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

Repeal of §21.3034

INTRODUCTION. The Texas Department of Insurance proposes to amend 28 TAC §21.3001 and §§21.3030 – 21.3033 and repeal §21.3034, concerning the transparency of certain information related to prescription drug coverage provided by certain individual health benefit plans. The amended sections implement House Bill 1227, 85th Legislature, Regular Session (2017).

EXPLANATION. Amending 28 TAC §21.3001 and §§21.3030 – 21.3033 is necessary to implement HB 1227. Section 21.3034 is proposed for repeal 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 to provide drug formulary information. HB 1227 clarified Insurance Code 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 proposal amends §21.3001 to 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. The amendment is necessary to implement HB 1227.

Section §21.3030. The proposal amends §21.3030 to clarify that the requirements under §21.3032 and §21.3033 only apply to individual health benefit plans. The amendment is necessary to implement HB 1227 and Insurance Code §§1369.077 – 1369.079.

Section §21.3031. The proposal amends §21.3031 to clarify that the requirement that health benefit plans post formulary information on their website only applies to individual health benefit plans. The amendment also amends the title of the section to clarify that the section applies only to individual health benefit plans. The amendment is necessary to implement HB 1227 and Insurance Code §§1369.077 – 1369.079.

Section §21.3032. The proposal amends §21.3032 to clarify that the formulary disclosure requirements only apply to individual health benefit plans. The amendment also amends the title of the section to clarify that the section applies only to individual health benefit plans. The amendment is necessary to implement HB 1227 and Insurance Code §§1369.077 – 1369.079.

Section §21.3033. The proposal amends §21.3033 to clarify that the requirements intended to facilitate comparison shopping only apply to an individual health benefit plan. The amendment also amends the title of the section to clarify that the section applies only to individual health benefit plans. The amendment is necessary to implement HB 1227 and Insurance Code §§1369.077 – 1369.079.

Section §21.3034. Section 21.3034 is proposed for repeal. The staggered effective dates are no longer required and the section is now obsolete.

FISCAL NOTE AND LOCAL EMPLOYMENT IMPACT STATEMENT. Rachel Bowden, manager, Accident and Health Program, has determined that for each year of the first five years the proposed amendments are in effect, there will be no measurable fiscal impact to state and local governments as a result of the enforcement or administration of this proposal. Ms. Bowden does not anticipate any measurable effect on local employment or the local economy as a result of this proposal.

PUBLIC BENEFIT AND COST NOTE. Ms. Bowden has determined that for each year of the first five years the proposed amendments are in effect, there are public benefits anticipated as a result of the administration and enforcement of the rule, and there will be no potential costs for persons required to comply with the proposal. TDI drafted the proposed rules to maximize public benefits consistent with the authorizing statutes while mitigating costs.

The anticipated public benefits are the implementation of rules necessary to comply with HB 1227, which amended the provisions added by HB 1624, 84th Legislature, Regular Session (2015). Insurance Code §§1369.078 – 1369.080 provide for transparency of formulary information for consumers so they can easily compare and shop among plans. Individual health benefit plan issuers will publish formulary information that is plan specific, discloses cost-sharing information, and contains a summary of formulary benefits.

Ms. Bowden expects that the proposed amendments will not increase the cost of compliance with Insurance Code Chapter 1369 because it does not impose requirements beyond those in the amended statute. HB 1227 limited the applicability of the newly designated subchapter. As a result, fewer entities and plans will face costs associated with compliance with 28 TAC Subchapter V Pharmacy Benefits.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS. TDI has determined that the proposed amendments will not have an adverse economic effect or a disproportionate economic impact on small or micro businesses or rural communities. The amendments limit the applicability of the formulary disclosure requirements, and, therefore, fewer entities and plans will be required to comply with the provisions than before. As a result, and in accordance with Government Code §2006.002(c), TDI is not required to prepare a regulatory flexibility analysis.

EXAMINATION OF COSTS UNDER GOVERNMENT CODE §2001.0045. TDI has determined that the proposed amendments do not require another rule or rules to be amended or repealed in order to reduce the total costs imposed on regulated persons. The effect of the proposed amendments is not expected to increase the cost of compliance with Insurance Code Chapter 1369 because it does not impose requirements beyond those in the amended statute. In addition, this proposal will eliminate costs for some regulated persons previously required to comply with the rules. Additionally, even if the proposed amendments were to impose additional costs, Government Code §2001.0045 does not apply to the proposed amendments because the changes are necessary to implement HB 1227.

GOVERNMENT GROWTH IMPACT STATEMENT. TDI had determined that each year of the first five years the proposed amendments are in effect, the rule will not create or eliminate a government program.

As a result of the proposed amendments, the rule will likely not require the creation of new employee positions or the elimination of existing employee positions.

The proposed amendments do not require an increase or decrease in future legislative appropriations to TDI.

The proposed amendments do not require an increase or decrease in fees paid to TDI. The proposed amendments do not create a new regulation.

The purpose of the proposed amendments is to conform existing rules to implement HB 1227, which narrowed the application of formulary information so that it applies only to individual health benefit plan issuers.

By implementing HB 1227, the proposed amendments limit an existing regulation. The most directly affected persons are health benefit plan issuers rather than individuals; and as a result of implementing HB 1227, fewer of those entities, and those entities' health plans, will be subject to the rule's applicability.

TDI has determined that each year of the first five years the proposed amendments are in effect, the rule will not positively or adversely affect this state's economy.

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

REQUEST FOR PUBLIC COMMENT. TDI seeks public comments on these amendments. Submit any written comments on the proposal no later than 5 p.m., Central time, on February 5, 2018. TDI requires two copies of your comments. Send one copy to ChiefClerk@tdi.texas.gov, or to the 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 Rachel Bowden, Life and Health Lines Office, Mail Code 107-2A, Texas Department of Insurance, P.O. Box 149104, Austin, Texas 78714-9104, or by email to lhlcomments@tdi.texas.gov. To request a public hearing on the proposal, send a separate request for hearing before the end of the comment period by email to ChiefClerk@tdi.texas.gov, or by mail to the Office of the Chief Clerk, Mail Code 113-2A, Texas Department of Insurance, P.O. Box 149104, Austin, Texas 78714-9104.

28 TAC §21.3001, and §§21.3030 – 21.3033

STATUTORY AUTHORITY. TDI proposes amendments to TAC §21.3001 and §§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 §21.3001 and §§21.3030 – 21.3033 implement 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.

§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 [~~a~~] 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 [~~a~~] 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 [~~a~~] 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 [~~displaying~~] 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 individual 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 <u>for Individual Health Benefit Plans.</u>

(a) The formulary information required by §21.3032 of this title (relating to Formulary Disclosure Requirements <u>for Individual Health Benefit Plans</u>) 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."

Repeal of §21.3034

STATUTORY AUTHORITY. TDI proposes the repeal of 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.

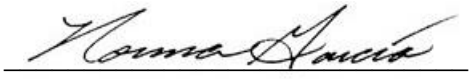
CROSS-REFERENCE TO STATUTE. Section §21.3034 is no longer necessary to implement Insurance Code §§1369.078 – 1369.080, enacted by HB 1227, 85th Legislature, Regular Session (2017).

TEXT.

§21.3034. Effective Date.

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

Issued in Austin, Texas, on December 7, 2017.



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