SUBCHAPTER V. Pharmacy Benefits
28 TAC §21.3001 and §§21.3030 – 21.3033

Repeal of §21.3034

INTRODUCTION. The Commissioner of Insurance adopts amendments to 28 TAC §§21.3001 and 21.3030 – 21.3033, and repeals §21.3034, concerning the transparency of certain information related to prescription drug coverage provided by certain individual health benefit plans. Amended 28 TAC §§21.3001, 21.3030, and 21.3032 – §21.3033, and repeal of §21.3034 are adopted without changes to the proposed text published in the January 12, 2018, issue of the *Texas Register* (43 TexReg 188). TDI adopts §21.3031 with nonsubstantive changes to the proposed text.

REASONED JUSTIFICATION. The amendments to 28 TAC §§21.3001 and 21.3030 – 21.3033 are necessary to implement House Bill 1227, 85th Legislature, Regular Session (2017). Section 21.3034 is repealed because it is no longer necessary.

HB 1227 amended Insurance Code Chapter 1369 by specifying that the disclosure requirements imposed by the chapter apply only to the individual health insurance market. The rules—as originally amended, effective August 18, 2016, and published in the *Texas Register* at 41 TexReg 6035—required applicable health benefit plans, including individual and group health benefit plans, to provide drug formulary information. HB 1227 clarified Chapter 1369 to specify that the requirements of §§1369.0542 – 1369.0544, redesignated by the bill as §§1369.078 – 1369.080, only apply to individual health benefit plans.

Section 21.3001. The amendments to §21.3001 reflect that Division 4 applies to health benefit plans under Insurance Code Chapter 1369 Subchapter B and clarifies that §§21.3031 – 21.3033 only apply to individual health benefit plans. Those amendments implement amended Insurance Code §§1369.078 – 1369.080.

Section 21.3030. The amendments to §21.3030 clarify that the requirements under §21.3032 and §21.3033 only apply to individual health benefit plans. Those amendments implement amended Insurance Code §§1369.077 – 1369.079.

Section 21.3031. The amendments to §21.3031 clarify that the requirement that health benefit plans post formulary information on their websites only applies to individual health benefit plans. The title of the section is amended to clarify that the section applies only to individual health benefit plans. Those amendments implement amended Insurance Code §§1369.077 – 1369.079.

TDI eliminated the term "individual" from the text of the proposed amendment to §21.3032(a), which stated, "The formulary information required under this section must include each individual prescription drug covered under the plan…" The addition of "individual" as proposed did not represent a substantive change and is not necessary to implement HB 1227. TDI is eliminating the term from the adoption in order to avoid the implication of a substantive change to the requirements of that subsection.

Section 21.3032. The amendments to §21.3032 clarify that the formulary disclosure requirements only apply to individual health benefit plans. The title of the section is also amended to clarify that the section applies only to individual health benefit plans. The amendments implement Insurance Code §§1369.077 – 1369.079.

Section 21.3033. The amendments to §21.3033 clarify that the requirements intended to facilitate comparison shopping only apply to an individual health benefit plan. The title of the section is amended to clarify that the section applies only to individual health benefit plans. The amendments implement Insurance Code §§1369.077 – 1369.079.

Section 21.3034. Section 21.3034 is repealed. The staggered effective dates are no longer required and the section is now obsolete.

SUMMARY OF COMMENTS. TDI did not receive any comments on the proposed amendments and repeal.

Subchapter V Pharmacy Benefits

Division 1. General Provisions

28 TAC §21.3001

STATUTORY AUTHORITY. The Commissioner adopts amendments to TAC §21.3001 under Insurance Code §§1369.078, 1369.079, and 36.001.

Insurance Code §1369.078 provides that a health benefit plan issuer display on a public internet website maintained by the issuer formulary information for each of the issuer's individual health benefit plans as required by the Commissioner by rule.

Insurance Code §1369.079 provides that the Commissioner develop and adopt by rule requirements to promote consistency and clarity in the disclosure of formularies to facilitate comparison shopping among individual health benefit plans.

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.

CROSS REFERENCE TO STATUTE. Section 21.3001 implements Insurance Code §§1369.078 – 1369.080, enacted by HB 1227, 85th Legislature, Regular Session (2017).

TEXT.

§21.3001. Applicability and Severability.

(a) Applicability. This subchapter implements the provisions of Insurance Code Chapter 1369 as follows:

(1) Division 2 of this subchapter applies to a health benefit plan that is subject to Insurance Code Chapter 1369, Subchapter D, and relates to pharmacy identification cards.

(2) Division 3 of this subchapter applies to a health benefit plan that is subject to Insurance Code Chapter 1369, Subchapter A, and relates to coverage of off-label drugs.

(3) Division 4 of this subchapter applies to a health benefit plan that is subject to Insurance Code Chapter 1369, Subchapter B, and relates to the use of a drug formulary by a health benefit plan. Consistent with Insurance Code §1369.077, §§21.3031 – 21.3033 apply only to an individual health benefit plan.

(b) Severability. If a court of competent jurisdiction holds that any provision of this subchapter is inconsistent with any statute of this state, is unconstitutional, or for any other reason

is invalid, the remaining provisions remain in full effect. If a court of competent jurisdiction holds that the application of any provision of this subchapter to particular persons, or in particular circumstances, is inconsistent with any statutes of this state, is unconstitutional, or for any other reason is invalid, the provision remains in full effect as to other persons or circumstances.

Subchapter V Pharmacy Benefits
Division 4. Prescription Drug Formulary Coverage and Disclosure Requirements
28 TAC §§21.3030 – 21.3033

STATUTORY AUTHORITY. The Commissioner amends 28 TAC §§21.3030 – 21.3033 under Insurance Code §§1369.078, 1369.079, and 36.001.

Insurance Code §1369.078 provides that a health benefit plan issuer shall display on a public internet website maintained by the issuer formulary information for each of the issuer's individual health benefit plans as required by the Commissioner by rule.

Insurance Code §1369.079 provides that the Commissioner shall develop and adopt by rule requirements to promote consistency and clarity in the disclosure of formularies to facilitate comparison shopping among individual health benefit plans.

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.

CROSS REFERENCE TO STATUTE. Sections 21.3030 – 21.3033 implement Insurance Code §§1369.078 – 1369.080, enacted by HB 1227, 85th Legislature, Regular Session (2017).

TEXT.

§21.3030. Availability of Formulary Information.

(a) An issuer of a health benefit plan, or its delegated entity, that covers prescription drugs and uses one or more drug formularies must provide, in plain language, the disclosures required by Insurance Code §1369.054. The plain language disclosure must be in the coverage

documentation provided to each enrollee and include the address and telephone number where the enrollee may contact the issuer of the health benefit plan, or its delegated entity, to determine if a specific prescription drug is on the formulary.

(b) An issuer of an individual health benefit plan must allow a current or prospective enrollee to obtain a paper copy of the formulary information required under §21.3032 and §21.3033 of this title (relating to Formulary Disclosure Requirements for Individual Health Benefit Plans and Facilitating Comparison Shopping for Individual Health Benefit Plans) by calling the toll-free number listed on the summary health plan document.

(c) An issuer may elect to exclude the plan-level cost-sharing information required under §21.3031(c) of this title (relating to Formulary Information for Individual Health Benefit Plans on Issuer's Website) from the paper format if the document provides a toll-free number through which a current or prospective enrollee may obtain formulary information contained in §21.3032 and §21.3033, including the plan-specific cost-sharing information required under §21.3032(c), for any formulary drug.

(d) The paper copy of the formulary information must use at least 10-point font.

§21.3031. Formulary Information for Individual Health Benefit Plans on Issuer's Website.

(a) Except as permitted under subsection (c) of this section, an issuer of an individual health benefit plan must display the formulary information required under §21.3032 and §21.3033 of this title (relating to Formulary Disclosure Requirements for Individual Health Benefit Plans and Facilitating Comparison Shopping for Individual Health Benefit Plans) on a website that is publicly accessible to enrollees, prospective enrollees, and others without requiring the use of paid software, a password, user name, or personally identifiable information. The formulary information must:

(1) be electronically searchable by drug name; and

(2) use at least 10-point font.

(b) Each summary health plan document must include a direct electronic link to the website that contains the formulary information. The direct electronic link must deliver the user directly to

the formulary information associated with the health benefit plan described by the health plan document, without requiring additional navigation or user input.

(c) As an alternative to displaying the information required under §21.3032(c) of this title, alongside the formulary information required generally under subsection (a) of this section, an individual health benefit plan issuer may elect to make plan-specific cost-sharing information available through a web-based tool. A direct electronic link to the web-based tool must be included on each page of the formulary disclosure that lists each drug. The purpose of this alternative method is to encourage the provision of the most timely and accurate drug price information. In order to qualify for this alternative method, a web-based tool must:

(1) be publicly accessible to enrollees, prospective enrollees, and others without requiring the use of paid software or the necessity of a password, user name, or personally identifiable information;

(2) allow consumers to electronically search formulary information by the name under which the health benefit plan is marketed;

(3) include the following plan-specific cost-sharing information for each drug:

(A) whether the drug is subject to a pharmacy or medical deductible and where the deductible may be found;

(B) the full price of the drug, based on the plan's median allowed amount or the actual cost for the drug using the most up-to-date data available, and a statement as to whether the price is based on the median or the actual cost;

(C) the cost-sharing amount the enrollee will owe for each drug under the pharmacy or medical benefit in a retail, mail order, or physician- or practitioner-administered setting, if applicable, excluding any deductible requirement, including as applicable:

(i) the dollar amount of a copayment; and

(ii) for a drug subject to coinsurance, the dollar amount of cost sharing the enrollee will owe, calculated based on the full price of the drug and the cost-sharing parameters under the enrollee's health benefit plan for the tier under which the drug is assigned; and

(4) include, prominently displayed on the web page under the header "Formulary by Health Benefit Plan," a direct electronic link to a chart that displays each formulary that applies to each individual health benefit plan issued by the issuer and includes a direct electronic link to the Summary of Benefits and Coverage and formulary document for each health plan listed. This chart may be limited to health benefit plans being sold in the market in which the applicable health benefit plan is issued.

§21.3032. Formulary Disclosure Requirements for Individual Health Benefit Plans.

(a) The formulary information required under this section must include each prescription drug covered under the plan that is dispensed in a network pharmacy or administered by a physician or health care provider and clearly differentiate between drugs covered under the plan's pharmacy benefits and medical benefits. Information pertaining to drugs covered under the plan's medical benefits may be provided as an addendum or link to the formulary and must include each parameter that is applicable.

(b) The formulary information must include the following coverage information for each drug:

(1) an explanation of coverage under the health benefit plan;

(2) an indication of whether the drug is preferred, if applicable, under the plan;

(3) a disclosure of any prior authorization, step therapy, or other protocol requirement; and

(4) the specific tier the drug falls under, if the plan uses a multitier formulary.

(c) The formulary information must include the following plan-specific cost-sharing information for each drug:

(1) whether the drug is subject to a pharmacy or medical deductible and where the deductible may be found;

(2) the cost-sharing amount for each drug under the pharmacy or medical benefit, in a retail, mail order, or physician- or practitioner-administered setting, if applicable, excluding any deductible requirement, including, as applicable:

(A) the dollar amount of a copayment; and

(B) for a drug subject to coinsurance:

(i) an enrollee's cost-sharing amount stated in dollars; or

(ii) a cost-sharing range denoted as follows:

(I) under $100 - $;

(II) $100 - $250 - $$;

(III) $251 - $500 - $$$;

(IV) $501 - $1,000 - $$$$; or

(V) over $1,000 - $$$$$.

(d) Cost-sharing amounts must reflect the cost to the consumer, rounded to the next highest dollar amount, for a month-long supply unless otherwise noted. Cost-sharing information reflecting the cost for a different duration supply should indicate the applicable duration. The cost-sharing amount for a given drug must be calculated based on the plan's median allowed amount or the actual cost for the drug, using the most up-to-date data available and the cost-sharing parameters under the enrollee's health benefit plan for the tier under which the drug is assigned. The information must include whether the cost-sharing amount is based on the median or the actual cost.

(e) Any formulary information presented using abbreviations must provide a legend on each page explaining the meaning of each abbreviation used, including the dollar amounts that correspond to the cost-sharing range.

§21.3033. Facilitating Comparison Shopping for Individual Health Benefit Plans.

(a) The formulary information required by §21.3032 of this title (relating to Formulary Disclosure Requirements for Individual Health Benefit Plans) must include a summary titled "Summary of Formulary Benefits" that includes this statement: "The information in this document is designed to help you understand the prescription drug benefits offered under this plan and to compare these benefits to those offered by other plans. Information contained in this summary is designed to help you compare both the value and scope of formulary benefits." The summary must also include, in the following order:

(1) Under the header, "How to Find Information on the Cost of Prescription Drugs," a description of how a consumer may use the plan's summary health plan document, formulary information, and web-based tool, if applicable, to determine the cost sharing they may owe, and an explanation that cost-sharing information reflects a consumer's share of the cost excluding any deductible requirement, calculated using an estimate of the full price of the drug, which is based on the plan's median or the actual cost allowed amount at a given point in time.

(2) Under the header, "Formulary by Health Benefit Plan," a chart that displays each formulary that applies to each individual health benefit plan issued by the issuer and includes a direct electronic link to the Summary of Benefits and Coverage for each individual health plan listed. This chart may be limited to individual health benefit plans being sold in the market in which the applicable health benefit plan is issued.

(3) Under the header, "Drugs by Cost-Sharing Tier," if the drug formulary is a multitier formulary, a summary that displays the percent of drugs in each cost-sharing tier for all drugs in the formulary.

(4) Under the header, "How Prescription Drugs are Covered under the Plan":

(A) under a section titled, "Formulary Composition," an explanation of the method the issuer uses to determine the prescription drugs to be included in or excluded from the formulary, an explanation of whether the formulary is open or closed, and a statement of how often the issuer reviews the contents of the formulary.

(B) Under a section titled, "Right to Appeal," an explanation that if a drug is not covered under the formulary, but the enrollee's physician has determined that the drug is medically necessary, the consumer has the right to appeal, consistent with §21.3023 of this title (relating to Nonformulary Prescription Drugs; Adverse Determination) and Insurance Code §1369.056. A statement of how cost sharing will be determined for drugs covered as a result of a successful appeal.

(C) Under a section titled, "Continuation of Coverage," an explanation of a consumer's right to continued coverage for a prescription drug at the coverage level or tier at which the drug was covered at the beginning of the plan year, until the enrollee's plan renewal date,

consistent with §21.3022 of this title (relating to Continuation of Benefits) and Insurance Code §1369.055 and §1369.0541.

(D) Under a section titled, "Off-Label Drug Use," an explanation of how formulary drugs are covered under the plan, including an explanation of coverage for off-label drug use.

(E) Under a section titled, "Cost Sharing," an explanation of how cost sharing is determined under the plan, including whether a deductible applies to prescription drug coverage; how cost sharing for prescription drugs counts towards the plan's deductible; how drugs are categorized into each of the formulary tiers or cost-sharing levels, whether the drug formulary is a multitier formulary; the difference between preferred and nonpreferred drugs, if applicable; the difference in coverage for drugs dispensed from in-network and out-of-network pharmacies; and the difference in coverage for drugs dispensed in a retail pharmacy and a mail-order pharmacy, if applicable.

(F) Under a section titled, "Medical Management Requirements," an explanation of each type of medical management requirement used by the individual health benefit plan, including prior authorization, step therapy, or other protocol requirements that limit access to prescription drugs, as applicable.

(b) Formulary information must include the summary information required under subsection (a) of this section beginning on the first page of the formulary document under the title, "Summary of Formulary Benefits."

Subchapter V Pharmacy Benefits

Division 4. Prescription Drug Formulary Coverage and Disclosure Requirements

Repeal of 28 TAC §21.3034

STATUTORY AUTHORITY. The Commissioner adopts the repeal of 28 TAC §21.3034 under Insurance Code §§1369.078, 1369.079, and 36.001.

Insurance Code §1369.078 provides that a health benefit plan issuer shall display on a public internet website maintained by the issuer formulary information for each of the issuer's individual health benefit plans as required by the Commissioner by rule.

Insurance Code §1369.079 provides that the Commissioner shall develop and adopt by rule requirements to promote consistency and clarity in the disclosure of formularies to facilitate comparison shopping among individual health benefit plans.

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.

CROSS REFERENCE TO STATUTE. Section 21.3034 is no longer necessary to implement Insurance Code §§1369.078 – 1369.080, enacted by HB 1227, 85th Legislature, Regular Session (2017).

TEXT.

§21.3034. Effective Date.

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

Issued at Austin, Texas, on May 1, 2018.

/s/ Norma Garcia
Norma Garcia
General Counsel
Texas Department of Insurance

The commissioner adopts amendments to §§21.3001 and 21.3030 – 21.3033, and the repeal of §21.304.

/s/ Kent C. Sullivan
Kent C. Sullivan
Commissioner of Insurance

COMMISSIONER'S ORDER NO. **2018-5484**