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

1. INTRODUCTION. The Texas Department of Insurance proposes amending 28 TAC Chapter 19 Subchapter S, Division 1, §19.1802 and §19.1803, and adding Subchapter S, Division 3, §19.1820. Subchapter S, Division 3 will prescribe a prior authorization request form for prescription drug benefits that will be accepted and used by health benefit plan issuers, and the agents of health benefit plan issuers that manage or administer issuers' prescription drug benefits, when a provider or facility submits the form to request prior authorization of a prescription drug benefit for which an issuer's plan requires prior authorization.

Background and 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 proposal, all references to Chapter 1369, Subchapter F mean the subchapter added by SB 644.

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 it requires TDI and the issuer and its agents to make the form available electronically on their websites. The proposed rule addresses these requirements.

SB 644 also directs the commissioner to develop the form with input from an advisory committee and 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 benefits.

In compliance with new Insurance Code §1369.255, the commissioner appointed an advisory committee composed as required by §1369.25(e). TDI staff met with the advisory committee on August 8, 2014, and September 12, 2014, and consulted the committee by email to get the committee's input, which staff used to create the form in this rule proposal.

Description of Proposed Rule.

In addition to SB 644, the 83rd Legislature passed SB 1216 during its regular session, which directs the commissioner to prescribe by rule a single, standard form for requesting prior authorization of health care services.

Because the prior authorization rules implementing SB 644 and SB 1216 are closely linked, both rules will be included in Subchapter S. Although this proposal addresses

only the prior authorization request form for prescription drug benefits mandated by SB 644, some provisions of this rule will amend the newly adopted rule prescribing a prior authorization request form for health care services.

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. It is not changed by this rule. Section 19.1802 lists the health benefit plans, coverages, and policies excepted from the rules. This section is amended by this rule. Section 19.1803 defines terms also defined in SB 1216 or SB 644 or used in the prescribed forms. This section is amended by this rule. Section 19.1804 is a severability provision. It is not changed by this rule.

Division 3, §19.1820, is specific to SB 644. Section 19.1820(a) adopts the form by reference and lists several ways to find and get 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 prescription drug benefit for which the issuer requires prior authorization. This subsection also lists purposes for which the form 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 its website.

2. FISCAL NOTE. Patricia Brewer, special advisor for policy development in TDI's Life, Accident, and Health Section, has determined that for each year of the first five years the proposed new sections will be in effect, there will be no fiscal impact to state or local governments resulting from enforcement or administration of the rule. The proposal will have no measurable effect on local employment or on the local economy.

3. PUBLIC BENEFIT AND COST NOTE. Ms. Brewer has also determined that for each year of the first five years the proposed new sections are in effect, the rule's anticipated public benefits include reduced administrative time spent by physicians, pharmacies, hospitals, and other health care providers identifying and completing each issuer's prior authorization form or forms; easy provider access to the standard prior authorization form on TDI's and the issuers' and agents' websites; and expedited delivery of prescription drug benefits to consumers.

The costs to persons who must comply with the proposed sections, for each year of the first five years they would be in effect, result from the enactment of SB 644, and not from the adoption, enforcement, or administration of the proposed sections. SB 644 explicitly prohibits TDI from declining to prescribe the form. TDI is unable to determine the actual cost for issuers and providers to adopt and use the form when adopted, as those costs will vary based on each entity's administrative processes. However, as

required by SB 644, TDI developed the proposed form with input from an advisory committee in which issuer representatives and health care provider and facility representatives, among others, participated. After extensively discussing the form's elements with the advisory committee, TDI does not anticipate that issuers or their agents or providers and facilities will incur undue material costs due to the particular elements of the proposed form. TDI does not anticipate a difference in the cost of compliance between small and large businesses.

4. ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS FOR SMALL AND MICRO BUSINESSES. In compliance with Government Code §2006.002(c), TDI has determined that the proposed new sections requiring issuers and their agents to use and accept the standard prior authorization request form and to make the form available electronically on their respective websites will not have an adverse economic effect on small or micro businesses required to comply with the proposed rule. The proposal does not impose on businesses any requirements or costs other than those required by SB 644. Costs to persons required to comply with the proposed new sections result from the enactment of SB 644, and not from the adoption, enforcement, or administration of the proposal. TDI has determined that a regulatory flexibility analysis is not required because the proposal will not have an adverse impact on small or micro businesses. It is not possible both to provide flexibility for small or micro businesses and to comply with the Legislature's mandate in SB 644 to create a single, standard prior authorization request form for Texas. Permitting small or micro

businesses to refuse to accept the adopted form, and instead require providers to use a form specific to or created by individual small or micro businesses, would increase, rather than decrease, providers' confusion.

5. TAKINGS IMPACT ASSESSMENT. TDI has determined that no private real property interests are affected by this proposal. This proposal does not restrict or limit an owner's right to property that would otherwise exist in the absence of government action and so does not constitute a taking or require a takings impact assessment under Government Code §2007.043.

6. REQUEST FOR PUBLIC COMMENT. TDI invites comments on the proposed rule. If you wish to comment on this proposal, your comments must be postmarked no later than 5 p.m., Central time, on February 2, 2015. Please send comments by mail to Office of the Chief Clerk, Mail Code 113-2A, Texas Department of Insurance, P.O. Box 149104, Austin, Texas 78714-9104, or by email to chiefclerk@tdi.texas.gov. Please simultaneously submit an additional copy of the comments by mail to Patricia Brewer, Special Advisor for Policy Development, Mail Code 107-2A, Texas Department of Insurance, P.O. Box 149104, Austin, Texas 78714-9104, or by email to lhlcomments@tdi.texas.gov. You must submit any request for a public hearing separately to the Office of Chief Clerk, Mail Code 113-2A, Texas Department of

Insurance, P.O. Box 149104, Austin, Texas 78714-9104, or by email to chiefclerk@tdi.texas.gov before the close of the public comment period. If there is a hearing on this proposal, you may present written comment and public testimony at the hearing.

7. STATUTORY AUTHORITY. TDI proposes the amendments to 28 TAC Chapter 19 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 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, or the issuer's agent who manages or administers prescription drug benefits to make the form available electronically on their websites. Section 1369.255 requires that the commissioner appoint an advisory committee to determine certain aspects of the form and its implementation. Section 36.001 provides that the commissioner may adopt any rules necessary and appropriate to implement the powers and duties of the department under the Insurance Code and other laws of this state.

8. CROSS REFERENCE TO STATUTE. Insurance Code §1369.253 is implemented by 28 TAC §19.1802 (Exception). Insurance Code §1369.251 is implemented by 28 TAC §19.1803 (Definitions). Insurance Code §1369.254 is implemented by 28 TAC §19.1820 (Prior Authorization Request Form for Prescription Drug Benefits, Required Acceptance, and Use).

9. 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:

(1) BIN-- Processor Identification Number.

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

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

(4)[~~(3)~~] Department or TDI--Texas Department of Insurance.

(5)[~~(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.

(6)[~~(5)~~] HCPCS--Healthcare Common Procedure Coding System.

(7)[~~(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 Chapter 62 Health and Safety Code, or the health benefits plan for children in Chapter 63 Health and Safety Code;

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

(iv) a basic coverage plan under Chapter 1551;

(v) a basic plan under Chapter 1575;

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

(vii) basic coverage under Chapter 1601.

(8)[~~(7)~~] Health benefit plan issuer--An entity authorized under the Texas 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)[~~(8)~~] Health care service--A service to diagnose, prevent, alleviate, cure, or heal a human illness or injury, which 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)[~~(9)~~] 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)[~~(10)~~] NPI number--A provider's or facility's National Provider Identifier.

(14) PCN--Processor Control Number.

(15)[~~(11)~~] 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 prescriber or the prescriber'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 requesting prescriber'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 prescriber'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 requester 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 requesting provider or facility 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 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 provider or facility may use to request prior authorization of a prescription drug benefit.

(2) This form may be used by a 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 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 health care services made by a provider or facility using the form on or after September 1, 2015.

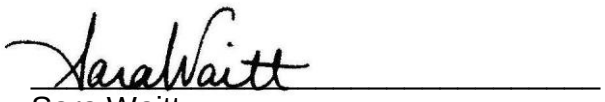
(d) Availability of the form.

(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.

10. CERTIFICATION. TDI certifies that legal counsel has reviewed the proposal and found it to be within the agency's legal authority to adopt.

Issued at Austin, Texas, on December 9. 2014



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