SUBCHAPTER S. FORMS TO REQUEST PRIOR AUTHORIZATION
28 TAC §§19.1802 and 19.1803, and 19.1820

1. INTRODUCTION. On December 1, 2014, the Texas Department of Insurance adopted 28 TAC Chapter 19 Subchapter S, §§19.1801 - 19.1810, Agents' Licensing, concerning Forms to Request Prior Authorization. That adoption order was published in the December 12, 2014, issue of the *Texas Register* (39 TexReg 9699).

This order adopts amendments to Subchapter S, §19.1802 and §19.1803, and adds Subchapter S, Division 3, §19.1820.

TDI adopts the new section with changes to the proposed text published in the January 2, 2015, issue of the *Texas Register* (40 TexReg 13). In response to a comment, TDI has revised §19.1820(c) as proposed to replace a reference to "health care services" with "prescription drug benefits." To conform the rule to the statute's language, in three places the word "standard" has replaced "standardized." In response to another comment, TDI reviewed the use of the terms "requesting provider," "provider," and "facility" in the rule to ensure that the proper term is used in the context of each rule provision, and has replaced those terms with the term "prescribing provider," to conform with the language of SB 644, 83rd Legislature, Regular Session, (2013). TDI has revised the text of the instruction page, as suggested by a commenter, by adding further explanatory language to Section IX.

2. REASONED JUSTIFICATION. SB 644, 83rd Legislature, Regular Session (2013) amended Insurance Code Title 8, Subtitle A, to add Chapter 1369, Subchapter F

(Standard Request Form For Prior Authorization of Prescription Drug Benefits) to require the commissioner of insurance to prescribe by rule a standard form for requesting prior authorization of prescription drug benefits. HB 1358, 83rd Legislature, Regular Session (2013) also amended Insurance Code Title 8, Subtitle A, to add a different Chapter 1369, Subchapter F (Audits of Pharmacists and Pharmacies). That Subchapter F is not the subject of this rule. Throughout this adoption order, all references to Chapter 1369, Subchapter F mean the subchapter added by SB 644.

The amendments and additions to Subchapter S, §19.1802 and §19.1803 are necessary to implement SB 644, 83rd Legislature, Regular Session (2013). SB 644 amends Insurance Code Title 8, Subtitle A, to add Chapter 1369, Subchapter F, which requires the commissioner of insurance to prescribe by rule a single standard form for requesting prior authorization of prescription drug benefits. SB 644 also requires an issuer and its agents to accept and use the form for all prior authorizations of prescription drug benefits for which the issuer's plan requires prior authorization, and requires TDI and the issuer and its agents to make the form available electronically on their websites. The adopted rule addresses these requirements by prescribing a form, by requiring its acceptance and use by issuers and their agents, and by requiring that the form be posted electronically as stated in the statute.

SB 644 directs the commissioner to develop the form with input from an advisory committee; to consider prior authorization forms now used widely in Texas, used by TDI, or established by the Centers for Medicare and Medicaid Services; and to consider

national standards or draft standards on electronic prior authorization of prescription drug benefits.

Insurance Code §1369.255 requires the commissioner to appoint an advisory committee composed of the designees of the commissioner of insurance and the executive commissioner of the Texas Health and Human Services Commission; three members from each of the following stakeholder groups: physicians, other prescribing health care providers, consumers experienced with prior authorizations, hospitals, pharmacists, specialty pharmacies, pharmacy benefit managers, specialty drug distributors, health benefit plan issuers for the Texas Health Insurance Pool, health benefit plan issuers, and health benefit plan provider networks. Although the bill calls for three representatives of health benefit plan provider networks, agency staff was unable to recruit a third member. The commissioner approved proceeding with the rule with two representatives from this group.

The advisory committee met on August 8, 2014, and September 12, 2014, and consulted by email to complete its work. In addition to advising the commissioner on the technical, operational, and practical aspects of developing the standard prior authorization form, the advisory committee was to determine the form's length, when and how an issuer or its agent is to acknowledge receipt of the form, and the penalty to be imposed on an issuer or its agent for failure to acknowledge receipt of the form.

In addition to SB 644, the 83rd Legislature also passed SB 1216, which directs the commissioner to prescribe by rule a standard form for requesting prior authorization

of health care benefits. Because the prior authorization rules implementing SB 1216 and SB 644 are closely linked, both rules will be included in Subchapter S.

3. HOW THE SECTION WILL FUNCTION. Division 1, §§19.1801 - 19.1804, includes sections common to both rules. Section 19.1801 lists the health benefit plans, coverages, and programs to which the subchapter applies. Section 19.1802 lists the health benefit plans, coverages, and policies excepted from the rules. Section 19.1803 defines terms also defined in SB 1216 or SB 644 or used in the prescribed forms. Section 19.1804 is a severability provision.

Division 2, §19.1810, is specific to SB 1216.

Division 3, §19.1820, is specific to SB 644. Section 19.1820(a) adopts the prior authorization form by reference and lists several ways to find and obtain the form. Subsection (a) also contains a description of the form sufficiently specific to provide the substantive detail about the form prescribed by 28 TAC §1.203(b)(2). Section 19.1820(b) states that issuers are required to accept and use the form when submitted by a provider seeking prior authorization of a health care service for which the issuer requires prior authorization. This subsection also lists purposes for which the form may and may not be used. Section 19.1820(c) states the rule's effective date. Section 19.1820(d) directs both the health benefit plan issuer and the agent of a health benefit plan issuer that manages or administers the issuer's prescription drug benefits to make the form available on their websites.

4. SUMMARY OF COMMENTS AND AGENCY RESPONSE.

Section 19.1803.

Comment: A commenter requested §19.1803 be amended to add "unless the context clearly indicates otherwise" to the end of the first sentence of the section.

Agency Response: TDI did not include the suggested language in this rule because that language had already been adopted in the December 1, 2014, rule.

Section 19.1820.

Comment: A commenter asked that TDI review the use of "requesting provider," "provider," and "facility" to ensure the terms as used are consistent and appropriate in the context of each rule provision, and to determine whether references to a "prescriber" or "facility" should be to a "requesting prescriber."

Agency Response: TDI agrees with the commenter, and has changed the text to use the term "prescribing provider" where appropriate, in conformity with the language of SB 644.

Section 19.1820(c).

Comment: A commenter noted that in the rule's effective date provision, a reference to "health care services" is a typographical error, and suggests the term be replaced with "prescription drug benefits."

Agency Response: TDI agrees with the commenter, and has made the requested change.

Queried Omissions.

Comment: A commenter noted that the rule does not include penalties or other sanctions that TDI intends to levy against health benefit plan issuers or their agents for violations of the rules. The commenter believes Insurance Code §1369.254(a)(4) and §1369.256 require that the rule include penalties for failure to accept and acknowledge receipt of the form. The commenter queried whether TDI intends to engage in further rulemaking for the purpose of establishing the rule's enforcement provisions, and if not, asks how TDI intends to enforce the rule without further rulemaking.

Agency Response: TDI notes that Insurance Code §1369.255 requires the commissioner to appoint an advisory committee, and charged the committee with determining the length of time allowed an issuer or agent to acknowledge receipt of the form, and to determine the penalty imposed on an issuer or agent for failure to acknowledge receipt of the form. The appointed advisory committee considered existing statutes and rules requiring issuer and agent compliance with rules adopted by the commissioner, and declined to require a unique penalty scheme for failure to use the form or acknowledge receipt of the form. The committee considered and determined that compliance with the time frames required in Insurance Code Chapter 4201 for providing notice of a favorable or adverse determination of a request for preauthorization were sufficient to constitute acceptable and timely acknowledgement of the form's receipt. The committee considered and determined that a failure to comply with those time frames is subject, under §4201.603, to the remedies and penalties

imposed by Insurance Code Chapters 82, 83, and 84, and that no other penalty scheme is needed. In addition, Insurance Code §1369.255(d) requires the commissioner to reconvene the committee every two years to determine whether changes to the rule are needed. The committee determined it would assess the effectiveness of this remedial scheme when reconvened.

Prior authorization form's instruction page.

Comment: A commenter noted that the prior authorization form's instruction page should more clearly identify the field in which providers are expected to enter information regarding step-therapy exceptions. Specifically, the commenter recommended the addition of a bullet under Section IX – Justification reading, "Provide information pertinent to any step-therapy exception, if applicable."

Agency response: TDI agrees with the comment and has revised the text of the instruction page to clarify this issue.

Section 19.1820(b) and prior authorization form's instruction page.

Comment: A commenter objected to the sentence on the form's instruction page stating that, "Some issuers may require more information or additional forms to process your request." The commenter believes that TDI's intent in including this sentence was to place providers on notice that state government programs may require additional information or an entirely different type of form (such as an affidavit for the Medicaid

program) to process the request. The commenter proposed that TDI amend the sentence by adding "such as state government programs" after "Some issuers." The commenter also contended that the sentence could be misconstrued, giving issuers an opportunity to circumvent the law by requiring prescribing providers to resubmit information that is already required on the standard form. The commenter requests that TDI add language stating that if a prescribing provider requests prior authorization using the standard form, the issuer may not require the prescribing provider to submit any other form for prior authorization purposes that duplicates information found on the standard form.

Agency response: TDI disagrees with the comment and declines to add the suggested language. SB 644 requires the commissioner to adopt a standard form for requesting prior authorization, but does not prohibit an issuer or a reviewer from asking for additional information needed to process the request. TDI also declines to add language prohibiting an issuer from requiring a prescribing provider to submit any other form for prior authorization purposes that may duplicate information found on the prior authorization form. The standard prior authorization form requires information that identifies the patient, the prescribing provider, and the requested prescription drug. This basic identifying information would almost certainly be needed by an issuer on any additional form a prescribing provider is required to submit. TDI will monitor the use of the prior authorization form and initiate future rulemaking as necessary.

Prior Authorization Form

Comment: A commenter suggested that in Section II of the form, where a prescribing provider can indicate whether expedited or urgent review is requested, the phrase "standard review time frame" be defined, or alternatively that the section include a space for the prescribing provider to state the date by which the prescribed medication is needed for treatment.

Response: Standard review time frames for commercial carriers are set out in Insurance Code Chapter 4201, but those standard review time frames do not apply to other plans or programs that are also required to comply with this rule, such as Medicaid and certain other governmental plans. Because differences in both the patient's circumstances and the identity of the issuer will affect the "standard review time frame," it is not possible to define the term. Because TDI lacks authority to require an issuer to meet a review date stated by a prescribing provider, including a space for a date could give a prescribing provider the mistaken impression that the issuer must review the request by the stated date.

Comment: A commenter requested that the form be easily convertible to an electronic format for direct submission to the insurance company. The commenter also queried whether issuers' responses would be standardized.

Response: While SB 644 requires that the standard form be available electronically, the form is intended to be accessible both to providers who wish to complete the form online, and to those who wish to print and fax the completed form. To this end, the form

will be available on TDI's website in a format that can be printed and completed by hand and in a format that can be downloaded, completed on a computer, printed, and faxed. The format that issuers' responses may take is outside the scope of SB 644 and this rule.

5. NAMES OF THOSE COMMENTING.

For with changes: The Texas Medical Association, and the Bone and Joint Clinic of Houston.

6. STATUTORY AUTHORITY. TDI adopts amended 28 TAC §19.1802 and §19.1803, and new §19.1820 under Insurance Code §§1369.251, 1369.252, 1369.253, 1369.254, 1369.255, and 36.001. Section 1369.251 provides definitions for Insurance Code Chapter 1369, Subchapter F. Section 1369.252 states applicability of Insurance Code Chapter 1369, Subchapter F. Section 1369.253 states exceptions to the applicability of Insurance Code Chapter 1369, Subchapter F. Section 1369.254 requires the commissioner to adopt a rule to prescribe a single, standard form for requesting prior authorization of prescription drug benefits; to require an issuer or its agent that manages or administers prescription drug benefits to use the form for all prior authorizations of prescription drug benefits for which the issuer's plan requires prior authorization; and to require TDI, the issuer, and its agent to make the form available electronically on their websites. Section 1369.255 directs the commissioner to appoint an advisory committee to determine the single standard form, its length, an appropriate

time and method for acknowledgement of receipt of the form, and the penalty to be imposed on an issuer or its agent for failure to acknowledge receipt of the form. Section 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 Texas.

7. TEXT.

SUBCHAPTER S. FORMS TO REQUEST PRIOR AUTHORIZATION

DIVISION 1. Texas Standard Prior Authorization Request Forms.

§19.1802. Exception.

This subchapter does not apply to:

(1) a health benefit plan that provides coverage:

(A) only for a specified disease or for another single benefit;

(B) only for accidental death or dismemberment;

(C) only for wages or payments to replace wages for a period during which an employee is absent from work because of sickness or injury;

(D) as a supplement to a liability insurance policy;

(E) for credit insurance;

(F) only for dental or vision care;

(G) only for hospital expenses; or

(H) only for indemnity for hospital confinement;

(2) a Medicare supplemental policy as defined by §1882, Social Security Act (42 U.S.C. §1395ss);

(3) medical payment insurance coverage provided under a motor vehicle insurance policy;

(4) a long-term care insurance policy, including a nursing home fixed indemnity policy, unless the commissioner determines that the policy provides benefit coverage so comprehensive that the policy is a health benefit plan as described by §1217.002 or §1369.252; or

(5) a workers' compensation insurance policy.

§19.1803. Definitions.

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

(1) BIN--Processor Identification Number.

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

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

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

(5) 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.

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

(7) 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.

(8) 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.

(9) 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.

(10) ICD--International Classification of Diseases.

(11) 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.

(12) NDC--National Drug Code.

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

(14) PCN--Processor Control Number.

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

DIVISION 3. Texas Standard Prior Authorization Request Form for Prescription Drug Benefits.

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

(a) Form requirements. The commissioner adopts by reference the Prior Authorization Request Form for Prescription Drug Benefits form, 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; or the form and its instruction sheet can be requested by mail from the Texas Department of Insurance, Rate and Form Review Office, Mail Code 106-1E, P.O. Box 149104, Austin, Texas 78714-9104. The form must be reproduced without changes. 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, identifying insurance information, and, if available, BIN, PCN, and pharmacy ID numbers;

(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, its:

(A) name;

(B) strength;

(C) route of administration;

(D) quantity;

(E) number of days' supply;

(F) expected therapy duration; and

(G) whether the medication is:

(i) a new therapy; or

(ii) continuation of therapy, and if so, the approximate date therapy was initiated;

(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;

(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; and

(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.

(13) A prescribing provider may also attach supporting clinical documentation (medical records, progress notes, lab reports, radiology studies, etc.).

(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 September 1, 2015.

(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.

Issued in Austin, Texas. April 1, 2015.

Sara Waitt, General Counsel
Texas Department of Insurance

The commissioner adopts amended 28 TAC §19.1802 and §19.1803, and new §19.1820.

David C. Mattax
Commissioner of Insurance