv) a basic coverage plan under Insurance Code Chapter 1551;

(v) a basic plan under Insurance Code Chapter 1575;

(vi) a primary care coverage plan under Insurance Code Chapter 1579; and

(vii) basic coverage under Insurance Code Chapter 1601.

(7) Health benefit plan issuer--An entity authorized under the Insurance Code or another insurance law of this state that delivers or issues for delivery a health

benefit plan or other coverage described in Insurance Code §1217.002 or Insurance Code §1369.252.

(8) Health care service--A service to diagnose, prevent, alleviate, cure, or heal a human illness or injury that is provided by a physician or other health care provider. The term includes medical or health care treatments, consultations, procedures, drugs, supplies, imaging and diagnostic services, inpatient and outpatient care, medical devices other than those included in the definition of prescription drugs in Occupations Code §551.003, and durable medical equipment. The term does not include prescription drugs or devices as defined by Occupations Code §551.003.

(9) ICD--International Classification of Diseases.

(10) Issuer--A health benefit plan issuer and the agent of a health benefit plan issuer that manages or administers the issuer's health care services or prescription drug benefits.

(11) NDC--National Drug Code.

(12) NPI number--A provider's or facility's National Provider Identifier.

(13) Prescription drug--Has the meaning assigned by Occupations Code §551.003.

SUBCHAPTER S. FORMS TO REQUEST PRIOR AUTHORIZATION
DIVISION 3. TEXAS STANDARD PRIOR AUTHORIZATION REQUEST FORM FOR PRESCRIPTION DRUG BENEFITS
28 TAC §19.1820

STATUTORY AUTHORITY. The Commissioner adopts amendments to §19.1820 under Insurance Code §1369.304 and §36.001.

Insurance Code §1369.304 requires that the Commissioner by rule prescribe a single standard form for requesting prior authorization of prescription drug benefits.

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.

§19.1820. Prior Authorization Request Form for Prescription Drug Benefits, Required Acceptance, and Use.

(a) Form requirements. The Commissioner adopts by reference the Texas Standard Prior Authorization Request Form for Prescription Drug Benefits, Rev. 05/2022, to be accepted and used by an issuer in compliance with subsection (b) of this section. The form and its instruction sheet are on TDI's website at www.tdi.texas.gov/forms/form10.html. The form must be reproduced without changes. A prescribing provider may attach supporting clinical documentation to the form (medical records, progress notes, lab reports, radiology studies, etc.). The form provides space for the following information:

(1) the name of the issuer or the issuer's agent that manages prescription drug benefits, telephone number, and facsimile (fax) number;

(2) the date the request is submitted;

(3) a place to request an expedited or urgent review if the prescribing provider or the prescribing provider's designee certifies that applying the standard review time frame may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function;

(4) the patient's name, contact telephone number, date of birth, sex, address, and identifying insurance information;

(5) the prescribing provider's name, NPI number, specialty, telephone and fax numbers, address, and contact person's name and telephone number;

(6) for a prescription drug:

(A) drug name;

(B) strength;

(C) route of administration;

(D) quantity;

(E) number of days' supply;

(F) expected therapy duration; and

(G) to the best of the prescribing provider's knowledge, whether the medication is:

(i) a new therapy; or

(ii) continuation of therapy, and if so, to the best of the prescribing provider's knowledge:

(I) the approximate date therapy was initiated;

(II) whether the patient is adhering to the drug therapy regimen; and

(III) whether the drug therapy regimen is effective;

(7) for a provider administered drug, the HCPCS code, NDC number, and dose per administration;

(8) for a prescription compound drug, its name, ingredients, and each ingredient's NDC number and quantity;

(9) for a prescription device, its name, expected duration of use, and, if applicable, its HCPCS code;

(10) the patient's clinical information, including:

(A) diagnosis, ICD version number (if more than one version is allowed by the U.S. Department of Health and Human Services), and ICD code;

(B) to the best of the prescribing provider's knowledge, the drugs the patient has taken for this diagnosis, including:

(i) drug name, strength, and frequency;

(ii) the approximate dates or duration the drugs were taken; and

(iii) patient's response, reason for failure, or allergic reaction;

(C) the patient's drug allergies, if any; and

(D) the patient's height and weight, if relevant;

(11) a list of relevant lab tests, and their dates and values;

(12) a place for the prescribing provider to:

(A) include pertinent clinical information to justify requests for initial or ongoing therapy, or increases in current dosage, strength, or frequency;

(B) explain any comorbid conditions and contraindications for formulary drugs; or

(C) provide details regarding titration regimen or oncology staging, if applicable; and

(13) a directive to the prescribing provider stating that:

(A) for a request for prior authorization of continuation of therapy (other than a request for a step-therapy exception as provided in subparagraph (B) of this paragraph), it is not necessary to complete the sections of the form regarding patient clinical information and justification for the therapy unless there has been a material change in the information previously provided; and

(B) for a request for a step-therapy exception, the section of the form regarding justification for the step-therapy exception must be completed.

(b) Acceptance and use of the form.

(1) If a prescribing provider submits the form to request prior authorization of a prescription drug benefit for which the issuer's plan requires prior authorization, the issuer must accept and use the form for that purpose. An issuer may also have on its

website another electronic process a prescribing provider may use to request prior authorization of a prescription drug benefit.

(2) This form may be used by a prescribing provider to request prior authorization of:

(A) a prescription drug;

(B) a prescription device;

(C) formulary exceptions;

(D) quantity limit overrides; and

(E) step-therapy requirement exceptions.

(3) This form may not be used by a prescribing provider to:

(A) request an appeal;

(B) confirm eligibility;

(C) verify coverage;

(D) ask whether a prescription drug or device requires prior authorization; or

(E) request prior authorization of a health care service.

(c) Effective date. An issuer must accept a request for prior authorization of prescription drug benefits made by a prescribing provider using the form on or after the effective date of this section. An issuer must accept a request using the form that was in place prior to the effective date of this section for 90 days after the effective date.

(d) Availability of the form.

(1) A health benefit plan issuer must make the form available electronically on its website.

(2) A health benefit plan issuer's agent that manages or administers prescription drug benefits must make the form available electronically on its website.

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

Issued in Austin, Texas on July 22, 2022.

DocuSigned by:
James Person
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James Person, General Counsel
Texas Department of Insurance

The Commissioner adopts amendments to 28 TAC §19.1803 and §19.1820.

DocuSigned by:
C Brown
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Cassie Brown
Commissioner of Insurance

Commissioner's Order No. 2022-7389